CVRx®

Press Release

FOR IMMEDIATE RELEASE

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CVRx® BAROSTIM Therapy Receives CMS Approval for Transitional Pass-Through Payment Status

Incremental Reimbursement in Outpatient Setting Will Expand Availability of the Breakthrough BAROSTIM Therapy Heart Failure Treatment

MINNEAPOLIS, Dec. 3, 2020 – CVRx®, developer of the world's first FDA-approved neuromodulation device to treat the symptoms of heart failure (HF), announced that the Centers for Medicare and Medicaid Services (CMS) granted approval for a transitional pass-through (TPT) payment for BAROSTIM Therapy as part of the 2021 Outpatient Prospective Payment System (OPPS) Final Rule issued December 2, 2020. The TPT status provides incremental payment for devices used in the hospital outpatient and ambulatory surgery center (ASC) settings.

TPT status for BAROSTIM Therapy will be effective January 1, 2021. TPT payment is intended to facilitate the use of newly FDA-approved medical devices, drugs, and biologics across all fields of medicine and to boost Medicare patients' access to these innovative therapies by temporarily paying more than established facility fees.

"We thank CMS for its work to expand access to innovative medical technologies such as the BAROSTIM Therapy," said Nadim Yared, President and CEO of CVRx. "The approval of TPT for BAROSTIM will help accelerate access to the therapy for the thousands of Medicare patients still suffering from the effects of heart failure."

In combination with the inpatient New Technology Add-On Payment (NTAP), which was approved and in effect since October 2020, incremental Medicare reimbursement for BAROSTIM Therapy is now available in both inpatient and outpatient settings.

BAROSTIM Therapy, designated as a Breakthrough Device technology by the FDA, received FDA PMA Approval in 2019 and is now commercially available to reduce the symptoms of HF for patients who are not indicated for cardiac resynchronization therapy (CRT) and have a left ventricular ejection fraction of 35% or less.

About CVRx BAROSTIM Therapy

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CVRx's **BAROSTIM Therapy™** 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 heart failure (HFrEF). BAROSTIM is delivered by the **BAROSTIM NEO™** system, an implantable device that uses CVRx-patented technology to send electrical pulses to baroreceptors located in the wall of the carotid artery. Baroreceptors trigger the body's baroreflex which in turn triggers an autonomic response to the heart. The therapy is designed to restore balance to the autonomic nervous system and thereby reduce the symptoms of HF. BAROSTIM NEO received the FDA Breakthrough Device designation and is FDA-approved for use in HF patients in the US. It has also received the CE Mark for HF and resistant hypertension in the European Economic Area. To learn more about BAROSTIM Therapy, 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.