American College of Radiology™

Section-by-Section Summary of CMS Notice with Comment Period
Medicare Program: Regulatory Alignment for Predictable and Immediate Device (RAPID) Coverage Pathway (CMS-3487-NC)

Executive Summary

On August 7, 2026, the Centers for Medicare & Medicaid Services (CMS) proposed a new voluntary Regulatory Alignment for Predictable and Immediate Device (RAPID) Coverage Pathway to accelerate Medicare coverage for certain FDA Breakthrough Devices. The pathway aligns FDA and CMS evidence requirements during device development, allowing CMS to issue a proposed National Coverage Determination (NCD) on the same day as FDA market authorization and finalize coverage approximately 60 days later for Class II devices and 90 days later for Class III devices. The pathway is limited to eligible FDA Breakthrough Devices, excluding most in vitro diagnostics (IVDs), and pauses the Transitional Coverage for Emerging Technologies (TCET) pathway for new candidates.

Resources

CMS published a Fact Sheet and Infographic on the RAPID Coverage Pathway.
Federal Register: https://public-inspection.federalregister.gov/2026-16368.pdf
FDA News Release (April 2026)
ACR will submit comments to CMS by the comment period deadline on Oct. 13.

Key Features of RAPID

- Applies to certain FDA Breakthrough Devices, including:
    - Class II Breakthrough Devices participating in FDA's Total Product Life Cycle Advisory Program (TAP).
    - Class III Breakthrough Devices seeking Premarket Approval (PMA).
- Manufacturers must work with FDA and CMS during the IDE (Investigational Device Exemption) stage to ensure clinical studies include Medicare beneficiaries and collect outcomes relevant to Medicare coverage decisions.
- If a device demonstrates improved health outcomes for Medicare beneficiaries and receives FDA authorization:
    - CMS would release a proposed National Coverage Determination (NCD) on the same day as FDA authorization.
    - CMS aims to finalize coverage within:
        - 60 days for Class II devices
        - 90 days for Class III devices

- Devices with remaining evidence gaps may receive Coverage with Evidence Development (CED) rather than immediate unrestricted national coverage.

How RAPID Differs from Existing Pathways

Pathway	Typical Coverage Timing
Claim-by-claim adjudication	Variable, local contractor decisions
LCD process	Often up to a year
Traditional NCD	Generally, 9-12 months
RAPID	Proposed NCD at FDA authorization; final NCD in 60-90 days

Reduced post-approval delays

- Historically, FDA approval and Medicare coverage decisions have occurred separately. RAPID seeks to close that gap and reduce delays in beneficiary access to innovative imaging technologies.

Potential benefit for imaging AI

- Breakthrough-designated AI and software-enabled imaging technologies could be strong candidates for RAPID if they demonstrate meaningful clinical outcomes in Medicare populations.

Key Policy Updates

Accelerated Medicare Coverage Timeline

- Proposed NCD issued on the same day as FDA market authorization.
- 30-day public comment period.
- Final NCD target:
    - 60 days after authorization for Class II devices.
    - 90 days after authorization for Class III devices.
- Significant reduction from the traditional 9-12 month NCD process.

Eligibility

- Limited to certain FDA Breakthrough Devices.
- Requires participation early in the IDE process.
- Requires enrollment of Medicare beneficiaries in pivotal studies.
- Clinical endpoints must be agreed upon by FDA and CMS.

Coverage with Evidence Development (CED)

- Devices with remaining evidence gaps may receive coverage under CED.
- CMS intends to coordinate evidence development requirements with FDA post market studies where possible.

IVD Exclusion

- Most IVDs and diagnostic laboratory tests would remain under MAC review pathways rather than RAPID.

TCET Paused

- CMS will pause TCET for new candidates while implementing RAPID.

I. Background (Pages 3-12)

Current Medicare Coverage Mechanisms

CMS describes three existing coverage pathways:

Claim-by-Claim Adjudication

- Used when no applicable LCD or NCD exists.
- MACs determine whether services are reasonable and necessary for individual patients.

Local Coverage Determinations (LCDs)

- Coverage decisions made by MACs on a regional basis.
- Typically completed within approximately one year.

National Coverage Determinations (NCDs)

- National Medicare coverage policies are issued by CMS.
- Generally, requires 9-12 months to complete.
- Frequently depends on robust health outcomes data.

CMS also reviews:

- Coverage with Evidence Development (CED)
- FDA-CMS Parallel Review Program
- Transitional Coverage for Emerging Technologies (TCET) Program

The RAPID pathway does not change statutory coverage standards; it changes the timing and coordination of evidence review.

Differences Between FDA and CMS Review
CMS emphasizes that FDA approval and Medicare coverage serve different purposes.
FDA Focus

- Safety
- Effectiveness
- Market authorization

CMS Focus

- Whether an item is "reasonable and necessary" for Medicare beneficiaries.
- Improvement in health outcomes.
- Applicability to older adults and beneficiaries with multiple comorbidities.

CMS notes that Medicare beneficiaries are often underrepresented in clinical trials. Therefore, FDA approval alone may not provide sufficient evidence to support Medicare coverage. RAPID seeks to address this gap by incorporating Medicare-focused outcomes into pivotal studies before FDA authorization.

