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Mehmet Oz, MD
Administrator
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Re: Medicare Program; Regulatory Alignment for Predictable and Immediate Device (RAPID)
Coverage Pathway (CMS-3487-NC)

Dear Administrator Oz:

On behalf of AdvaMed, the Medtech Association, we thank the Centers for Medicare & Medicaid Services (CMS) for the substantial work on the Regulatory Alignment for Predictable and Immediate Device (RAPID) Coverage Pathway and for the opportunity to comment on the Notice in the *Federal Register* (CMS-3487-NC). We appreciate the opportunity to share comments and commend CMS and the Food and Drug Administration (FDA) for partnering to modernize the Medicare coverage process for medical devices and technologies. AdvaMed and CMS share a common goal – ensuring timely access for Medicare beneficiaries to services grounded in scientifically sound clinical evidence with appropriate safeguards that protect patients and preserve the integrity of the coverage process.

AdvaMed member companies develop and produce a wide range of medical devices, diagnostic tests, and digital health solutions that transform care through earlier detection, less invasive approaches, prevention-focused modalities, and more effective disease management. AdvaMed members range from the largest to the smallest medical technology innovators and companies. We are committed to ensuring patient access to lifesaving and life-enhancing devices and other advanced medical technologies in the most appropriate care settings.

In that spirit, we support CMS's efforts to reimagine Medicare coverage and establish a more predictable pathway for Breakthrough-designated Devices. RAPID has the potential to improve beneficiary access to important innovations while providing greater regulatory certainty for



developers. AdvaMed has long advocated for policies that accelerate access to critical Breakthrough-designated Devices, and we applaud CMS and FDA for designing a pathway to achieve that goal. Patients face meaningful delays to Breakthrough technologies, and the cross-agency collaboration throughout the RAPID pathway will promote essential coordination that expedites the accessibility of these devices for Medicare beneficiaries.

To achieve its intended objectives, RAPID requires adequate capacity at both CMS and FDA to build a predictable pathway and support clinical development, investment, and commercialization decisions. We believe that the RAPID coverage pathway will have the greatest impact and likelihood to substantially improve beneficiary access to Breakthrough-designated Devices with the allocation of sufficient, dedicated resources for CMS and FDA.

As CMS continues to pursue coverage reform and Medicare modernization, we respectfully offer the following comments for CMS's and FDA's consideration and re-emphasize our commitment to working with both agencies to create stable, predictable, and accessible coverage pathways for innovative technologies.

Innovation Ecosystem

AdvaMed appreciates CMS efforts to expedite coverage and bring consistency to manufacturers of Breakthrough-designated Devices. The proposal to establish the RAPID coverage pathway is a positive step toward these goals, and we encourage CMS and FDA to support RAPID's long-term predictability and sustainability, which is necessary to facilitate Medicare beneficiary access to Breakthrough innovation. We recognize that the RAPID pathway includes limitations on scope given corresponding limitations on CMS and FDA resources. The RAPID notice describes a particularly narrow eligibility pathway that, when combined with the recent repeal of the alternative pathways for Breakthrough-designated Devices¹, presents unique challenges for medtech innovation and could be interpreted as signals that dissuade investment in Breakthrough technologies.

AdvaMed urges CMS to consider how its Breakthrough policies conflict with previously stated goals to cut red tape and increase transparency, predictability, and cost savings for innovators.² Breakthrough-designated Device manufacturers are often small, early stage, and working in areas with high unmet clinical need – precisely the innovators that require consistent, stable, and predictable coverage policy to secure the funding necessary to sustain this critical work over many years. Without sufficient investment, these therapies may never make it to market and, if

¹ As finalized in the FY 2027 Hospital Inpatient Prospective Payment System (IPPS) Final Rule, 91 FR 49773 through 49788

² CMS and FDA Announce RAPID Coverage Pathway to Accelerate Patient Access to Life-Changing Medical Devices. April 23, 2026.
<https://www.cms.gov/newsroom/press-releases/cms-fda-announce-rapid-coverage-pathway-accelerate-patient-access-life-changing-medical-devices>



they do, face barriers to adoption because of payment instability. We encourage CMS to examine the holistic implications of RAPID and the repeal of the alternative pathways, and we welcome the opportunity to collaborate on solutions that address CMS's evidentiary responsibilities while preserving essential medtech investment and innovation.

