

CMS Seeks Comments on RAPID Medicare Pathway for Breakthrough Devices

October 8, 2026

In August 2026, the Centers for Medicare & Medicaid Services (CMS) announced a notice with comment period (notice) providing information on the process CMS proposes to use to facilitate Medicare national coverage determinations (NCDs) under the Regulatory Alignment for Predictable and Immediate Device (RAPID) coverage pathway.¹ CMS describes the proposed RAPID coverage pathway as a voluntary process designed to provide accelerated Medicare beneficiary access to certain eligible Class II and Class III US Food and Drug Administration (FDA) breakthrough-designated devices (BDDs). The notice provides an opportunity for stakeholders to provide feedback on the proposed RAPID coverage pathway, with comments due on October 13, 2026.

RAPID reflects CMS's latest effort to address stakeholder concerns that Medicare coverage of medical devices lags behind FDA market authorization. CMS has indicated that this lag may result, at least in part, from frequent underrepresentation of Medicare beneficiaries in the pivotal studies that support FDA marketing authorization determinations. In the notice, CMS states that "it is difficult for CMS to make an evidence-based decision on whether [a] device is reasonable and necessary" under the statutory standard for Medicare coverage if the device's supporting clinical evidence does not adequately reflect the Medicare population.²

Prior CMS efforts to address these concerns include the now-repealed 2021 Medicare Coverage of Innovative Technology (MCIT) final rule and the Transitional Coverage for Emerging Technologies (TCET) pathway established in 2024. CMS states in the notice that the "TCET pathway will be paused for new candidates upon publication of this notice with comment period as CMS focuses on the successful implementation of the RAPID coverage pathway."³

The notice seeks input on several aspects of the proposed RAPID coverage pathway, such as eligibility criteria, procedural considerations and roles for participants, including manufacturers, FDA, CMS and the Agency for Healthcare Research and Quality (AHRQ).

Proposed eligible devices

CMS proposes that the RAPID coverage pathway would be available only for certain BDDs. Specifically, CMS proposes that **eligible** devices generally must be one of the following:

- Presumptive Class II FDA BDDs participating in FDA's Total Product Life Cycle Advisory Program (TAP) and planning to submit a de novo request to FDA.
- Class III BDDs planning to submit a premarket approval (PMA) application, regardless of TAP participation.

CMS further proposes that, in either case, the device must be in the investigational device exemption (IDE) pre-submission stage, and the manufacturer must plan to conduct an IDE study that enrolls Medicare beneficiaries and evaluates clinical outcomes agreed upon by both FDA and CMS. In particular, the IDE study would be required to evaluate clinical outcomes that FDA determines are appropriate for the device and CMS confirms would provide evidence demonstrating that the device "improves health outcomes for Medicare beneficiaries."⁴

CMS proposes that otherwise eligible devices would be **ineligible** for the RAPID coverage pathway if any of the following factors applied:

- Based on the information available, there is evidence indicating the device will not fall under a Medicare benefit category.
- The device is already the subject of a controlling Medicare NCD.
- The device is not a separately payable device that could, if approved, be billed to Medicare.

- The device is otherwise excluded from coverage through law or regulation.
- The device is an in vitro diagnostic (IVD), such as a diagnostic laboratory test.⁵

On IVD products, CMS states that IVDs are a “highly specific area of coverage policy development,” and that the agency has historically delegated the review of many IVD products to specialized Medicare administrative contractors (MACs).⁶ CMS states its view that the majority of coverage determinations for IVDs that are BDDs “should continue to be determined by the MACs through existing pathways,” and that IVD products therefore “will not be accepted into the RAPID coverage pathway.”⁷

Regarding the proposed criterion that eligible devices must be in the IDE pre-submission stage, CMS specifically solicits feedback on whether it should establish a temporary process under which devices that have already progressed beyond the IDE pre-submission stage and are currently being studied under an IDE could become eligible for the RAPID coverage pathway. CMS states that, as part of this potential process, CMS and FDA would assess whether ongoing IDE studies evaluate clinical health outcomes that both agencies “have agreed are appropriate to assess the health benefits to the Medicare beneficiary population,” or whether modifications to those studies would be needed to support such assessment.⁸ CMS is seeking input on whether such a process should be established and, if so, how long it should remain available.

