



## Comments on the RAPID Coverage Pathway

October 13, 2026

Via Regulations.gov  
Centers for Medicare & Medicaid Services  
Attention CMS-3487-NC  
7500 Security Boulevard, Baltimore, MD 21244-1850

**Re:** Regulatory Alignment for Predictable and Immediate Device Coverage Pathway  
Docket CMS-2026-2674 | 91 FR 51710 | August 11, 2026

Dear Administrator:

The Heart Rhythm Society (HRS) and Heart Rhythm Advocates (HRA) support the goal of the proposed Regulatory Alignment for Predictable and Immediate Device (RAPID) coverage pathway: timely Medicare access to beneficial medical technologies through earlier coordination between CMS and the Food and Drug Administration (FDA). We urge CMS to finalize a pathway with clear evidence, expectations, a transition process for devices already in development, and safeguards that ensure an accelerated coverage decision results in practical access for patients.

HRS is a professional society for clinicians and scientists working in heart rhythm care; HRA is its advocacy organization. Our comments reflect the needs of patients with heart rhythm disorders and the clinicians who diagnose and treat them. For these patients, coverage policies should support timely access to clinically appropriate innovation while maintaining rigorous evaluation of safety, effectiveness, and benefit to the Medicare population.

### **Establish a transition process for ongoing studies**

In response to the request in section II.C, we recommend a temporary application window of 24 months following the effective date of the final notice for otherwise eligible devices already being studied under an Investigational Device Exemption (IDE). CMS and FDA should assess existing protocols and available evidence individually and identify whether feasible amendments or supplemental analyses would address Medicare evidence needs. Sponsors should not have to restart an otherwise sound study solely because it began before RAPID was available.

CMS should publish the transition application requirements and decision timelines when the pathway becomes effective. The agencies should explain how they will address studies whose enrollment is complete and when additional prospective evidence is necessary. For otherwise eligible devices that receive FDA market authorization while CMS is finalizing RAPID, CMS should clarify whether they may participate through the temporary transition process.

This transition should preserve the applicable evidentiary standards while avoiding a coverage disadvantage based solely on development timing.

### **Broaden eligibility while preserving appropriate evidence standards**

CMS should broaden eligibility in the final notice for Breakthrough-designated devices whose evidence development programs can meet Medicare coverage requirements. Participation in FDA's voluntary Total Product Life Cycle Advisory Program (TAP) should facilitate RAPID access rather than serve as a mandatory gate for Class II devices. CMS should permit otherwise qualifying devices pursuing FDA clearance through the 510(k) pathway to participate without limiting eligibility to the proposed narrow predicate history. CMS should also establish, in coordination with FDA as appropriate, an entry process for otherwise suitable devices whose clinical studies do not require a formal IDE application to FDA.

For eligible lower-risk devices, the agencies should consider coordinated review of an FDA pre-submission and an appropriately approved clinical protocol as an alternative entry route. Sponsors should not be encouraged to pursue a more burdensome regulatory pathway solely to qualify for expedited Medicare review. CMS should expressly address software and AI-enabled medical devices, including diagnostic technologies used within an electrophysiology procedure, under these principles. These recommendations preserve Breakthrough designation and the substantive coverage evidence standard while making the pathway more responsive to different forms of heart rhythm innovation.

### **Define evidence expectations with clinical and patient input**

We recommend that the agencies document, before pivotal enrollment, their expectations for endpoints, comparators, follow-up, Medicare representation, and analyses. The written feedback should distinguish requirements for FDA authorization from those for Medicare coverage, identify foreseeable evidence gaps, and explain how later changes will be communicated and resolved. A named CMS contact and a defined process for resolving disagreements would help sponsors act on this guidance.

CMS and FDA should seek input from electrophysiologists, other relevant clinicians, and our patients when developing general guidance for heart rhythm technologies. Depending on the indication, meaningful outcomes may include symptom relief, functional status, quality of life, hospitalization, or survival. The agencies should clarify how validated patient-reported measures and disease-specific outcomes can support coverage, and when an intermediate endpoint requires additional clinical evidence.

Evidence plans should address older adults and beneficiaries with disabilities or common comorbidities when relevant to the intended population. Enrollment targets and subgroup analyses should be clinically justified and feasible. CMS should explain when well-designed supplemental evidence, including appropriate real-world data, can address generalizability without requiring a separate duplicative trial.

### **Resource both agencies and preserve review timelines**

CMS should have sufficient dedicated staff and clinical expertise to participate on equal operational footing with FDA from the first protocol discussion through the coverage decision. Each agency should retain responsibility for decisions under its own statutory authority. We recommend defined response timelines, a shared schedule, and an escalation process for unresolved issues so that Medicare evidence requirements are addressed early and consistently.