AdvaMed recognizes that FDA's Breakthrough Device designation and CMS's reasonable and necessary coverage standard serve different purposes. Breakthrough designation is granted during device development, before the evidence needed for marketing authorization or Medicare coverage is complete. That timing, however, does not justify the categorical exclusions in the notice, including the outright exclusion of in vitro diagnostics (IVDs), conditioning Class II device eligibility on enrollment in FDA's Total Product Life Cycle Advisory Program (TAP) (a separate, voluntary FDA program), and the omission of any provision for Class I Breakthrough-designated Devices. As we describe throughout these comments, RAPID eligibility should be based on whether a device and its planned evidence development program can generate the evidence needed to support coverage – not on device type, FDA marketing pathway, or participation in another voluntary program. To be most effective for manufacturers, CMS, FDA, and beneficiaries, RAPID should preserve FDA's risk-based regulatory framework while allowing FDA and CMS to align their respective evidence expectations early in development.

Our remaining comments focus on the specific details of the proposed RAPID coverage pathway.

Appropriate Candidates

CMS proposes the following criteria to define appropriate candidates for RAPID:

- Presumptive Class II FDA Breakthrough-designated Devices participating in FDA's Total Product Life Cycle Advisory Program (TAP) planning to submit a De Novo request to FDA within 18 months following application to RAPID;
- Or Class III FDA Breakthrough-designated Devices planning to submit a Premarket Approval (PMA) application regardless of TAP participation;
- Devices in the investigational device exemption (IDE) pre-submission stage with manufacturer plans to enroll Medicare beneficiaries in the IDE study and evaluate clinical outcomes determined by FDA and confirmed by CMS;
- Devices that would fall under an existing Medicare benefit category and can be separately payable if approved to be billed to Medicare;
- Devices not already subject to a Medicare National Coverage Determination (NCD) or otherwise excluded from coverage; and
- Devices that are not in-vitro diagnostics (IVDs).



We acknowledge the need for a sufficiently targeted coverage pathway that manages CMS and FDA resources while still offering meaningful procedural improvements for Breakthrough-designated Devices. At the same time, we are concerned that the details of the proposal effectively allow CMS to indirectly dictate a sponsor's FDA regulatory pathway through RAPID eligibility criteria. AdvaMed is concerned that, as proposed, the RAPID eligibility criteria create incentives for sponsors to pursue De Novo or submit an IDE when a 510(k), a Non-Significant Risk (NSR) study, or another regulatory approach is appropriate under FDA's existing framework, and that this may result in unintended consequences. RAPID eligibility should be based on whether the sponsor can generate evidence that addresses both FDA and CMS's respective requirements.

Class II Breakthrough Devices

AdvaMed recognizes the benefits that TAP participation can offer to RAPID applicants and appreciates the notice's inclusion of a TAP advisor to provide support and guidance for Class II applicants that pursue RAPID. Many Class II Breakthrough-designated Devices that would otherwise meet the eligibility criteria for RAPID are not presently participating in TAP.^{3 4} As written, the RAPID notice does not offer a pathway for otherwise eligible applicants to pursue TAP participation in order to qualify for RAPID. Nor is TAP enrollment within the sponsor's control. TAP has its own entry gate tied to developmental stage, and our members report that FDA has declined TAP enrollment for Breakthrough-designated Devices whose sponsors had already engaged FDA through the pre-submission program after designation or had already completed a pivotal study. A sponsor that has followed FDA procedures by engaging early and generating pivotal evidence could therefore be locked out of RAPID by a TAP criterion it has no means of satisfying. The notice also lacks justification for the requirement that RAPID applicants participate in a voluntary FDA program to remain eligible for Medicare coverage through the RAPID pathway. AdvaMed requests that CMS, in collaboration with FDA, remove the requirement to participate in TAP.

