

# CMS Agrees With VisCardia on the Value of Synchronized Diaphragmatic Stimulation

PORTLAND, OR, UNITED STATES, November 5, 2024 /EINPresswire.com/ -- [VisCardia](#), Inc. announced today that they have received payment assignments for the designated CPT III codes for VisONE SDS® therapy by the Centers for Medicare and Medicaid Services (CMS). These payment assignments were created

subsequently to the FDA approval of the RECOVER-HF clinical trial for the VisONE SDS system as a category B device and related services. The primary CPT code previously designated by the American Medical Association for the VisONE SDS system implantation has been assigned to APC 5465 which carries an average payment rate of over \$30,000 in the CY 2025 OPPTS Final Rule.

Peter Bauer, Ph.D., CEO of VisCardia, expressed his excitement regarding this latest milestone, “We would like to express our thanks to CMS for recognizing the value of this Breakthrough Technology that represents a minimally-invasive, alternative for the treatment of heart failure with reduced ejection fraction (HFrEF) in patients who remain symptomatic on medical therapy and are ineligible for cardiac resynchronization therapy.” The reimbursement rule is effective January 1, 2025.

With both FDA and CMS approvals for the pivotal clinical trial, RECOVER-HF, VisCardia is now recruiting clinical sites to help bring this innovative technology to the U.S. market with first U.S. implants anticipated in Q1 2025. In contrast to other device-based heart failure therapies, minimally-invasive [Synchronized Diaphragmatic Stimulation](#)® (SDS) allows for a wide access to the healthcare system through outpatient procedures not limited to transplant centers, cardiac surgery centers, other subspecialty surgical suites or even interventional cardiology laboratories. Once approved, the VisONE SDS system will be able to be implanted in basically any surgical suite in a hospital or ambulatory surgical center currently performing laparoscopic procedures or over 30,000 facilities nationwide.

Dr. Michael Mirro, Director of Medical Affairs, stated, “The minimally-invasive implant technique lends itself perfectly as an outpatient procedure utilizing facilities that are less congested with high volumes or long procedure times such as cardiac catheterization/EP labs or high acuity



VisCardia

Pioneered Synchronized Diaphragmatic Stimulation Therapy

surgical suites.”

#### About VisONE® SDS® Therapy

The VisONE implantable system delivers VisCardia's proprietary Synchronized Diaphragmatic Stimulation (SDS) therapy for improving cardiac function in heart failure patients. By electrically stimulating the diaphragm in an imperceptible manner, transient intrathoracic pressures synchronized to cardiac activity are modulated, improving both cardiac filling and output. The therapy is non-invasively adjusted and programmed using an external programmer to improve hemodynamic benefit and optimize stimulation parameters.

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