FDA Programs Supporting RAPID Breakthrough Devices Program
Applies to devices that:

- Provide more effective treatment or diagnosis of serious conditions.
- Represent significant technological advancements or unmet needs.

Total Product Life Cycle Advisory Program (TAP)

- Provides early FDA engagement.
- Required for eligible Class II RAPID devices.

Investigational Device Exemption (IDE)

- Allows devices to be studied in clinical trials to collect safety and effectiveness data.
- Allows coverage for certain items and services in FDA approved IDE studies if certain requirements are met. CMS assesses Medicare health outcomes in the study.
- Serves as the foundation for the RAPID pathway.

II. Provisions of the Notice (Pages 12-30)
A. Opportunity to Accelerate Patient Access
CMS states that many technologies reach market authorization before sufficient Medicare-specific evidence exists.
RAPID seeks to:

- Incorporate Medicare health outcome requirements into IDE studies.

- Align CMS and FDA expectations earlier.
- Reduce delays between FDA authorization and Medicare coverage.

Manufacturers must demonstrate improvements in Medicare-relevant clinical outcomes identified jointly by FDA and CMS.
If successful, CMS would issue a proposed NCD immediately upon FDA authorization.

B. RAPID Coverage Pathway General Principles
CMS outlines several core principles:

Voluntary Participation
Manufacturers may opt into or withdraw from RAPID.

Early Evidence Development
Manufacturers must evaluate Medicare-relevant outcomes during IDE studies.

Coordinated FDA-CMS Review
FDA and CMS jointly review outcomes important to Medicare coverage. FDA and CMS will provide manufacturers information on appropriate clinical health outcomes applicable to Medicare beneficiaries to include in the IDE protocol.

Coverage Depends on Evidence
Coverage decisions will depend on whether devices demonstrate meaningful health outcomes. If clinical evidence demonstrates the appliable health outcomes, CMS will issue a proposed NCD upon FDA market authorization.

Potential Use of CED
Higher-risk devices or devices with evidence gaps may receive CED rather than immediate unrestricted coverage.

Withdrawal Provisions
Manufacturers may leave the pathway before a proposed NCD is issued if:

- Data is insufficient.
- Local coverage is preferred.
- Business priorities change.

C. Appropriate Candidates
Eligible devices must satisfy all requirements:
Eligible Devices

- Class II Breakthrough Devices participating in TAP and pursuing De Novo review.

- Class III Breakthrough Devices pursuing PMA review, regardless of whether they are participating in TAP.

Additional Requirements

- IDE pre-submission stage.
- Medicare beneficiary enrollment.
- Medicare health outcomes evaluation.
- No existing controlling NCD.
- Must be separately payable.
- Must fit within a Medicare benefit category.
- Not otherwise excluded from coverage through law or regulation.

Excluded Devices

- Most IVDs, including diagnostic laboratory tests
- Devices are already marketed.
- Devices are already under active IDE studies.

CMS Requests Comments On

CMS states devices that are FDA market authorized or those already the subject of an IDE are more appropriate for an NCD outside the RAPID coverage pathway or coverage at the local level through an LCD or claim by claim adjudication. CMS solicits public comments on this approach. CMS is seeking feedback on whether it should establish a temporary process under which devices that have progressed beyond IDE pre-submission and are currently being studied under an IDE could become eligible for the RAPID coverage pathway, including whether such a process should be established and, if so, its appropriate duration.

Radiology Impact

Many imaging AI products could potentially receive Breakthrough designation. However, manufacturers would need to demonstrate clinical outcomes rather than solely improved diagnostic performance. This may represent a significant evidence-generation challenge.

D. Procedures for the RAPID Coverage Pathway

Stage 1: IDE Pre-Submission

FDA and CMS will work with manufacturers to develop a clinical study synopsis and review pertinent information at a RAPID kick-off meeting that will be used to develop the complete IDE study protocol. Prior to the kickoff meeting CMS will initiate a preliminary benefit category assessment if all other pathway criteria have been met. Of note, CMS states this is an interim

step subject to change upon FDA's decision regarding market authorization and that participation in the pathway should not be viewed as a final benefit category determination.

Manufacturers:

- Notify FDA of RAPID interest. Email inquiries should be sent to TPLC-Advisory-Program@fda.hhs.gov, after receiving Breakthrough Device designation and being accepted into TAP as applicable.
- Participate in a RAPID kickoff meeting with FDA and CMS.
- Develop a study synopsis.
- Receive coordinated written feedback.

CMS evaluates:

- Medicare benefit category status.
- Appropriate Medicare health outcomes.
- Potential evidence gaps.

Stage 2: Formal IDE Submission

The manufacturer will submit the IDE application to the FDA if applicable, and FDA will review it per the normal IDE review process. The FDA will provide an IDE decision letter informing the manufacturer about any study design considerations (SDCs). The decision letter will be shared with CMS. CMS will communicate directly with the manufacturer regarding the SDCs that must be addressed to continue participation.