Within the notice, CMS includes a footnote that states, "510(k) cleared devices where the primary predicate was authorized via the De Novo classification pathway no earlier than 18 months prior to acceptance into the RAPID coverage pathway." This footnote has significant implications for potential Class II applicants. AdvaMed requests that CMS and FDA clarify whether the footnote applies to devices planning to submit a 510(k), devices that have already received clearance, or both. We encourage CMS to deem eligible Class II Breakthrough-designated Devices pursuing a 510(k) when the clinical evidence program can satisfy both FDA

³ US Food and Drug Administration. Total Product Life Cycle Advisory Program (TAP). July 1, 2026. <https://www.fda.gov/medical-devices/how-study-and-market-your-device/total-product-life-cycle-advisory-program-tap>

⁴ US Food and Drug Administration. Breakthrough Devices Program. June 5, 2026. <https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program>



and CMS requirements rather than limiting the eligibility for those devices based on their regulatory pathway or the specific history of the predicate.

Class III Breakthrough Devices

AdvaMed supports CMS's inclusion of Class III Breakthrough-designated Devices regardless of their participation in TAP. As noted above, we believe the assignment of a dedicated steward from FDA (i.e., TAP advisor) is important for manufacturers as they navigate the RAPID application process. We recommend that CMS and FDA each consider providing a dedicated advisor for all RAPID applicants, regardless of Class or TAP participation, to ensure manufacturers have sufficient support and a consistent resource from both agencies throughout the RAPID process.

Class I Breakthrough Devices

The RAPID notice makes no provision for Class I Breakthrough-designated Devices. A De Novo request does not presume a Class II outcome: under Section 513(f)(2) of the Food, Drug & Cosmetics (FD&C) Act, FDA may classify a novel device into Class I where general controls alone provide reasonable assurance of safety and effectiveness, and FDA has granted De Novo requests as Class I for devices that hold Breakthrough Device Designation. By limiting eligibility to "presumptive Class II" De Novo candidates and Class III PMA candidates, RAPID would exclude the lowest risk Breakthrough technologies outright, and would essentially penalize a sponsor for FDA's determination that its device warrants the least burdensome classification. Device classification reflects device risk and the level of regulatory controls necessary to provide reasonable assurance of safety and effectiveness; it does not determine whether the sponsor's evidence development program can meet CMS's reasonable and necessary coverage standard, which is the question RAPID seems intended to address. Many such devices are non-invasive, home-use therapies for conditions that are highly prevalent among Medicare beneficiaries, and excluding them from a national coverage pathway pushes those devices toward fragmented and inconsistent local coverage. AdvaMed requests that CMS and FDA consider eligibility pathways into RAPID for Class I Breakthrough-designated Devices provided that the sponsor's evidence development program sufficiently addresses CMS coverage questions.

Devices Beyond IDE Pre-Submission Stage

CMS states that devices that are beyond the IDE pre-submission stage are not appropriate for the RAPID coverage pathway. (91 FR 51714 through 51715) We appreciate that the agency is directly soliciting comments on this approach. AdvaMed recognizes the importance of early collaboration with CMS, FDA, and manufacturers to design an IDE that meets RAPID eligibility requirements. While we support a pathway design that fosters coordination, we are concerned that the IDE pre-submission criteria unnecessarily limit applicability based solely on procedural



technicalities and changes to CMS policy. This issue is particularly acute for devices that are beyond the pre-submission stage but are still being studied under an IDE. It also applies to devices that already hold FDA market authorization for one indication and are pursuing a new Breakthrough-designated indication through a new clinical study. Those sponsors are at the IDE pre-submission stage for the new indication and should presumably be eligible on that basis, irrespective of the device's existing authorization. AdvaMed strongly urges CMS and FDA to establish a process under which devices that have progressed beyond the IDE pre-submission stage could become eligible for RAPID to ensure manufacturers of otherwise eligible devices qualify for participation. We encourage the agencies to keep the process open for at least 12 months following the official start of RAPID, and we recommend that CMS and FDA publish information on the number of devices that utilized this process in the quarterly NCD Dashboard to inform potential future expansion of the RAPID Coverage Pathway. Any process for devices beyond the IDE pre-submission stage should be clear and defined as early as possible to ensure sufficient time for manufacturers to consider a RAPID application.

