CVRx®

Press Release

FOR IMMEDIATE RELEASE

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CVRx®'s BAROSTIM NEO™ Receives CMS NTAP Effective October 1, 2020

MINNEAPOLIS, Nov. 2, 2020 – CVRx®, developer of the world's first FDA-approved neuromodulation device to treat chronic heart failure (HF), announces that its BAROSTIM NEO™ implantable device has received the Centers for Medicare & Medicaid Services (CMS) inpatient New Technology Add-On Payment (NTAP). Additionally, CMS proposed national coverage determination (NCD) for Breakthrough designation treatments like BAROSTIM NEO.

Effective October 1, 2020, and for a three-year duration, Medicare will provide an add-on payment for BAROSTIM NEO of up to 65% of the device cost (maximum amount allowed $22,750) in addition to the Medicare Severity-Diagnosis Related Group (MS-DRG) payment for the implant procedure. The overall procedure reimbursement is expected to be in the range of $39,895 - $44,170, according to the Medicare National Rate for Medicare patients in the inpatient setting.

BAROSTIM NEO received the highly sought-after Breakthrough Designation status by the FDA in 2016, which is only given to drugs and devices that demonstrate the potential to become a more effective treatment for a life-threatening or debilitating condition. In efforts to remove barriers to innovation, CMS established alternative streamlined pathways for FDA Breakthrough devices to qualify for NTAPs. Following this pathway, CMS awarded the NTAP for BAROSTIM NEO due to the device's FDA Breakthrough Therapy designation.

The NTAP program supports access to novel therapies that offer substantial clinical benefits over existing treatment options. The add-on payment addresses the delay between market introduction of a technology and the MS-DRG recalibration that reflects the added cost of the technology. The NTAP bridges the delay with a temporary payment in addition to the MS-DRG payment normally made to the hospital.

On August 31, 2020, Medicare proposed a national Medicare Coverage of Innovative Technology (MCIT) rule for Breakthrough implantable technologies. BAROSTIM NEO is already widely reimbursed on a claim-by-claim adjudication basis; however, the NCD will eliminate the need for any adjudication in the claim-by-claim process.

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About CVRx's BAROSTIM NEO

CVRx's BAROSTIM NEO™ is the first medical device approved by the FDA to use the power of the brain and nervous system to improve the symptoms of patients with systolic heart failure (HFrEF). Designed to treat patients by electrically activating the baroreflex, the body's natural mechanism to regulate cardiovascular function, BAROSTIM NEO uses CVRx-patented technology to send electrical pulses to baroreceptors located in the wall of the carotid artery, to deliver BAROSTIM THERAPY™. The therapy is designed to restore balance to the autonomic nervous system and thereby improve the symptoms of HF. BAROSTIM NEO received the coveted "Breakthrough Device" FDA designation and is the first device approved by the FDA to use the power of the brain and the nervous system to improve the symptoms of patients with HFrEF. BAROSTIM NEO is approved by FDA for HF in the US, and has received the CE Marking for HF and resistant hypertension in the European Economic Area. To learn more about BAROSTIM NEO, watch this video.

About CVRx, Inc.

Headquartered in Minneapolis, MN., CVRx® is a leader in innovative medical technologies that address the unmet needs in cardiovascular diseases with safe and effective therapies that harness and harmonize the body's natural systems. CVRx is dedicated to improving patient outcomes, quality of life and overall cardiovascular health via novel baroreceptor neuromodulation therapies.