

CAPITOL STREET

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Medicare Reopens TAVR NCD for Asymptomatic Patients

Coverage Expansion Would be an Incremental Positive for EW

Relevant Companies



»» Our Take & Next Up

We believe there's a good chance CMS will expand Medicare coverage for EW's SAPIEN 3 for asymptomatic patients by September 2026. CMS yesterday evening opened a National Coverage Analysis (NCA) on Transcatheter Aortic Valve Replacement (TAVR) at the request of Edwards LifeSciences. Coverage expansion would likely provide an incremental gain in procedure volumes for EW's SAPIEN 3, the only platform approved for treating asymptomatic severe aortic stenosis (here). In our view, the NCA has a high probability of success given EW's track record of successfully navigating Medicare's NCD process. The proposed and final NCD are expected June 15, 2026 and Sept. 13, 2026, respectively.

»» Key Points

CMS yesterday evening opened a National Coverage Analysis (NCA) on Transcatheter Aortic Valve Replacement (TAVR) at the request of Edwards LifeSciences. The proposed National Coverage Determination (NCD) is due June 15, 2026 and a final NCD is expected by Sept. 13, 2026.

EW calls for TAVR coverage update to include asymptomatic patients and scrap outdated CED rules. According to the company "the reconsideration is needed to reflect new published evidence demonstrating improved outcomes with the use of TAVR for asymptomatic patients that are beyond the scope of the current NCD, as well as additional evidence supporting the removal of coverage with evidence development (CED) and other outdated requirements in the current NCD."

Coverage expansion would likely provide an incremental gain in procedure volumes. According to CMS, this NCA will focus on coverage of TAVR for aortic stenosis (AS) in symptomatic and asymptomatic patients. This NCA will analyze clinical evidence for characteristics or comorbidities that make patients more or less likely to benefit from the device and whether specific treatment conditions are necessary to achieve the outcomes demonstrated in clinical studies.

In our view, the NCA has a high probability of success given EW's track record of successfully navigating Medicare's NCD process. EW worked closely with both FDA and CMS on the initial TAVR

application in 2012, which allowed for Medicare coverage 6 months after FDA approval. More recently, CMS on March 19 finalized coverage of EW's EVOQUE system for Transcatheter Tricuspid Valve Replacement (TTVR) ([here](#)) under the Transitional Coverage for Emerging Technologies (TCET) pathway.

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