Furthermore, we are concerned that the IDE eligibility requirement represents unnecessary overuse of FDA and manufacturer resources simply to meet RAPID eligibility criteria. FDA does not require an IDE submission for NSR studies, and doing so as part of RAPID procedural requirements needlessly diverts critical agency resources away from higher risk technologies. Eligibility should be evaluated based on whether the existing or planned evidence development program can still be aligned with CMS's identified coverage needs, rather than solely on the procedural stage of the FDA process. CMS has stated its interest in maintaining a consistent, evidence-based standard rather than reliance on external designations that may be based on different evidentiary thresholds or policy objectives. (91 FR 49779) However, we do not believe that a universal IDE requirement is necessary to achieve that goal, especially based on the possibility that CMS may require further evidence via Coverage with Evidence Development (CED) following the completion of an IDE. AdvaMed recommends that CMS and FDA reconsider whether the IDE requirement is necessary for all devices to be considered eligible for RAPID. One potential alternative could include following existing FDA IDE requirements, including Significant Risk (SR) and NSR study criteria. Under 21 CFR 812.2(b), an NSR device study may proceed under the abbreviated IDE requirements upon Institutional Review Board (IRB) approval, without submission of an IDE application to FDA. On the other hand, the proposed universal requirement for an IDE submission to FDA would therefore require sponsors of low-risk devices either to seek a SR determination that their device does not warrant, or to submit an IDE that the IDE regulations do not require, solely to become eligible for coverage consideration. As proposed, the RAPID framework unintentionally penalizes lower risk devices by categorically excluding certain technologies critical for the Medicare population. It is clinically and economically counterproductive that having a lower risk profile would disqualify a



Breakthrough-designated Device from the benefits of the RAPID pathway. As an alternative to the current proposal's universal IDE requirement, for NSR studies, CMS and FDA could accept a Pre-Submission (Q-Submission) with CMS participation, together with the IRB-approved protocol, as the RAPID entry point for NSR devices and allow CMS's study design input to attach to that protocol in the same way it would attach to an IDE.

Devices That Are In-Vitro Diagnostics (IVDs)

AdvaMed opposes CMS's proposal to categorically exclude IVDs from the RAPID program. CMS states that IVDs, including diagnostic laboratory tests, are a highly specialized area of coverage policy development and that the agency has historically delegated review of many such products to specialized Medicare Administrative Contractors (MACs). CMS therefore concludes that IVDs should not be eligible for RAPID, even while acknowledging that an NCD may be appropriate for certain IVDs. (91 FR 51714–15). Diagnostics represent a small fraction of technologies authorized through the Breakthrough Program. Between 2016 and June 2026, the FDA has only authorized 34 Breakthrough IVDs — and 7 are not relevant to Medicare beneficiaries. Ultimately, clinical diagnostic laboratory tests (CDLTs) eligible for CMS coverage account for just 16% of all authorized Breakthrough technologies.

CMS's rationale does not support a wholesale exclusion, especially based on the importance of diagnostics to physicians and their patients. Approximately 70% of healthcare decisions depend on laboratory test results according to the Centers for Disease Control and Prevention (CDC). Some Breakthrough diagnostics are intended for broad use across the Medicare population and raise coverage questions that are inherently national in scope. Cancer screening tests are a clear example: CMS has issued NCDs for multiple cancer screening technologies. Breakthrough diagnostics are also emerging in other serious conditions that disproportionately affect Medicare beneficiaries. For these technologies, a national coverage process may be both appropriate and necessary. Crucially, for certain screening tests, the statutory basis for CMS's authority to cover these tests does not allow coverage decisions to be delegated to the MACs, which means there is no way to cover these tests without an NCD.

