

02.02.19 Baroreflex Stimulation Device Components and Ancillary Services

Original Effective Date: January 2016

Review Date: July 2026

Revised: January 2025

DISCLAIMER/INSTRUCTIONS FOR USE

This policy contains information which is clinical in nature. The policy is not medical advice. The information in this policy is used by Wellmark to make determinations whether medical treatment is covered under the terms of a Wellmark member's health benefit plan. Physicians and other health care providers are responsible for medical advice and treatment. If you have specific health care needs, you should consult an appropriate health care professional. If you would like to request an accessible version of this document, please contact customer service at 800-524-9242.

Benefit determinations are based on the applicable contract language in effect at the time the services were rendered. Exclusions, limitations, or exceptions may apply. Benefits may vary based on contract, and individual member benefits must be verified. Wellmark determines medical necessity only if the benefit exists and no contract exclusions are applicable. This medical policy may not apply to FEP. Benefits are determined by the Federal Employee Program.

This Medical Policy document describes the status of medical technology at the time the document was developed. Since that time, new technology may have emerged, or new medical literature may have been published. This Medical Policy will be reviewed regularly and updated as scientific and medical literature becomes available; therefore, policies are subject to change without notice.

Related Policies:

- [02.02.17 Cardiac Contractility Modulation Therapy and Ancillary Services](#)
- [02.21 Cardiac Hemodynamic Monitoring for the Management of Heart Failure in the Outpatient Setting](#)
- [02.02.22 Noninvasive Heart Failure and Arrhythmia Management and Monitoring System](#)

Summary

Description

Note: This Wellmark medical policy is NOT an evidence review for the implantation or replacement of a total baroreflex stimulation system (64654), but rather a supplemental coverage policy for Baroreflex Stimulation Device components and ancillary services (64655-64658, 93145, 93146 and C1825).

Refer to [Wellmark Authorization Table](#) for the prior approval requirements and the applicable EviCore Evidence-based Guideline regarding the implantation or replacement of a total baroreflex stimulation system (64654).

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 medical policy is a supplemental coverage policy for Baroreflex Stimulation Device components and ancillary services (64655-64658, 93145, 93146 and C1825).

PRIOR APPROVAL

Not applicable.

POLICY

Refer to [Wellmark Authorization Table](#) for the prior approval requirements and the applicable EviCore Evidence-based Guideline regarding the implantation or replacement of a total baroreflex stimulation system (64654).

The use of Baroreflex Stimulation Device components and ancillary services (64655-64658, 93145, 93146 and C1825) are also considered **investigational** for all indications, including but not limited to the treatment of hypertension and heart failure, because the primary procedure of implantation or replacement of a total baroreflex stimulation system (64654) is considered investigational per the applicable EviCore evidence-based Guideline.

POLICY GUIDELINES

Coding

See the [Codes table](#) for details.

BACKGROUND

Baroreceptors are pressure sensors contained within the walls of the carotid arteries. They are part of the autonomic nervous system that regulates basic physiologic functions such as heart rate and blood pressure. When these receptors are stretched, which occurs with increases in blood pressure, the baroreflex is activated. Activation of the baroreflex signals the brain, which responds by inhibiting sympathetic nervous system output and increasing parasympathetic nervous system output. The effect of this activation is to reduce heart rate and blood pressure, thereby helping to maintain homeostasis of the circulatory system.

The use of baroreflex stimulation devices (also known as baroreflex activation therapy) is a potential alternative treatment for resistant hypertension and heart failure. Both hypertension and heart failure are

relatively common conditions and are initially treated with medications and lifestyle changes. A substantial portion of patients are unresponsive to conventional therapy and treating these patients is often challenging, expensive, and can lead to adverse events. As a result, there is a large unmet need for additional treatments.

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.

In 2019, Barostim Neo was granted premarket approval (PMA P180050) and is indicated for the improvement of symptoms of heart failure (i.e., 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 $\leq 35\%$ and a N-terminal pro-B-type natriuretic peptide (NT-proBNP) < 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. The Expedited Access Pathway was a mechanism used to hasten the approval of novel therapies that target life-threatening conditions. The Expedited Access Pathway was subsequently replaced by the Breakthrough Devices Program.

In 2023, following the extended phase of the BEAT-HF study, Barostim Neo's indication was expanded for patients who are NYHA Class III or Class II (who had a recent history of Class III) despite treatment with guideline-directed medical therapies (medications and devices), have a left ventricular ejection fraction of $\leq 35\%$, and a NT-proBNP < 1600 pg/ml.

RATIONALE

Not applicable

SUPPLEMENTAL INFORMATION

Not applicable.

REFERENCES

Not applicable

CODES

To report provider services, use appropriate CPT codes, HCPCS codes, Revenue codes, and/or ICD diagnosis codes.

Codes	Number	Description
CPT		
	64655	Revision or replacement of baroreflex activation therapy (BAT) modulation system, with intraoperative interrogation and programming; lead only
	64656	Revision or replacement of baroreflex activation therapy (BAT) modulation system, with intraoperative interrogation and programming; pulse generator only
	64657	Removal of baroreflex activation therapy (BAT) modulation system; total system, including lead and pulse generator
	64658	Removal of baroreflex activation therapy (BAT) modulation system; lead only
	64659	Removal of baroreflex activation therapy (BAT) modulation system; pulse generator only
	93145	Percutaneous transluminal revascularization of chronic total occlusion, single coronary artery, coronary artery branch, or coronary artery bypass graft, and/or subtended major coronary artery branches of the bypass graft, any combination of intracoronary stent, atherectomy and angioplasty; combined antegrade and retrograde approaches
	93146	Interrogation device evaluation (in person), carotid sinus baroreflex activation therapy (BAT) modulation system including telemetric iterative communication with the implantable device to monitor device diagnostics and programmed therapy values, with interpretation and report (eg, battery status, lead impedance, pulse amplitude, pulse width, therapy frequency, pathway mode, burst mode, therapy start/stop times each day); without programming
HCPCS		
	C1825	Generator, neurostimulator (implantable), non-rechargeable with carotid sinus baroreceptor stimulation lead(s)
Type of Service	Medicine	
Place of Service	Inpatient/Outpatient	

POLICY HISTORY

Date	Reason	Action
July 2026	Annual Review	Policy Renewed
July 2025	Annual Review	Policy Renewed
January 2025	Interim Review	Policy Revised
August 2024	Annual Review	Policy Revised
July 2023	Annual Review	Policy Renewed
January 2023	Annual Review	Policy Revised
April 2022	Interim Review	Policy Revised
January 2022	Annual Review	Policy Revision, Content Moved and New Policy Created

New information or technology that would be relevant for Wellmark to consider when this policy is next reviewed may be submitted to:

Wellmark Blue Cross and Blue Shield
Medical Policy Analyst
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