# SeaStar Medical Announces New ICD-10-PCS Codes for Its SCD Therapy for Acute Kidney Injury

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*Enables standardized inpatient hospital billing for QUELIMMUNE® (SCD-PED) therapy*

*Universal code paves the way for billing of future potential SCD therapies requiring renal replacement therapy*

DENVER, June 23, 2026 (GLOBE NEWSWIRE) -- SeaStar Medical Holding Corporation (Nasdaq: ICU), a commercial-stage healthcare company focused on transformational treatments for critically ill patients facing organ failure and potential loss of life announced today that its Selective Cytopheretic Device (SCD) therapy has received dedicated ICD-10-PCS (International Classification of Diseases, 10th Revision, Procedure Coding System) codes from the Centers for Medicare & Medicaid Services (CMS). This assignment enables administrative, billing, and statistical reporting for the use of SeaStar Medical's SCD therapy in patients with acute kidney injury (AKI) requiring renal replacement therapy (RRT) in the inpatient hospital setting.

"We are thrilled that we were able to obtain universal billing codes for our SCD therapy. This will ease the logistics for our existing QUELIMMUNE customers, but importantly, has significant implications for the potential launch of our SCD therapy in the adult AKI indication. We estimate this market is about 50 times larger than the pediatric market, or approximately $4.5 billion. Having reimbursement codes in place will be a substantial benefit for rapid adoption of a product in this market," stated Tim Varacek, Senior Vice President of Commercial and Business Operations of SeaStar Medical.

A PCS code refers to the ICD-10-PCS developed and maintained by the CMS specifically for use in United States hospitals use to report inpatient procedures for billing, data tracking, and reimbursement purposes. The new codes provide hospitals with a clear, specific mechanism to document and seek payment when using QUELIMMUNE, addressing previous coding limitations that could hinder broader adoption. The new ICD-10-PCS codes are expected to take effect on October 1, 2026.

**About QUELIMMUNE**

The QUELIMMUNE® (SCD-PED) therapy is being commercialized for children with AKI and sepsis or septic condition weighing 10 kilograms or more who are on antibiotics and being treated in the ICU with RRT. It was approved in February 2024 under a Humanitarian Device Exemption application.

Data from two clinical trials of the QUELIMMUNE therapy, published in *Kidney Medicine*, showed a 77% survival rate in patient treated with QUELIMMUNE versus standard of care, representing an approximate 50% reduction in loss of life compared to historical data in this patient population. No dialysis was required for survivors, and 87.5% of survivors had normal kidney function at Day 60 after ICU discharge.

Real-world data published in the prestigious, peer-reviewed journal, *Pediatric Nephrology,* highlighted the early experience from the QUELIMMUNE SAVE Registry, a post-approval surveillance registry, evaluating the role of the QUELIMMUNE therapy in the treatment of critically ill pediatric patients with life-threatening AKI and sepsis requiring renal replacement therapy. Observations from the first 21 pediatric patients with AKI and sepsis requiring renal replacement therapy showed no device-related adverse events or infections and no reports of immunosuppressive effects by the device. In addition, preliminary outcomes analyses show a 76% survival rate at Day 28 and Day 60, and a 71% survival rate at Day 90. These new data are on track to validate a 50% reduction in patient mortality at 60 days compared to historical data, similar to what was observed in the registration study reported in *Kidney Medicine*.

In January 2025, SeaStar Medical was awarded the 2025 Corporate Innovator Award by the National Kidney Foundation for its significant contribution to improving the lives of pediatric patients with AKI based on the approval and introduction of the QUELIMMUNE therapy.

The patented technology behind QUELIMMUNE is known as the Selective Cytopheretic Device (SCD) therapy and has broad applications for treating the destructive hyperinflammation that shuts down organ function and causes loss of life.

**About NEUTRALIZE-AKI Pivotal Trial**

The NEUTRALIZE-AKI (NEUTRophil and monocyte deActivation via SeLective Cytopheretic Device – a randomIZEd clinical trial in Acute Kidney Injury) pivotal trial is evaluating the safety and efficacy of the SCD therapy in 339 adults with AKI in the ICU receiving continuous RRT. 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 continuous RRT as the standard of care, compared with the control group receiving only continuous RRT standard of care. Secondary endpoints include mortality at 28 days, ICU-free days in the first 28 days, major

adverse kidney events at Day 90 and dialysis dependency at one year. The study will also include subgroup analyses to explore the effectiveness of the SCD therapy in AKI patients with sepsis and acute respiratory distress syndrome.

SeaStar Medical's SCD therapy has been awarded Breakthrough Device Designation for the treatment of immunomodulatory dysregulation in adult patients with AKI.

**About Acute Kidney Injury (AKI) and Hyperinflammation**

AKI is characterized by a sudden and temporary loss of kidney function and can be caused by a variety of conditions such as severe infections or other septic conditions, severe trauma, surgery, and organ failures. AKI can cause destructive hyperinflammation, which is the overproduction or overactivity of inflammatory effector cells and other molecules that can be toxic. Damage resulting from this destructive hyperinflammation in AKI can progress to other organs, such as the heart or liver, and potentially to multi-organ dysfunction or even failure that could result in worse outcomes, including increased risk of death. Even after resolution, these patients may face complications including chronic kidney disease or end-stage renal disease (ESRD) requiring dialysis. Extreme hyperinflammation may also contribute to added healthcare costs, such as prolonged ICU stays and increased reliance on dialysis and mechanical ventilation.

**About Selective Cytopheretic Device (SCD) Therapy**

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 SCD therapy is designed for broad applications in multiple acute and chronic kidney and cardiovascular diseases, representing patients who today have no FDA-approved options for treating their disease. Unlike pathogen removal and other blood-purification tools, the SCD therapy is integrated with an existing continuous RRT hemofiltration system to selectively target and transition proinflammatory monocytes to a reparative state and promote activated neutrophils to be less inflammatory. This unique immunomodulation approach may promote long-term organ recovery, eliminate the need for future continuous RRT, including dialysis, and prevent loss of life.

**About SeaStar Medical**

SeaStar Medical is a commercial-stage healthcare company focused on transformational treatments for critically ill patients facing organ failure and potential loss of life. SeaStar Medical'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 requiring renal replacement therapy (RRT) in critically ill pediatric patients. SeaStar Medical's 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 the NEUTRALIZE-AKI pivotal clinical trial of its SCD therapy in adult patients with AKI requiring continuous renal replacement therapy, a life-threatening condition with no effective treatment options that impacts over 200,000 adults in the U.S. annually.

For more information visit www.seastarmedical.com or visit us on LinkedIn or X.

**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 1955. These forward-looking statements include, without limitation, SeaStar Medical's expectations with respect to ICD-10-PCS codes are expected to take effect; anticipated patient enrollment and the expansion of the clinical trial sites; the total addressable market for the SCD applications; the ability of SeaStar Medical to gain market share and generate; broadening QUELIMMUNE adoption by the addition of top-ranked children's medical centers; the amount and timing of future QUELIMMUNE commercial sales; commercial acceptance of QUELIMMUNE; the ability of SCD to treat patients with AKI and other diseases; the expected regulatory approval process and timeline for commercialization; 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.

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