Reliance on MACs also does not provide the principal benefits RAPID is intended to create. MACs have regional jurisdiction, and their policies may differ in timing, evidentiary requirements, and coverage criteria. These policies and procedures can even differ within a single MAC depending on the type of diagnostic technology under evaluation. For example, DNA-, RNA-, or proteomics-based diagnostics fall within the MoIDx program's scope. However, diagnostics using different technologies are evaluated via different, non-MoIDx processes at Palmetto GBA. Recent examples include protein tests to assist in Alzheimer's diagnosis, which were FDA-authorized through the Breakthrough Program and fall outside of



MolDx scope. An LCD issued by one MAC does not establish a uniform national policy or bind other contractors. As a result, reliance on local processes may require manufacturers to pursue coverage separately across jurisdictions and can leave similarly situated Medicare beneficiaries with different access depending on where they live. That outcome is difficult to reconcile with RAPID's stated purpose of providing timely, predictable, and nationally consistent coverage for qualifying Breakthrough Devices.

This is especially concerning for molecular diagnostics coverage through the MolDx Program. Presently, MolDx has a 2–3-year backlog of LCDs. Coverage is already unable to keep pace with innovation and technology development, which threatens patient access and would be further burdened by additional delegated RAPID diagnostic applications. Furthermore, current MolDx policy requires a Foundational LCD be established prior to a test undergoing a technical assessment (TA) to enable test-specific coverage and reimbursement. This effectively non-covers any new test that does not fit under an existing Foundational LCD policy for multiple years, with no opportunity for interim reimbursement analogous to the claim-by-claim adjudication in the absence of an LCD available in other circumstances and jurisdictions. RAPID's proposed treatment of diagnostic Breakthrough-designated Devices compounds existing challenges at the MAC level and addressing these challenges requires both greater resources and process improvements. This investment is needed even in the absence of the additional workload that could be expected in order to accommodate tests that might otherwise be RAPID applicants. For example, the TA process can take 6-12 months to complete for a diagnostic test that falls under an existing LCD, and multiple rounds of review are common. Delays, combined with a lack of transparency and consistency across and within MACs, create gaps in access that demand serious consideration from CMS as it contemplates RAPID's impact on diagnostics.

CMS also has substantial experience developing national coverage policy for diagnostics. The agency maintains NCDs pertaining to clinical diagnostic laboratory services, such as national policies addressing genetic testing, next-generation sequencing, infectious-disease testing, and cancer screening. Moreover, the only technologies that successfully completed the FDA-CMS Parallel Review program were IVDs. That experience demonstrates that diagnostics are not inherently unsuitable for coordinated FDA-CMS review; to the contrary, IVDs provide some of the clearest evidence that early coordination can produce timely national coverage.

The notice does not explain why exclusion from RAPID and reliance on MACs would produce a more timely or efficient coverage pathway for diagnostics, and we urge CMS to consider diagnostic RAPID applications on a case-by-case basis to facilitate access to these critical Breakthrough technologies. If CMS nevertheless concludes that IVD coverage requires a separate, tailored approach, there are more appropriate alternatives than categorical exclusion.



CMS could establish a limited or phased IVD track, allow additional review time where necessary, cap initial participation, or draw upon the expertise of specialized MACs, external technology assessors, and other subject-matter experts while retaining national responsibility for the ultimate coverage determination. Further, CMS could supplement its internal expertise through the establishment of a Medicare Evidence Development and Coverage Advisory Committee (MedCAC) to evaluate coverage of IVDs.⁵ AdvaMed strongly recommends that CMS finalize a pathway that permits diagnostic participation in RAPID.

Procedures for RAPID

CMS details the three stages of RAPID: IDE pre-submission, formal IDE submission to FDA and CMS, and transition from IDE to coverage.

AdvaMed supports CMS and FDA goals to foster early and frequent collaboration. The details in the notice frequently describe CMS in a consulting capacity – for instance, the initial applicant consideration and assessment are stated as FDA responsibilities where FDA “will share the relevant information and consult CMS.” (91 FR 51715) Similarly, manufacturers appear only to submit communications directly to FDA, with FDA sharing information with CMS, consulting with CMS, and confirming with CMS at multiple stages in the candidate consideration process. FDA appears to own the documentation, communication, and procedural responsibilities of the IDE pre-submission and formal IDE submission stages, with the exception of the Medicare Benefit Category review component. Even the IDE is submitted only to FDA, with CMS described as receiving the results of the IDE application decision from FDA at the same time as the manufacturer. We recognize that CMS may lack the existing resources to be more engaged early in the RAPID process and understand that FDA resources may be necessary to support early, continuous, and equivalent partnership across both agencies. To ensure the long-term sustainability of the RAPID pathway, additional and adequate resource for the CMS Coverage and Analysis Group (CAG) are essential to ensure that all parties – manufacturers, FDA, and CMS – can fully engage in meaningful coordination through the RAPID process.