Stakeholders with views on the proposed eligibility criteria for RAPID are encouraged to provide input to CMS through public comments.

Proposed key features of RAPID

As outlined in the notice, RAPID would be a voluntary pathway intended to provide manufacturers with “information on the specific health outcomes needed to support Medicare NCDs much earlier in the process,” before FDA market authorization, such that the clinical evidence generated to support FDA review could also support a Medicare coverage decision.⁹

Key proposed features of the RAPID coverage pathway under the notice include:

- **Development stage coordination.** FDA and CMS would work together, along with the manufacturer, during IDE pre-submission to agree on the clinical health outcomes the IDE study would evaluate. Those outcomes would be intended to support FDA review and provide evidence demonstrating that the device “improves health outcomes for Medicare beneficiaries” to support a CMS coverage determination.
- **Accelerated NCD timing.** If the completed IDE study showed that the device improves the agreed-upon health outcomes for Medicare beneficiaries, CMS would issue a proposed NCD on the same day as FDA market authorization, with a final NCD to be issued as early as 60 days later for Class II devices and 90 days later for Class III devices. Additionally, CMS proposes “to prioritize the opening of RAPID NCDs over non-RAPID NCDs from the NCD Wait List” if CMS is unable to address the total volume of NCDs with its available resources at any given time.¹⁰ This proposal creates timing implications for both RAPID and non-RAPID NCDs.
- **Potential requirement for further evidence development.** The notice states that CMS may issue proposed NCDs for the RAPID pathway under the Coverage with Evidence Development (CED) framework. While many NCDs involve determinations pursuant to Medicare’s “reasonable and necessary” coverage standard under section 1862(a)(1)(A) of the Social Security Act (SSA), CMS also has issued several NCDs under section 1862(a)(1)(E) of the SSA, which CMS describes as supporting the CED pathway under which “Medicare provides coverage for certain promising technologies that have limited supporting evidence.”¹¹ NCDs issued under the CED framework specify that Medicare coverage is available only in the context of CMS-approved clinical research studies, which CMS reviews in collaboration with AHRQ. For RAPID, CMS proposes that it may issue a proposed NCD under the CED framework if there is “insufficient evidence” to support Medicare coverage under SSA section 1862(a)(1)(A).¹² The notice indicates that the degree to which the device improves health outcomes and the relative risk of the device would determine whether further evidence development (i.e., CED) would be part of the NCD.¹³
- **Voluntary exit.** CMS proposes that manufacturers may withdraw from the RAPID pathway at any point before a proposed NCD is issued, and that FDA and CMS also may determine that the RAPID pathway is no longer appropriate.

Proposed stages of the RAPID coverage pathway

CMS describes the RAPID coverage pathway as unfolding in three stages. Below is an overview of the proposed steps and roles of manufacturers, FDA and CMS at each stage:

Stage 1: IDE pre-submission

- **Manufacturer:** Expresses interest in RAPID to FDA before IDE pre-submission and then participates in a RAPID kick-off meeting with FDA and CMS to discuss the proposed IDE study design.
- **FDA:** Screens the device against RAPID eligibility criteria and consults with CMS on benefit category and coverage eligibility considerations. Participates in the kick-off meeting and provides formal written feedback on the IDE study protocol.
- **CMS:** Conducts a preliminary benefit category analysis and consults with FDA. Participates in the kick-off meeting and provides written feedback on whether the proposed health outcomes would be sufficient to support a future NCD.

Stage 2: Formal IDE submission

- **Manufacturer:** Submits the IDE application to FDA and addresses study design considerations identified by FDA and CMS. After FDA approves a revised protocol (if needed), submits the IDE protocol to CMS for approval.
- **FDA:** Reviews the IDE application through its normal process. Issues a decision letter, including any study design considerations, and shares it with CMS.
- **CMS:** Reviews the IDE protocol under its existing IDE review process. If approved, issues a letter confirming its intent to issue a proposed NCD concurrently with FDA market authorization.

