

# CAPITOL STREET

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August 8, 2024

## Finalized BT Device Coverage Pathway

Some Policies Better/Worse: 5+ Yrs Coverage, 5 Device Limit  
Unchanged

Relevant Companies

*Johnson & Johnson*



Boston  
Scientific

Medtronic

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### »» Our Take & Next Up

Late yesterday, a finalized **Transitional Coverage for Emerging Technologies (TCET)** pathway was released by CMS with little fanfare, outlining coverage for certain **FDA-designated Breakthrough Devices** ([here](#)). CMS has not changed 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 release soon the proposed factors CMS 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 5 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 requirement 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.

### »» Key Points

**Positively for MedTech & innovators, CMS expects coverage of 5+ years (longer than 3-5 years as proposed).** In general, CMS intends for coverage to continue to facilitate the timely generation of evidence, which is anticipated to take 5 or more years. Coverage is tied to the CMS and AHRQ-approved EDP. The review date specified in the EDP will provide one additional year of coverage after study completion to allow manufacturers to complete their analysis.

**More negatively, only Breakthrough Devices will qualify for TCET, with a limit of 5 per year (unchanged from proposed) which is miniscule.** in vitro diagnostic (IVDs) will not be prioritized but imaging tests may be included.

- **CMS is not budging from the 5 per year limit as it is the largest number that they can address within current resources.** Appropriate candidates for TCET are Breakthrough Devices, determined to be within a Medicare benefit category, not already the subject of an existing Medicare NCD, and not otherwise excluded from coverage through law or regulation.

- **CMS notes more than 1 device could fall under the same NCD.** NCDs are limited to specific items or services, but it is possible that more than one device could fall under the same NCD because it addresses the same indication. If necessary, CMS intends to provide flexibility for follow-on devices under same coverage conditions, including a requirement to propose an EDP. These follow-on devices must also have BT designation but will not count against the annual cap of devices accepted into the TCET pathway.
- **In vitro diagnostic tests, while not explicitly excluded, will not be prioritized.** The final pathway notes that FDA's definition of medical device now includes in vitro diagnostic (IVD) products, such as laboratory tests. The proposed pathway stated Dx lab tests will not qualify. CMS continues to intend for most coverage determinations for IVDs with Breakthrough Device status to be decided by MACs through existing pathways. However, the agency does acknowledge there may be instances where manufacturers and CMS agree that an NCD is appropriate for a diagnostic laboratory test.
- **Other non-IVD diagnostic devices, such as diagnostic imaging devices, may be considered for TCET.**

**Changes to the final pathway include clinical endpoints review, revised timeframe for nominations, interim reporting, and inclusion in the NCD Dashboard.** TCET leverages the existing NCD and coverage with evidence development (CED) processes to provide coverage for emerging technologies.

- Manufacturers will be allowed to submit a non-binding letter of intent to nominate a potentially eligible device approximately 18 to 24 months before anticipated FDA marketing authorization. Submission of a non-binding letter of intent may avoid delays in TCET reviews, particularly if a clinical endpoints' review is required.
- Where appropriate clinical endpoints are uncertain, CMS may preemptively conduct a clinical endpoints' review and may convene a MEDCAC panel.
- CMS will review TCET nominations on a quarterly basis. NOTE: This is *slower* than the proposed timeframe which required CMS to act upon nominations within 30 days of submission.
- Evidence Development Plans (EDPs) will be required to incorporate interim reporting to ensure adequate progress and timely completion. Interim reports must disclose any meaningful changes to prespecified study protocols.
- CMS will release soon the proposed factors CMS will use to *prioritize* TCET nominations to provide greater transparency, consistency, and predictability.
- Info on TCET devices will be added to the NCD Dashboard ([link](#)), including the number of devices in the TCET pathway, the date of nomination, the date of acceptance, and the date the NCD process was initiated.

**Key components remain unchanged with the requirement of an evidence review and evidence development plan.** Positively for medical device makers, CMS notes that an NCD *without* CED is an option under TCET if there is sufficient evidence to support Medicare coverage.

- **Evidence review is a focused literature review that provides early feedback on the strengths and weaknesses of the available evidence, including any evidence gaps.** It will inform CMS and manufacturers about the best available coverage options and on the state of the evidence and any notable evidence gaps. CMS intends for Evidence Previews to be conducted by a contractor using standardized evidence grading, risk of bias assessment, and applicability assessment.

- **An Evidence Development Plan (EDP) will be submitted by manufacturers to address any evidence gaps identified in the Evidence Preview.** EDPs may include traditional clinical study designs and/or fit-for-purpose study designs, including those that rely on secondary use of real-world data. The EDP development will include CMS-AHRQ collaboration to evaluate the EDP.

**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](#), 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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