For technologies that are novel not only in their regulatory pathway but also in their anticipated clinical use or Medicare reimbursement considerations, AdvaMed encourages CMS and FDA to establish an early, structured joint consultation opportunity with the manufacturer before the pivotal clinical program is finalized. Such an engagement could build on FDA's existing pre-submission framework while enabling CMS to identify Medicare-specific evidence considerations, benefit-category questions, and other coverage issues at a sufficiently early stage to inform prospective evidence development. Early alignment would reduce the risk that

⁵ Medicare Evidence Development & Coverage Advisory Committee, CMS



manufacturers complete pivotal studies that satisfy FDA's regulatory needs but leave avoidable evidence gaps for Medicare coverage. This consultation should remain advisory and should preserve the distinct statutory standards and decision-making responsibilities of FDA and CMS.

Furthermore, under FDA's existing IDE requirements, study design considerations (SDCs) are recommendations regarding study design and are not IDE deficiencies or conditions that a sponsor must address before conducting the investigation. The notice, however, states that manufacturers must satisfactorily address certain SDCs to continue participating in RAPID. This could convert recommendations issued through FDA's IDE process into mandatory RAPID requirements and create confusion regarding the purpose and need for the feedback. We request that CMS and FDA clearly distinguish between FDA requirements, FDA SDCs, and CMS coverage requirements. CMS should not characterize its coverage recommendations as FDA SDCs or use FDA's IDE process to enforce them, and CMS coverage requirements should not drive FDA marketing authorization. Any requirements for continued RAPID participation should be provided separately and in writing.

Additionally, we request that CMS and FDA provide greater detail regarding the process through which manufacturers authorize interagency sharing of regulatory submissions and communications. We appreciate that CMS clarifies in the notice that the agencies will protect trade secrets, confidential commercial information, personal privacy information, and pre-decisional regulatory information consistent with applicable law and the CMS and FDA memorandum of understanding. Specifically, we request that CMS and FDA provide additional detail and context when a manufacturer is asked for clarification, and we encourage both agencies to specify the need for the request and whether it is to address regulatory needs, or coverage needs.

AdvaMed further recommends that CMS and FDA clarify that RAPID participation will not create additional FDA review milestones or otherwise delay IDE approval, PMA review, or marketing authorization. Because the value of RAPID depends on earlier alignment without slowing FDA decision-making, CMS engagement should be coordinated with existing FDA interactions and should not expand the evidence expectations needed to establish safety and effectiveness. Any additional evidence expectations should be proportional, focused on specific remaining Medicare coverage questions, and, where appropriate, addressed through post-market evidence development rather than pre-market requirements. We ask that CMS and FDA describe how they will protect FDA review timelines while still enabling meaningful CMS input on Medicare-relevant outcomes. To that end, we recommend that both agencies provide detailed timelines for RAPID procedures, including the timing parameters within which each stage of the RAPID process will transpire and how manufacturers experiencing process-related timing delays



can engage both agencies. As part of the final notice, AdvaMed requests that CMS clarify when RAPID will be implemented, the date the pathway will be in effect, and whether the pathway will remain continuously available to eligible manufacturers or operate for a defined period. To the extent that manufacturers experience delays, CMS and FDA should communicate the reason for any delays in writing directly to the manufacturer along with a date of resolution or resumption of the process. CMS and FDA should also publicly report timeline data for each RAPID application, regardless of its ultimate coverage determination outcome, to provide transparency into the process, inform potential applicant consideration of the RAPID coverage pathway, and direct appropriate resource allocation.

Throughout the notice, CMS discusses the possibility that a RAPID applicant may opt out of the process before an NCD is issued. We request CMS and FDA detail the process for applicants in this scenario. We recommend that CMS confirm that if a manufacturer withdraws from the RAPID pathway for any reason, they can still pursue an NCD in the future.