Participation in RAPID should not extend FDA review timelines or delay IDE approval or market authorization while CMS completes its coverage analysis. The agencies should conduct their work concurrently wherever possible, avoid adding FDA review milestones, and specify how FDA review will proceed if CMS needs additional time. CMS should establish maximum timeframes of 60 days for Class II devices and 90 days for Class III devices from FDA authorization to a final national coverage determination (NCD), subject to clearly defined exceptions consistent with applicable law. When an exception is necessary, CMS should explain the reason in writing, provide a revised decision date, and publicly report performance against these timeframes.

### **Preserve appropriate coverage for a class of devices**

CMS should clarify when an NCD developed through RAPID will apply to a clinically defined class of devices rather than only to the product whose evidence initiated the review. Where the evidence supports a common coverage policy, the NCD should state objective criteria for other FDA-authorized devices to qualify, including relevant indications, clinical characteristics, and evidence requirements. A class policy should not presume that every device has equivalent safety or effectiveness; CMS should identify when device-specific evidence remains necessary.

CMS should explain how follow-on devices, device modifications, and expanded FDA-authorized indications will be evaluated under an existing RAPID NCD. Where supported by the evidence, coverage should extend to qualifying products within the defined class without requiring a separate RAPID application or duplicative NCD. CMS should state when additional device-specific evidence or NCD reconsideration is necessary, whether existing Coverage with Evidence Development (CED) protocols can accommodate follow-on products, and how manufacturers can satisfy any remaining requirements. An existing NCD should not prevent timely consideration of a clinically meaningful advance.

### **Make additional evidence development proportionate and time limited**

When CED is necessary, CMS should specify the unresolved question, the evidence needed to answer it, and why the available evidence is insufficient for routine coverage. We recommend that device risk inform this assessment without serving as the sole basis for

requiring CED. Each decision should reflect the evidence for the particular device and indication.

CMS should align CED with FDA post-approval requirements wherever scientifically appropriate, using a common protocol or registry when it can satisfy both agencies. Each CED decision should include enrollment and reporting milestones, a planned completion date, and a timetable for reassessment after the required evidence is submitted. Coverage restrictions should be reconsidered promptly when the relevant questions have been answered; they should not continue solely because no party has requested reconsideration. CMS should also coordinate CED study approval with the final coverage decision to avoid an additional period in which an NCD exists but patients cannot obtain covered care. Research participation should be feasible for community practices and patients who live far from academic centers. Study requirements and associated costs should be transparent, with data collection limited to what is needed to answer the coverage questions.

### **Ensure coverage can be implemented in clinical practice**

CMS should clarify how the separately payable device eligibility criterion applies to technologies furnished within a procedure or paid through a bundled payment. We urge CMS to avoid excluding an otherwise suitable technology solely because its payment is packaged with the clinical service, to the extent permitted under existing authority. Guidance should distinguish a statutory coverage limitation from an administrative coding or payment issue that can be resolved.

CMS should confirm that the absence of an existing product-specific billing code, separate payment mechanism, or established payment methodology at the time of application does not, by itself, make an otherwise qualifying device ineligible. The agencies should identify a process for resolving these issues during RAPID participation and explain how coverage can be implemented when a new or revised coding or payment arrangement is needed.

We recommend early coordination among the relevant CMS coverage, coding, payment, and claims implementation teams. Before a final NCD takes effect, clinicians and facilities should have clear billing instructions for the device and associated services, the applicable care settings, and any CED requirements. CMS should identify unresolved coding or payment needs during development and publish an implementation plan. This recommendation does not seek to combine legally distinct coverage and payment decisions; it seeks to make the resulting coverage usable.

### **Protect access outside RAPID and report program performance**

RAPID should expand access without delaying important coverage decisions for technologies that do not qualify. CMS should maintain sufficient capacity for conventional NCDs and reconsiderations. It should establish an explicit transition process for otherwise suitable technologies whose clinical development or coverage planning materially advanced under Transitional Coverage for Emerging Technologies (TCET) before RAPID was announced, including consideration without retrospective TAP or formal IDE prerequisites when the evidence program can meet Medicare needs. CMS should also provide clear guidance on

alternative pathways for technologies outside RAPID. Decisions to prioritize requests should account for patient need and potential clinical benefit across pathways.

We recommend public reporting of aggregate participation, time to key decisions, reasons for delays, and the use and duration of CED, consistent with confidentiality protections. Reporting should protect confidential product development information and clarify the process for voluntary manufacturer disclosure of participation. CMS should also report wait times for non-RAPID requests and seek regular feedback from patients, professional societies, and treating clinicians. These measures would help determine whether faster administrative decisions are improving access and where the process needs adjustment. Thank you for considering these recommendations. HRS and HRA support earlier FDA-CMS coordination and urge CMS to implement RAPID with the clinical input, clear timelines, and practical coverage arrangements needed to benefit Medicare patients with heart rhythm disorders.

Sincerely,

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