



SeaStar Medical Announces CMS Coverage for Medicare and Medicaid Eligible Patients with Cardiorenal Syndrome Awaiting LVAD in Investigational Trial of SCD Therapy

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Coverage marks SeaStar Medical's second award by CMS for reimbursement of medical expenses for Medicare and Medicaid patients in a clinical trial

Stands out as rare award with less than 100 clinical trials covered annually

DENVER, May 28, 2025 (GLOBE NEWSWIRE) -- SeaStar Medical Holding Corporation (Nasdaq: ICU), a commercial-stage healthcare company focused on transforming treatments for critically ill patients facing organ failure and potential loss of life, announced today that the U.S. Centers for Medicare & Medicaid Services (CMS) has agreed to pay for certain expenses incurred by medical centers treating patients covered by Medicare or Medicaid who are enrolled in the NEUTRALIZE-CRS investigational clinical trial. This follows the company's first award for reimbursement by the CMS that was granted in July 2024 for qualified patients treated in the ongoing NEUTRALIZE-AKI pivotal clinical trial.

"To receive CMS coverage of certain expenses for patients in a clinical trial is rare, with less than 100 per year, and we believe reflects the life-saving potential of our technology," said Eric Schlorff, SeaStar Medical CEO. "We fulfilled multiple criteria set forth by the CMS for this award, including ten study criteria elements that included assessment of how we could improve health outcomes, how generalizable the Selective Cytopheretic Device (SCD) therapy would be to the Medicare population, and how the study results would not duplicate existing knowledge."

Mr. Schlorff continued, "As we initiate our pre-commercialization efforts for our SCD therapy in patients with Acute Kidney Injury (AKI), we recognize that CMS coverage in the commercial setting will be a key element to bringing our potential organ-sparing and life-saving therapies to more patients. We have already engaged a third-party reimbursement policy expert to analyze the feasibility of obtaining reimbursement coverage upon a potential FDA approval for our SCD therapy in adult patients with AKI. Based on the results of the analysis, the high unmet need, and Healthcare Economics and Outcomes Research (HEOR) data supporting reduced healthcare costs, we are building a compelling case that should enable CMS and private payers to understand the value of the SCD therapy in adult patients with AKI."

The NEUTRALIZE-AKI pivotal clinical trial and NEUTRALIZE-CRS investigational clinical trial are evaluating the ability of SeaStar Medical's SCD therapy to neutralize destructive hyperinflammation to improve health outcomes. The SCD therapy is designed as a disease-modifying device that neutralizes over-active immune cells and stops the cytokine storm that yields destructive hyperinflammation and creates a cascade of events that wreak havoc in the patient's body.

The [NEUTRALIZE-AKI](#) pivotal trial was granted CMS coverage in July 2024 for qualified patients. The trial is evaluating the safety and efficacy of the SCD therapy in 200 adults with AKI in the ICU receiving CRRT. It is currently 50% enrolled, with full enrollment anticipated near the end of 2025. The trial's primary endpoint is a composite of 90-day mortality or dialysis dependency of patients treated with the SCD therapy in addition to CRRT as the standard of care, compared with the control group receiving only CRRT standard of care. The FDA has granted Breakthrough Device Designation for the SCD therapy in adult patients with AKI and CRRT.

The NEUTRALIZE-CRS trial is designed to evaluate the safety and initial efficacy of the SCD therapy in reducing destructive hyperinflammation in adult patients with acute heart failure with worsening renal function due to cardiorenal syndrome or severe right ventricular failure awaiting a left ventricular assist device (LVAD) implantation. The trial is expected to enroll 20 patients at up to five clinical sites and will be funded by a previously announced [\\$3.6 million National Institutes of Health \(NIH\) grant](#) awarded to Innovative BioTherapies (IBT), which is led by SCD inventor H. David Humes, MD, Professor, Division of Nephrology, Internal Medicine, University of Michigan and SeaStar Medical Scientific Advisor. Dr. Humes will serve as lead investigator for the study and SeaStar Medical will act as clinical research organization (CRO). The FDA has granted Breakthrough Device Designation for the SCD in [cardiorenal syndrome](#) awaiting LVAD implantation.

About SeaStar Medical

SeaStar Medical is a commercial-stage healthcare company focused on transforming treatments for critically ill patients facing organ failure and potential loss of life. SeaStar's first commercial product, QUELIMMUNE (SCD-PED), was approved in 2024 by the U.S. Food and Drug Administration (FDA). It is the only FDA approved product for the ultra-rare condition of life-threatening acute kidney injury (AKI) due to sepsis or a septic condition in critically ill pediatric patients. SeaStar's Selective Cytopheretic Device (SCD) therapy has been awarded Breakthrough Device Designation for six therapeutic indications by the FDA, enabling

the potential for a speedier pathway to approval and preferable reimbursement dynamics at commercial launch. The company is currently conducting a pivotal trial of its SCD therapy in adult patients with AKI requiring continuous renal replacement therapy (CRRT), a life-threatening condition with no effective treatment options that impacts over 200,000 adults in the U.S. annually.

Forward-Looking Statements

This press release contains certain forward-looking statements within the meaning of the “safe harbor” provisions of the Private Securities Litigation Reform Act of 1995. These forward-looking statements include, without limitation, SeaStar Medical’s expectations with respect to anticipated patient benefits and cost savings from our products; the expected regulatory approval process and timeline for our products; and the ability of SeaStar Medical to meet the expected timeline. Words such as “believe,” “project,” “expect,” “anticipate,” “estimate,” “intend,” “strategy,” “future,” “opportunity,” “plan,” “may,” “should,” “will,” “would,” “will be,” “will continue,” “will likely result,” and similar expressions are intended to identify such forward-looking statements. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to significant risks and uncertainties that could cause the actual results to differ materially from the expected results. Most of these factors are outside SeaStar Medical’s control and are difficult to predict. Factors that may cause actual future events to differ materially from the expected results include, but are not limited to: (i) the risk that SeaStar Medical may not be able to obtain regulatory approval of its SCD product candidates; (ii) the risk that SeaStar Medical may not be able to raise sufficient capital to fund its operations, including current or future clinical trials; (iii) the risk that SeaStar Medical and its current and future collaborators are unable to successfully develop and commercialize its products or services, or experience significant delays in doing so, including failure to achieve approval of its products by applicable federal and state regulators, (iv) the risk that SeaStar Medical may never achieve or sustain profitability; (v) the risk that SeaStar Medical may not be able to secure additional financing on acceptable terms; (vi) the risk that third-party suppliers and manufacturers are not able to fully and timely meet their obligations, (vii) the risk of product liability or regulatory lawsuits or proceedings relating to SeaStar Medical’s products and services, (viii) the risk that SeaStar Medical is unable to secure or protect its intellectual property, and (ix) other risks and uncertainties indicated from time to time in SeaStar Medical’s Annual Report on Form 10-K, including those under the “Risk Factors” section therein and in SeaStar Medical’s other filings with the SEC. The foregoing list of factors is not exhaustive. Forward-looking statements speak only as of the date they are made. Readers are cautioned not to put undue reliance on forward-looking statements, and SeaStar Medical assumes no obligation and do not intend to update or revise these forward-looking statements, whether as a result of new information, future events, or otherwise.

For more information visit www.seastarmedical.com or visit us on [LinkedIn](#) or [X](#).

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