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Clarity When It's Critical

Ceribell Launches ClarityPro™ AI, Expanding Access to Critical Diagnosis of Electrographic Status Epilepticus

October 30, 2023

ClarityPro™ algorithm provides clinicians with unprecedented abilities to quickly and accurately detect, diagnose, and monitor electrographic status epilepticus in critically ill patients

SUNNYVALE, Calif., Oct. 30, 2023 /PRNewswire/ -- Ceribell, Inc.® today announced the commercial release of its new AI algorithm, ClarityPro™, accompanying the availability of potential additional reimbursement for eligible Medicare patients.



ClarityPro is an AI-based software algorithm within the Ceribell EEG system that analyzes EEG waveforms to diagnose electrographic status epilepticus (ESE). It is the first acute care device to be FDA indicated for stand-alone diagnosis. It is also the first critical care monitoring device to secure both FDA Breakthrough Designation and Centers for Medicare & Medicaid Services (CMS) New Technology Add-on Payment (NTAP) reimbursement, based on the substantial clinical benefit over existing devices for suspected seizure patients. With a unique code, hospitals may now be reimbursed up to \$913.90 per eligible Medicare patient when using this groundbreaking technology.

ClarityPro can continuously monitor patients' brain activity for suspected seizures and can diagnose and alert for ESE, giving clinicians at the bedside and remotely the vital, real-time data needed to rapidly identify and treat seizures and to evaluate the efficacy of seizure medication. With automated cues highlighting significant areas of concern within the EEG, ClarityPro provides insights to aid neurologists during EEG review, facilitating a quick response when escalation of care is needed. Importantly, the Ceribell system also enables hospitals with ClarityPro to more easily expand brain monitoring capabilities to acute care departments at a fraction of the cost of conventional EEG, while also helping to reduce use of unnecessary medication, intubations and patient transfers, and shortening ICU length of stay.¹⁻⁴

"Every minute counts when it comes to treating status epilepticus. Ceribell is dedicated to expanding access to neurodiagnostics, which is essential to improving patient care and outcomes," said Jane Chao, Ph.D., Ceribell's Co-founder and CEO. "ClarityPro harnesses the power of AI to bring acute seizure management to a new level, helping clinicians make precise treatment decisions while also helping hospitals extend care to more patients."

For additional information about ClarityPro, the FDA Breakthrough Device program, the CMS NTAP program, and status epilepticus, visit <https://ceribell.com/ClarityPro>.

About Status Epilepticus (SE)

SE is a life-threatening condition of prolonged seizure activity that affects up to approximately 200,000 or more Americans each year^{5,6,7}. It can manifest in physical symptoms such as convulsions, or sub-clinically, with electrographic patterns on an EEG as

the only diagnostic clue. While SE has a mortality rate of over 20% for adults⁷, outcomes for patients are strongly tied to how quickly the condition is recognized and controlled, with mortality rates increasing 13%⁸ with every hour that seizures go untreated.

About the New Technology Add-on Payment (NTAP) Program

The NTAP reimbursement program recognizes new technologies that provide substantially improved clinical benefits over currently available therapies, giving eligible Medicare beneficiaries timelier access to advancements in healthcare.

About Ceribell

Ceribell, Inc., the developer of the first AI-powered point-of-care EEG diagnostic system, is revolutionizing seizure management in acute care. Ceribell's mission is to make EEG diagnostics widely available, more efficient, and more cost-effective, to improve the detection and treatment of neurological conditions. The Ceribell system provides rapid access to accurate diagnostic information and continuous monitoring at the bedside 24/7, enabling precise patient care and hospital-wide efficiencies. The Ceribell system first received FDA 510(k) clearance in 2017 and is commercially available in the United States. The latest ClarityPro™ AI algorithm is the first and only FDA-indicated software for the diagnosis of electrographic status epilepticus with U.S. Centers for Medicare and Medicaid Services approved New Technology Add-on Payment (NTAP). For more information visit www.ceribell.com.

References

1. Kurup, D., et al. (2022) *Epileptic Disorders*. 24(5): 1-7
2. Ward, J., et al. (2023) *Front. Digit. Health*. 5(1)
3. Ney, J.P., et al. (2021) *J Med Econ*. 24(1):318-327
4. Eberhard, E., et al. (2023) *J Neurosci Nurs*. 55(5):p 157-163
5. Dham, BS., et al (2014) *Neurocrit Care*. (3):476-83
6. DeLorenzo, R. J., et al. (1996) *Neurology*. 46 (4) 1029-1035
7. Lu, M., et al (2020) *Epilepsy Behav*. 112:102459
8. Young, G.B., et al. (1996) *Neurology*. 47(1):83-89

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