To continue participating in the voluntary pathway, the manufacturer will be expected to satisfactorily address any SDCs necessary to enable the study to support a future marketing application to FDA. Once the manufacturer addresses any SDCs, and FDA has approved a revised protocol if needed, manufacturers will submit their IDE protocol to CMS for approval using the existing CMS IDE review process. If all CMS IDE requirements and RAPID eligibility criteria have been met, CMS will provide the manufacturer with an approval letter including the intent to issue a proposed NCD concurrently with FDA market authorization.

FDA:

- Reviews IDE application.

CMS:

- Reviews study design considerations.
- Conducts IDE review.

- Issues approval letter if requirements are met.

Approved IDE studies will be listed on the CMS website. CMS intends to publicly identify approved RAPID participants. If a manufacturer wishes to make any changes to the IDE study protocol after CMS approval, these changes must be reviewed and agreed upon by FDA and CMS to continue participation in the RAPID coverage pathway.

Stage 3: Transition from IDE to Coverage
After study completion:

- FDA shares final study reports with CMS.
- Manufacturer submits NCD request cover letter requesting CMS open a RAPID NCD analysis.
- CMS posts proposed NCD concurrently with FDA authorization.
- 30-day public comment period on the proposed NCD.
- Final NCD issued within targeted timelines.

CMS' goal is to release the final NCD approximately 60 days after FDA market authorization for Class II devices and 90 days after for Class III devices, with additional information on the NCD process set forth in the August 2013 Federal Register notice (78 FR 48164). CMS notes the timing of the proposed NCD is contingent upon the relevant FDA Decision Summary or Summary of Safety and Effectiveness Data (SSED) being made publicly available on the day of market authorization, and CMS will include a link to that document on the NCD tracking sheet. RAPID national coverage will be limited to the FDA authorized indications for use of the device. View the RAPID Coverage Pathway Infographic.

RAPID NCD Format
CMS anticipates shorter and more streamlined NCDs because evidence review occurs during IDE development rather than after-market authorization.

Evidence Development
Where evidence remains incomplete:

- CMS may require CED.
- CMS will attempt to align CED requirements with FDA post market studies.
- Coverage may begin once CED studies are approved.

CMS says RAPID will not change the existing NCD or CED standards. CMS will continue to use its current processes. For NCDs that require CED, coverage can begin once CMS approves the related study, and approved studies will be posted on the CMS CED webpage. RAPID NCDs will stay in place until CMS reconsiders them, but CMS emphasizes that CED coverage should be time-limited and used to collect enough evidence to support a final Medicare coverage decision.

E. Roles

CMS outlines the general roles of each participant in the pathway:

Manufacturers

- Participate in pathway and express interest to FDA prior to their IDE submission.
- Conduct IDE studies and comply with all existing FDA and CMS requirements related to the IDE and NCD processes, including any CED study.
- Generate Medicare-relevant evidence.

CMS

- Defines acceptable Medicare outcomes.
- Reviews IDE protocols.
- Issues NCDs.
- Administers CED when necessary.
- Work with manufacturers to leverage FDA required post-market studies if any to address specific evidence gaps for Medicare beneficiaries.

FDA

- Assess each candidate expressing interest to determine whether the device is appropriate for the pathway and provides expertise during pre-market phase.
- Reviews safety and effectiveness.
- Coordinates with CMS throughout development.

AHRQ

- Reviews CED proposals.
- Defines standards for clinical research studies addressing CED questions.
- Continues current oversight role for evidence development studies.

F. RAPID and Parallel Review

CMS states that FDA-CMS Parallel Review will remain available.

Key distinction:

RAPID	Parallel Review
Breakthrough Devices only	Broader eligibility
Medicare-specific outcomes built into IDE	Simultaneous FDA/CMS review
Accelerated NCD automatically anticipated	Traditional NCD process

CMS also signals possible future modernization of Parallel Review. To achieve greater efficiency and simplify coverage processes, CMS intends to work with FDA to consider updates to the Parallel Review program and other initiatives to align procedures as appropriate.

G. RAPID and TCET

CMS will:

- Pause TCET acceptance of new candidates.
- Focus implementation efforts on RAPID.
- Continue discussions with manufacturers that already progressed beyond IDE initiation.

Since the April 23 announcement of RAPID, CMS and FDA began engaging with manufactures of devices potentially eligible for the new pathway. This effectively makes RAPID CMS's primary accelerated coverage pathway for eligible breakthrough devices.

H. RAPID Prioritization

CMS proposes prioritizing RAPID NCDs over non-RAPID NCDs from the NCD wait list if the agency is unable to address the total volume of NCDs within available resources at any given time.

Implications

Potential advantages:

- Faster review of innovative technologies.

Potential concerns:

- Other NCD requests may experience longer delays.
- Reconsideration requests could face increased competition for CMS resources.

I. Transparency

CMS proposes public disclosure of:

- RAPID participants.
- Manufacturers.
- Devices accepted into the pathway.

Potential publication locations:

- Approved IDE Studies webpage.
- NCD Dashboard.

This would provide stakeholders with greater visibility into pending coverage decisions.