

ASX ANNOUNCEMENT

5 August 2025

Final CMS Approval Received for NTAP Reimbursement

Key Highlights:

- U.S. Centers for Medicare & Medicaid Services (CMS) has confirmed approval for EBR's novel WiSE® System under the New Technology Add-On Payment (NTAP) scheme for Medicare inpatients¹
- CMS has finalized NTAP reimbursement at the maximum rate
- The NTAP payment is in addition to Diagnosis Related Groups (DRG) payments received for the procedure
- NTAP approval supports EBR's commercialisation strategy, with the initial limited market release set to coincide with NTAP reimbursement commencing 1 October 2025

Sunnyvale, California; 5 August 2025: EBR Systems, Inc. (ASX: “EBR”, “EBR Systems”, or the “Company”), developer of the world’s only wireless cardiac pacing device for heart failure, is pleased to announce the U.S. Centers for Medicare & Medicaid Services (CMS) has confirmed approval of the New Technology Add-On Payment (NTAP) for EBR’s novel WiSE® CRT System.

The NTAP is designed to bridge the financial gap between the costs of innovative technologies and the standard Medicare Severity Diagnosis Related Groups (MS-DRG or DRG) payment structure in place, while encouraging early adoption of breakthrough medical advancements used in the inpatient setting for Medicare patients. This confirmation secures the maximum reimbursement rate of up to US\$41,145 based on an average WiSE selling price of US\$63,300. This is in addition to the DRG payments, which are intended to cover the procedure and remaining device costs. NTAP reimbursement will remain in effect for 3 years. CMS uses this 3-year period to collect actual costs for the device and procedure based on Medicare claims data. The Company will petition CMS during the second year to move WiSE procedures to a DRG that fully covers the cost of the WiSE System and procedure.

The approval received from CMS represents a significant advancement in EBR’s commercialisation strategy, establishing a reimbursement pathway for the novel WiSE System for Medicare inpatients commencing 1 October 2025, which coincides with the initial limited market release.

John McCutcheon, EBR Systems’ President & Chief Executive Officer said:

“We are thrilled to announce that the WiSE System has received NTAP reimbursement approval, effective October 2025. The NTAP program supports innovative technologies by addressing gaps in existing DRG payments, ensuring that hospitals can adopt important, cutting-edge solutions. This milestone enhances the commercial attractiveness of our product, accelerates hospital adoption, and expands patient access to our groundbreaking cardiac pacing technology across the U.S.”

Additionally, the company expects to receive final Transitional Pass-Through (TPT) payment approval from CMS prior to 1 October 2025. CMS has already recommended TPT approval for WiSE in outpatient settings, subject to the final ruling.²

ENDS

¹ See prior ASX Market Announcement, 14 Apr 2025 – CMS Proposes Approval of NTAP Reimbursement

² See prior ASX Market Announcement, 14 Jul 2025 – Preliminary Approval for TPT Reimbursement Received

This announcement has been authorised for release by the EBR Systems General Disclosure Committee, a committee of the Board of Directors

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About EBR Systems

Silicon Valley-based EBR Systems (ASX: EBR) is dedicated to superior treatment of cardiac rhythm disease by providing more physiologically effective stimulation through wireless cardiac pacing. The patented proprietary Wireless Stimulation Endocardially (WiSE) technology was developed to eliminate the need for cardiac pacing leads, historically the major source of complications, effectiveness and reliability issues in cardiac rhythm disease management. The initial product is designed to eliminate the need for coronary sinus leads to stimulate the left ventricle in heart failure patients requiring Cardiac Resynchronisation Therapy (CRT). Future products potentially address wireless endocardial stimulation for bradycardia and other non-cardiac indications.

EBR Systems' WiSE Technology

EBR Systems' WiSE technology is the world's only wireless, endocardial (inside the heart) pacing system in clinical use for stimulating the heart's left ventricle. This has long been a goal of cardiac pacing companies since internal stimulation of the left ventricle is thought to be a potentially superior, more anatomically correct pacing location. WiSE technology enables cardiac pacing of the left ventricle with a novel cardiac implant that is roughly the size of a large grain of rice. The need for a pacing wire on the outside of the heart's left ventricle – and the attendant problems – are potentially eliminated. WiSE has been approved by the FDA and is currently available for sale in the U.S.

Forward-Looking Statements

This announcement contains or may contain forward-looking statements that are based on management's beliefs, assumptions, and expectations and on information currently available to management. Forward-looking statements involve known and unknown risks, uncertainties, contingencies and other factors, many of which are beyond the Company's control, subject to change without notice and may involve significant elements of subjective judgment and assumptions as to future events which may or may not be correct.

All statements that address operating performance, events or developments that we expect or anticipate will occur in the future are forward-looking statements, including without limitation our expectations with respect to our ability to commercialize our products including our estimates of potential revenues, costs, profitability and financial performance; our ability to develop and commercialize new products including our ability to obtain reimbursement for our products; our expectations with respect to our clinical trials, including enrolment in or completion of our clinical trials and our associated regulatory applications and approvals; our expectations with respect to the integrity or capabilities of our intellectual property position.

Management believes that these forward-looking statements are reasonable as and when made. You should not place undue reliance on forward-looking statements because they speak only as of the date when made. EBR does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise. EBR may not actually achieve the plans, projections or expectations disclosed in forward-looking statements, and actual results, developments or events could differ materially from those disclosed in the forward-looking statements.

Foreign Ownership Restriction

EBR's CHES Depositary Interests (CDIs) are issued in reliance on the exemption from registration contained in Regulation S of the US Securities Act of 1933 (Securities Act) for offers or sales which are made outside the US. Accordingly, the CDIs have not been, and will not be, registered under the Securities Act or the laws of any state or other jurisdiction in the US. The holders of EBR's CDIs are unable to sell the CDIs into the US or to a US person unless the re-sale of the CDIs is registered under the Securities Act, or an exemption is available. Hedging transactions with regard to the CDIs may only be conducted in accordance with the Securities Act.