CMS NCD Timing

AdvaMed requests specific information on NCD timing. CMS's stated goal is to release final NCDs "as early as" 60 days after FDA market authorization for Class II and 90 days for Class III. We appreciate CMS's intent to expedite the NCD process for RAPID participants and applaud the agency's efforts to align within existing FDA market authorization timelines. However, we are concerned at the ambiguity that "as early as" introduces into the process and request the agency provide a maximum timeline for final NCDs rather than a minimum goal. As currently written, a manufacturer has little to no recourse if an NCD exceeds the stated 60- and 90-day timelines. To promote timeline adherence and manufacturer resource allocation, we encourage CMS to commit to the stated 60-day timeline for Class II and 90-day timeline for Class III.

Evidence for NCDs

CMS states that if there is insufficient evidence to support Medicare coverage, the agency may issue a proposed NCD under the CED framework. We request more detailed information on the exact stage of the process at which manufacturers engage with CMS to discuss viable paths to coverage at the conclusion of the IDE trial. While the notice encourages manufacturers to remain engaged with their FDA TAP advisor and CMS point of contact throughout their IDE study to ensure that CMS can discuss an evidence gap, we request additional guidance from CMS to better understand the appropriate timeline during the process to engage with CMS to discuss potential pathways to coverage and what, if any, remaining evidence gaps may need to be addressed via CED. We reiterate our recommendation that CMS and FDA fully and equally integrate staff contacts across the entire RAPID process to ensure sufficient engagement and



information sharing between CMS, FDA, and the manufacturer, particularly at critical junctures that could impact the potential for CED.

Pathway from RAPID Coverage to Coding and Payment

AdvaMed requests that CMS specify how coding and payment processes will be coordinated with coverage review under RAPID, including the stage within the RAPID pathway that these activities are expected to occur. Although the notice requires eligible devices to fall within, or not be clearly excluded from, a Medicare benefit category and to be separately payable if approved for billing to Medicare, the proposed process does not describe how or when applicable coding and payment issues will be identified, reviewed, or resolved. A favorable and timely NCD may not, on its own, result in timely beneficiary access if an appropriate billing code, payment mechanism, or payment methodology is not available when coverage becomes effective. We recommend that CMS clarify whether coding and payment reviews may proceed concurrently with RAPID evidence development and NCD preparation and provide information on how CMS will address situations where no suitable coding or payment mechanism exists at the time a RAPID NCD is finalized, including whether RAPID participants may receive coordinated or expedited consideration through existing coding and payment processes. AdvaMed additionally requests information on how payment rates for RAPID-covered technologies will be established under the applicable Medicare payment system, particularly in instances where there is no comparable existing service or established payment methodology. Specifically, we request that CMS confirm that the absence of an existing product-specific code, separate payment mechanism, or established payment methodology at the time of RAPID application does not, by itself, render an otherwise qualifying device ineligible for the pathway.

To promote transparency and predictability, we encourage CMS to reflect these and all RAPID process milestones in the final RAPID process map or implementation guidance to provide manufacturers with clear expectations regarding any coding or payment steps that may remain outstanding when an NCD becomes effective.

Transition Protections for TCET and Pre-RAPID Devices

We appreciate CMS's recognition of other coverage pathways, including Parallel Review. However, as the agency notes, Parallel Review is applicable to non-Breakthrough-designated Devices and is therefore an insufficient substitute for potential RAPID applicants. Similarly, devices that were pursuing TCET are ineligible for RAPID and face an indefinite pause of that coverage pathway. Manufacturers have made substantial clinical and financial investments based on existing coverage pathways and expectations. Abrupt policy changes disrupt development programs, delay patient access, and create significant uncertainty for developers and investors.



We urge CMS to recognize the disruption for manufacturers that were pursuing TCET and clearly identify how such products may qualify for expedited coverage consideration.