Stage 3: Transition from IDE to coverage

- **Manufacturer:** Conducts the IDE study and submits marketing application to FDA. If electing to proceed with RAPID, submits a formal NCD request cover letter to CMS.
- **FDA:** Shares the IDE final study report with CMS. Reviews and authorizes (if approved) the marketing application.
- **CMS:** On the day of FDA market authorization, posts a proposed NCD and opens a 30-day comment period. Targets a final NCD on the 60- or 90-day timeline described above, depending on the FDA class of the device. If CMS believes evidence gaps remain, CMS may issue the NCD under the CED framework. Throughout all proposed stages of the RAPID coverage pathway, CMS would communicate and coordinate with manufacturers, FDA and (for potential CED) AHRQ.

Considerations for stakeholders

RAPID represents CMS's third attempt in five years to close the timing gap between FDA market authorization and Medicare coverage for innovative devices, following the now-repealed MCIT final rule and the now-paused TCET pathway. Unlike MCIT, which would have provided automatic, time-limited national coverage upon FDA market authorization without requiring Medicare-specific evidence, RAPID takes a fundamentally different approach: It requires manufacturers to build Medicare-relevant clinical outcomes into their IDE studies from the outset, coordinating with both FDA and CMS well before market authorization. This front-loaded evidence requirement means manufacturers that participate successfully may secure a final NCD within 60 to 90 days of FDA authorization, but it also demands a significantly earlier and more sustained investment in the CMS engagement process than prior pathways contemplated.

Several practical considerations stand out for manufacturers evaluating whether to participate:

- **Timing and development stage.** Because RAPID eligibility is generally limited to devices still at the IDE pre-submission stage, manufacturers that have already progressed further in their IDE studies may face a narrow window, or none at all, to participate. Manufacturers should assess where their device programs currently stand and consider whether the potential temporary process for devices that have already progressed beyond IDE pre-submission could apply to their products. Companies with devices at early development stages should begin evaluating RAPID's potential fit now, since the pathway requires engagement with both FDA and CMS before IDE submission.
- **IDE study design implications.** RAPID requires IDE studies to evaluate clinical outcomes agreed upon by both FDA and CMS – specifically, outcomes that CMS confirms would demonstrate that the device “improves health outcomes for Medicare

beneficiaries.” This dual-agency alignment requirement may necessitate adjustments to study populations, endpoints, study duration or sample sizes beyond what FDA alone would require. Manufacturers should factor in the additional time and cost of designing studies that satisfy both agencies’ expectations, including ensuring adequate enrollment of Medicare-eligible populations.

- **Comment opportunity.** Because RAPID is still at the proposal stage, manufacturers and other stakeholders have a meaningful opportunity to shape the potential final pathway through comments due October 13, 2026. CMS has specifically requested feedback on several open questions, including whether to establish a temporary process for devices beyond the IDE pre-submission stage, how long such a process should remain available, and other aspects of the proposed eligibility criteria and procedures. Stakeholders are encouraged to submit detailed comments addressing the aspects of the proposal that affect their device programs and the broader policy questions CMS has raised.

Cooley’s life sciences and healthcare regulatory team closely monitors FDA and CMS regulatory developments and actively works with clients navigating FDA approval pathways, CMS coverage strategies, IDE study design and policy development opportunities. For assistance evaluating the RAPID coverage pathway or preparing comments on the notice, please contact the authors listed below.

Notes

1. 91 Fed. Reg. 51710 (Aug. 11, 2026).
2. Id. at 51712.
3. Id. at 51718.
4. Id. at 51714.
5. Id.
6. Id.
7. Id. CMS adds that, “[i]n the rare case where manufacturers and CMS agree that an NCD is appropriate for an IVD product, manufacturers may submit an NCD request” under the regular NCD request process. Id.
8. Id. at 51715.
9. Id. at 51713–51714.
10. Id. at 51718.
11. Id. at 51711.
12. Id. at 51716.
13. Id. at 51714.

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Key Contacts

Eric Greig Washington, DC	egreig@cooley.com +1 202 728 7095
Stephanie P. Hales Washington, DC	shales@cooley.com +1 202 776 2175

Sonia Nath Washington, DC	snath@cooley.com +1 202 776 2120
Son Nguyen Washington, DC	snguyen@cooley.com +1 202 728 7100
Wyatt Kernell Colorado	wkernell@cooley.com +1 720 566 4490

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