CAPITOL STREET

April 23, 2026

CMS & FDA Announce RAPID Coverage Pathway for Breakthrough MedTech

Medicare Coverage & Payment Within Two Months Is an Incremental Positive But Not Game Changing

Relevant Companies

Our Take & Next Up

CMS and FDA today announced a new voluntary expedited Medicare coverage pathway for certain FDA-designated Class II and Class III Breakthrough Devices. While full details of the program should be out shortly in the form of a proposed notice, the new pathway appears to be an incremental improvement from the current TCET pathway (limited to five devices per year), but not as generous as the original MCIT proposal from the first Trump administration, which would have provided four years of automatic Medicare coverage.

Under the Regulatory Alignment for Predictable and Immediate Device (RAPID) pathway, CMS will issue a proposed National Coverage Determination (NCD) the same day an eligible device receives FDA market authorization, with coverage and payment in as soon as 2 months. This would likely speed up the 9-12 month NCD process by at least six months as it typically takes six months between the initiation of a National Coverage Analysis to a proposed NCD and another three months for a final NCD.

Key Points

We had said that we believed CMS would move ahead – versus waiting for Congress to pass costly legislation – on a coverage pathway for breakthrough MedTech (here and here). The *Ensuring Patient Access to Critical Breakthroughs Product Act* ($900 M/10), sponsored by Reps Moore (R-UT), Delbene (D-WA), Sewell (D-AL), and Bilirakis (R-FL), would create a four-year transitional coverage period during which these devices are generally reimbursed while CMS conducts its full coverage review. The bill also forces CMS to make faster designation decisions within six months of application and report annually to Congress on approvals and denials.

Does two months sound familiar? The FDA's Commissioner's Voucher (CNPV) program provides ultra-fast (1-2 month) approvals for medicines that address unmet needs. RAPID reminds us of the Parallel Review pathway that didn't have much uptake (see below).

- The FDA Commissioner's Voucher program (CNPV) allows ultra-fast therapeutic FDA approvals and was rolled out in 2025 under Commissioner Makary. There was no regulatory guidance provided; however, the agency is changing course and providing a public forum in June (here) as the legality has been questioned.
- For RAPID, CMS and FDA will collect comments before finalizing the pathway. A proposed procedural notice on RAPID will soon be published in the Federal Register (FR) with a 60-day public comment period and will be effective upon publication of the final notice in the FR.
- The two-month timeline also resembles the CMS-FDA Parallel Review program. Only two products successfully navigated Parallel Review - Cologuard (**EXAS/ABT**) received coverage 2 months after FDA approval and FoundationOne CDx (**RHHBY**) received coverage 3.5 months after FDA approval.

The RAPID coverage pathway is designed to reduce delays between FDA approval and Medicare NCDs via earlier collaboration with innovators, but we don't see it as moving the needle that much. We have been anticipating such an announcement since late March (our take here). HHS Secretary RFK Jr. also previewed the new pathway at a House Ways and Means Committee hearing on April 16 (our take here).

- According to CMS, RAPID would enable Medicare national coverage and payment as soon as two months after market authorization, compared to approximately a year or more under the current pathway.
- CMS will issue a proposed NCD the same day an eligible device participating in this pathway receives FDA market authorization, triggering the statutorily required 30-day public comment period.
- The RAPID coverage pathway will be available for certain Class II devices participating in the FDA Total Product Life Cycle Advisory Program (TAP) and Class III devices, regardless of whether they are participating in TAP.
- To be eligible for the RAPID coverage pathway, devices must be the subject of an Investigational Device Exemption (IDE) study that enrolls Medicare beneficiaries and studies clinical health outcomes agreed upon by the FDA and CMS.

RAPID includes elements of the prior Trump plan (MCIT), though it does not include a blanket four-year approval period, the hallmark of MCIT 1.0. Recall that under the first Trump administration, CMS proposed the Medicare Coverage of Innovative Technologies pathway (MCIT - here), which would have provided automatic coverage for four years for all FDA-approved breakthrough devices. The MCIT rule was rescinded by the Biden administration and replaced with the Transitional Coverage for Emerging Technologies (TCET) pathway.

CMS notes that the existing Biden-era TCET pathway will be paused for new candidates to focus on implementation of RAPID. Recall, TCET has included only a handful of devices, with the pilot including **EW**, **ABT, Impulse Dynamics,** and possibly **CVRx** (see our past TCET analysis here). The MCIT pathway is favored by the MedTech industry as v1 provided no limit on the number of devices eligible and no restriction on diagnostic devices.

Ipsita Smolinski
Managing Director I Capitol Street
ipsita@capitol-street.com
202.250.3741 I www.capitol-street.com
900 19th St NW 6th Fl
Washington, D.C. 20006
CAPITOL STREET