

Company

CVRx®

Drug or Device Name

Barostim™

Category

Medical Technology

Compound/Technical Name

Barostim NEO™

Trade Name

Barostim™

Date of Approval

08/16/2019

Therapeutic Categories

Best Medical Technology.

Indications

Heart Failure with Reduced Ejection Fraction (HFrEF)

Background

There are an estimated 6.2 million adults living with heart failure (HF) in the United States. For those individuals, everyday activities become exceedingly challenging, resulting in impaired mobility, frequent hospitalizations, and an increased risk of mortality of 42.3% at five years. While HF symptoms can be managed through various methods, not all can be tailored to the particular needs of a patient. CVRx®, headquartered in Minneapolis, MN., has developed a novel therapy designed to help HF patients regain an active, normal lifestyle. CVRx's Barostim – or Baroflex Activation Therapy (BAT™) is the first medical technology approved by the FDA that uses neuromodulation - the power of the brain and nervous system - to improve the symptoms of patients with systolic HF. Barostim uniquely takes advantage of the baroreflex, the body's intrinsic system to regulate cardiovascular function. Barostim works by electrically stimulating carotid baroreceptors, which trigger the baroreflex. The nervous system responds with an integrated autonomic response, increasing parasympathetic activity while also decreasing parasympathetic activity to the heart, kidneys and blood vessels. The simple implantable device is similar to a pacemaker and implanted in the chest. A small electrode is implanted next to the carotid artery to deliver electrical impulses. The entire procedure is typically performed on an outpatient basis in less than an hour. After the device is programmed, patients only need to return to their cardiologist for routine check-ups. Barostim received the FDA Breakthrough Device Designation and is FDA-approved for use in HF with reduced ejection fraction (HFrEF) patients in the U.S and European Economic Area (EEA). It has also received the CE Mark for resistant hypertension in the European Economic Area. Barostim is also the recipient of the Centers for Medicare and Medicaid Services (CMS) Transitional Pass-Through Payment Status (TPT) and inpatient New Technology Add-On Payment (NTAP).

Development

Electrical stimulation of the carotid baroreceptors has been known for decades to produce a robust autonomic response and have potential therapeutic benefits in various cardiovascular diseases. CVRx pioneered the concept of using an implantable device to take advantage of the baroreflex and has been developing and

optimizing the therapy since the company's inception in 2001. Originally focused on treating hypertension patients through neuromodulation therapies, CVRx pivoted in 2015 to address the needs of heart failure (HF) patients under the leadership of CEO Nadim Yared, who saw great promise in CVRx's innovations to treat HF patients. He had full confidence that the CVRx team could compete with larger medtech companies to deliver an alternative to cardiac resynchronization therapy (CRT) for the majority of HFrEF patients who are not indicated for that therapy. The original device approved in the EEA utilized bilateral carotid sinus cuffs to stimulate. In close partnership with clinicians, a greatly simplified unilateral lead system (Barostim NEO) was developed which is simply sutured to the outside of the carotid sinus. In 2011, Barostim received CE Mark approval for resistant hypertension in the European Economic Area before receiving additional approval for HF in 2014. US FDA approved Barostim for HFrEF in 2019 after successful completion of the pivotal BeAT-HF randomized study. BeAT-HF demonstrated significant improvements in symptoms of heart failure for patients in whom drugs were insufficient. Today, Barostim is the first medical technology approved by the FDA to use the power of the brain and nervous system to improve the symptoms of patients with systolic HF. Future development of Barostim will focus on simplification of the carotid sinus lead implant, evaluation of novel waveforms to further optimize stimulation, further miniaturization of the implant.

Innovation

Barostim is the only medical technology that uses neuromodulation – the power of the brain and nervous system – to improve symptoms of heart failure (HF). The therapy is delivered by the Barostim NEO system that uses CVRx-patented technology to send electrical pulses to baroreceptors located in the wall of the carotid artery. Barostim triggers the body's own natural regulation system to treat HF symptoms and is designed for HF patients with reduced ejection fraction (HFrEF) who have no proven treatment options today. Barostim Therapy can be adjusted to meet each patient's individual therapy needs, making it the only personalized medical device therapy available for the treatment of hypertension and HF. Recipients of Barostim undergo a minimally invasive 60-minute procedure and are generally able to return home on the same day, compared to a pacemaker implant, after which patients generally remain hospitalized for a 24-hour period. The therapy works through electrical stimulation of the baroreceptors, which does not alter or destroy the structure of the baroreflex. Anecdotally, there appears to be no accommodation to the therapy over years and effectiveness remains consistent. Unlike other devices that are used to improve cardiac function, Barostim Therapy does not touch the heart or blood vessels. Future potential applications of Barostim are significant. CVRx is currently collecting longer term data on morbidity and mortality benefits in HFrEF patients that could potentially expand the indication for the therapy. CVRx has also already received FDA Breakthrough designations for heart failure with preserved ejection fraction (HFpEF) and treatment-resistant hypertension (HTN), two other large patient populations with limited effective options. Based on its unique mechanism of action, the technology may have other potential applications in chronic kidney disease (CKD) and other diseases that may be impacted by autonomic dysfunction.

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Zile MR, Lindenfeld J, Weaver FA, Zannad F, Galle E, Rogers T, Abraham WT. Baroreflex Activation Therapy in Patients With Heart Failure With Reduced Ejection Fraction. *J Am Coll Cardiol*. 2020 Jul 7;76(1):1-13. doi: 10.1016/j.jacc.2020.05.015. PMID: 32616150. <https://pubmed.ncbi.nlm.nih.gov/32616150/>

Attachments

- 1623099744CVRx_Background_Prix_Galien_Award_2021.pdf
- 1623100148CVRx_Prix_Galien_Award_2021_Development.pdf
- 1623100678CVRx_Prix_Galien_Award_2021_Innovation.pdf
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