

# CAPITOL STREET

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## Abbott and Edwards Lifesciences Likely Successful TCET Candidates

Medicare Opens Second NCD Under TCET Pilot

Relevant Companies



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### »» Our Take & Next Up

**Abbott and Edwards Lifesciences will likely be the first two companies to successfully navigate Medicare's Transitional Coverage of Emerging Technology (TCET) pilot, in our view.** As the first two applicants for a National Coverage Determination (NCD) under TCET, medical devices from the two companies were likely hand-picked by CMS to show the value of the pilot program. CMS took a similar approach with its earlier Parallel Review pilot, which was successfully navigated by **Exact Sciences** (Cologuard) and **Foundation Medicine** (FoundationOne CDx). The proposed and final NCD for the Edwards Lifesciences device is expected December 20, 2024 and March 20, 2025, respectively. The proposed and final NCD for the Abbott device is expected April 3, 2025 and July 2, 2025, respectively.

### »» Key Points

**CMS late last week opened a National Coverage Analysis (NCA) on Transcatheter Edge-to-Edge Repair for Tricuspid Valve Regurgitation (T-TEER) at the request of Abbott.** The proposed National Coverage Determination (NCD) is due April 3, 2025 and a final NCD is expected by July 2, 2025.

**According to CMS, tricuspid regurgitation (TR) occurs when the valve between the right atrium and right ventricle does not function properly and blood flows from the right ventricle back into the right atrium.** TR can lead to symptoms of leg swelling, fluid accumulation in the abdomen, an enlarged spleen and liver, and heart failure.

**The NCA is the second to test Medicare's Transitional Coverage of Emerging Technology (TCET) pilot.** CMS on June 20 accepted a formal NCD request for **Edwards Lifesciences'** EVOQUE system for Transcatheter Tricuspid Valve Replacement (TTVR) ([here](#)) under the TCET pathway. The proposed NCD is due December 20, 2024 and a final NCD is expected by March 20, 2025.

**In our view, the two NCAs have a high probability of success as they were likely hand-picked by CMS to show the value of TCET.** CMS took a similar approach with its earlier Parallel Review pilot, which was successfully navigated by **Exact Sciences** (Cologuard) in 2014 and **Foundation Medicine** (FoundationOne

CDx) in 2017. Parallel Review is a voluntary program launched in 2011 to expedite Medicare coverage of medical devices following FDA approval.

**CMS discussed operational issues for TCET during a September 23 webinar (transcript [here](#)).** Among other program updates, CMS officials noted that the agency expects to soon release guidance on fit-for-purpose studies and real-world data protocols, followed by prioritization guidance after several quarterly review cycles. CMS also recommended that TCET nominations be submitted approximately 12 months before the manufacturer anticipates an FDA decision on market authorization.

## **BACKGROUND ON TCET**

**CMS finalized the TCET pathway in August, outlining coverage for certain FDA-designated Breakthrough Devices (see our analysis [here](#)).** CMS maintained the five (5) TCET candidate limit on breakthrough (BT) devices per year and diagnostic laboratory tests will still likely not be selected. For technologies accepted into and continuing in the TCET pathway, CMS' goal is to finalize a national coverage determination (NCD) within six months after FDA marketing authorization.

**CMS will soon release the proposed factors the agency will use to prioritize TCET nominations.** The new pathway does not do much to move the needle on medical device coverage with a continued limit of five per year with limited CMS resources, despite the hundreds of devices that receive BT designation each year. The pathway also comes with rather rigorous data generation requirements and we expect that larger companies (MDT, BSX, ABT) will benefit the most, having the capacity to conduct the additional clinical and/or fit-for-purpose studies that will be required by CMS-AHRQ.

**Meanwhile, legislation that mirrors Medicare Coverage of Innovative Technologies (MCIT) is being considered, but unlikely to pass this year & could see momentum in a GOP administration/Congress.** The [Ensuring Patient Access to Critical Breakthrough Products Act](#), is a bipartisan bill that requires Medicare to temporarily cover all FDA approved, breakthrough medical devices for four years, starting on the day of approval. The bill advanced out of the House Ways and Means committee at the end of June. However, it lacks a Senate companion bill at this time.

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