

CMS Initiates National Coverage Determination for WiSE

Key highlights:

- EBR's WiSE System is the first technology to gain entry to CMS's TCET program, underscoring the differentiated clinical significance and impact of leadless left ventricular endocardial pacing.
- The TCET program expedites national Medicare coverage for FDA designated Breakthrough Devices, and CMS has formally initiated the National Coverage Determination (NCD) process for the WiSE[®] System, a major step toward broad national access for patients.
- EBR is working toward CMS's projected timeline, which would deliver WiSE NCD approval by early 2027, significantly faster than the typical pathway of greater than five years without TCET.
- A positive NCD decision would establish a uniform national Medicare coverage framework, materially expand patient access, and support accelerated U.S. commercialization for EBR.

Sunnyvale, California; 4 June 2026: EBR Systems, Inc. (ASX: "EBR", "EBR Systems", or the "Company"), developer of the world's only wireless cardiac pacing device for heart failure, announces that the U.S. Centers for Medicare & Medicaid Services (CMS) has initiated a National Coverage Determination to evaluate Medicare coverage for leadless left ventricular endocardial pacing (LVEP) used in cardiac resynchronization therapy (CRT).

The initiation of the NCD process is a key outcome of EBR's engagement with CMS through the Transitional Coverage for Emerging Technologies (TCET) pathway and represents the most tangible milestone to date in establishing national Medicare coverage for the WiSE System.

EBR was the first company selected for the TCET program from CMS approximately eighteen months ago, reflecting a materially fast-tracked pathway relative to the typical three to five-year time frame for companies pursuing national Medicare coverage. The WiSE System received U.S. FDA Breakthrough Device designation and U.S. FDA approval, supporting EBR's progress through TCET toward national Medicare coverage. A positive NCD outcome will support broader Medicare coverage, expanded patient access and accelerated U.S. commercialisation efforts.

The WiSE System received FDA approval in April 2025. CMS granted approval for both the New Technology Add-on Payment (NTAP) program for inpatient procedures and the Transitional Pass-Through (TPT) payment for outpatient procedures, effective 1 October 2025. Both allow a selling price of US\$63,300. Additionally, the Company has signed more than 39 contracts with individual hospitals as well as numerous regional and national contracts with major hospital systems at a price of \$63,300 as previously announced. The ongoing NCD process is intended to establish a national Medicare coverage framework for eligible patients and providers, further supporting access and adoption of the therapy across the U.S.

Under the NCD process, CMS conducts a national coverage analysis (NCA) to evaluate whether a medical technology meets the statutory standard of being reasonable and necessary for Medicare beneficiaries. The process may ultimately result in a national Medicare coverage policy for the WiSE System.

Medicare is the U.S. federal health insurance program for people aged 65 years or older, certain people under 65 years with disabilities, and people of all ages with End-Stage Renal Disease. EBR Systems submitted a request for an NCD for leadless LV endocardial pacing for Medicare beneficiaries with heart failure indicated for CRT who were previously untreatable or considered high-risk for upgrade procedures.

CMS publishes updates regarding the NCD process through its publicly available tracking sheet: [LINK](#)

According to the tracking sheet, the agency has established the following timeline for the review:

- Formal Request Accepted and Review Initiated: June 3, 2026
- Public Comment Period: June 3, 2026 – July 3, 2026
- Proposed Decision Memo Due Date: December 3, 2026
- Public Comment Period: December 3, 2026 – January 2, 2027
- Final NCD expected: March 3, 2027

For more information about EBR, please visit <https://www.ebrsystemsinc.com/>.

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This announcement has been authorised for release by the EBR Systems Routine 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 is an investigational device in most markets and is currently only available for sale in the US.

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 and achieve broad market adoption including our estimates of potential revenues, costs, profitability and financial performance; our ability to develop and commercialize new products; our expectations with respect to our clinical trials, including enrollment 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. These forward-looking statements are based on EBR Systems' current

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expectations and inherently involve significant risks and uncertainties. EBR Systems' actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of certain risks and uncertainties including those risks described in more detail in its most recently filed Annual Report on Form 10-K, Quarterly Report on Form 10-Q, and other documents on file with the SEC from time to time and available on the SEC's website at www.sec.gov.

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 ASX-traded (ASX: EBR) 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.