The CMS-FDA RAPID Coverage Pathwa Is a Capital Markets Event Disguised a Coverage Policy: What the Regulatory-Reimbursement Clock Syr Means for Medtech Investment & Device Commercialization

APR 24, 2026 • PAID

Table of Contents

Abstract

CMS and FDA jointly announced the Regulatory Alignment for Predictable and Immediate Device (RAPID) coverage pathway on April 23, 2026. Key mechanics:

- Targets FDA-designated Class II and Class III Breakthrough Devices

- CMS issues proposed NCD same day as FDA market authorization

- 30-day public comment triggers; coverage potentially finalized within 60-90 da post-authorization

- Replaces the TCET pathway (paused for new candidates)

- ~40 devices currently eligible, ~20 additional potentially qualifying

- Devices must be subject to an IDE study enrolling Medicare beneficiaries with clinical endpoints jointly agreed by FDA and CMS

- Forthcoming Federal Register procedural notice opens 60-day public comment period before pathway is finalized

- Stanford Byers/Duke-Margolis survey: average 5 years from FDA auth to natior coverage; RAPID targets ~2 months

- Core structural shift: FDA approval becomes a trigger event for CMS coverage workflow, not a separate proceeding

The Problem This Is Actually Solving

There is a failure mode that has existed in medtech for decades that people in th industry kind of just accepted as the cost of doing business. A device company r multi-year pivotal trial, clears FDA, throws a press release, and then waits. Not (Not weeks. In some cases, years. Medicare, which covers a disproportionate shar the patients who need many of these breakthrough technologies, does not automatically cover a device just because FDA said it is safe and effective. Those two entirely separate determinations, governed by two entirely separate legal standards, administered by two agencies that historically operated on two compl different clocks.

FDA asks whether a device is safe and effective. CMS asks whether it is reasonal and necessary for Medicare beneficiaries. Sounds like they should overlap almos

entirely, and for the most part clinically they do, but the administrative machine that produces each answer has never been synchronized. FDA authorization historically triggers nothing at CMS. CMS has to open its own NCD proceeding, gather its own evidence, run its own comment periods, and reach its own conclu and that process has averaged somewhere between one and several years depend complexity and controversy. In the interim, a newly authorized device is in a kin commercial purgatory. It is legal to sell. It is legal to implant. But the largest sin payer in the country has not made a coverage determination, which means most hospitals are not going to stock it, most physicians are not going to recommend the device company cannot build a commercial ramp worth anything.

A Stanford Byers Center for Biodesign and Duke-Margolis Center for Health Pc survey put the average time from FDA device authorization to national Medicare commercial coverage at five years. Five. That is not a gap. That is a chasm. And i not because the evidence is usually ambiguous or because CMS has good reason doubt what FDA reviewed. It is mostly a structural problem – two agencies runn sequential processes that were never designed to be connected. That is the failu mode RAPID is targeting, and it is worth being precise about what it is because policy literature sometimes blurs it. The problem is not regulatory uncertainty. Breakthrough Device program has been running since 2016 and has designated 1,246 devices as of end of 2025. The problem is reimbursement uncertainty after regulatory certainty. Companies knew they could probably get FDA cleared. The no idea when, or whether, CMS would follow.

What RAPID Actually Does (Mechanical

Or purchase a paid subscription.

← Previous