Specifically, CMS should establish an explicit transitional pathway for Breakthrough-designated Devices whose manufacturers materially advanced clinical development or Medicare coverage planning under TCET or other applicable CMS coverage pathways before the RAPID notice was issued. Manufacturers should not be disadvantaged because they relied on the coverage framework that CMS had established at the time their clinical programs were designed and evidence was (and continues to be) gathered.

This is particularly important for presumptive Class II devices. These manufacturers may not have participated in TAP because TAP participation was not a requirement for TCET eligibility or Medicare coverage. Similarly, FDA may have appropriately determined that a clinical investigation was NSR, eliminating the need for the formal IDE submission around which RAPID is now structured. Requiring these manufacturers to have participated in TAP or to have entered RAPID during IDE pre-submission would effectively impose new procedural requirements retrospectively, after the relevant clinical development decisions have been made.

AdvaMed requests that CMS and FDA therefore establish a time-limited transitional period under which otherwise eligible Breakthrough-designated Devices that materially advanced development before the release of the RAPID notice may qualify for RAPID without prior TAP participation and regardless of whether their clinical investigation was conducted under either the SR or NSR IDE requirements. Eligibility under this transitional process should depend on whether the existing clinical development program can satisfy RAPID's substantive objectives, including generation of clinically meaningful evidence relevant to Medicare beneficiaries, rather than whether the manufacturer satisfied procedural requirements that did not exist and were not applicable when the clinical program was initiated. This transitional process would not guarantee Medicare coverage or alter CMS's reasonable and necessary evidentiary standard. Rather, it would ensure that manufacturers that reasonably relied on TCET and FDA's applicable risk-based regulatory framework are provided with an opportunity to demonstrate that their evidence satisfies RAPID's substantive coverage requirements.

Absent such a transition mechanism, CMS risks creating an unintended coverage gap in which Breakthrough-designated Devices that were too advanced to satisfy RAPID's newly established procedural prerequisites are simultaneously unable to pursue TCET because CMS has paused that pathway. Such an outcome would disadvantage precisely those manufacturers that had already invested in clinical development under the coverage framework CMS had previously established.



We recommend that CMS and FDA describe the process, timing, and information requirements for manufacturers that are potentially eligible for this transitional pathway, including the latest stage of development an otherwise eligible device may request consideration, the process CMS will use to determine whether the existing evidence development program remains capable of addressing RAPID's substantive evidence requirements, and whether modifications to an ongoing or planned study may permit participation.

CMS states in the notice, both directly and indirectly, that it lacks the resources and capacity to offer both TCET and RAPID. The TCET pathway resulted in 5 NCDs after two years, only one of which was explicitly enrolled in the program. CMS has estimated that 40 devices would qualify for RAPID outright, with the potential for approximately 20 additional devices in the future. While RAPID has the benefit of early FDA engagement and procedural goals to align with FDA market authorization timelines, we believe additional resources are necessary to ensure that CMS can sufficiently review potentially eligible devices in addition to its standard coverage workload within the stated time parameters of the RAPID pathway. We share recommendations for appropriately resourcing CMS's overall coverage work in greater detail below. AdvaMed requests that the agency provide additional information on the timing and pace of RAPID application review, and that both CMS and FDA report detailed data on the RAPID application, review, approval, and coverage processes to assess whether each agency has sufficient resources to support the pathway, and to specify what additional resources may be necessary.

Coverage Pathway Prioritization

In the RAPID notice, CMS proposes to prioritize RAPID NCDs over non-RAPID NCDs, including those from the NCD Wait List. (91 FR 51718) As of September 2026, there are 11 NCDs on the NCD Wait List.⁶ On the NCD Wait List, CMS notes that given the volume of requests and the agency's current level of resources, there are times when CMS must tell requestors that an NCD request is accepted but the NCD process cannot immediately begin. Some NCDs have been on the Wait List for five or more years.

AdvaMed is concerned that the RAPID Coverage Pathway is presented at the expense of non-RAPID coverage policy. As we have detailed throughout our comments, and as CMS has indicated across the notice, there are severe resource limitations within the agency and AdvaMed sees the potential for these constraints to threaten the long-term success of RAPID and the stability of CMS's overall coverage efforts. We are especially aware of the consequences for

⁶ CMS NCD Dashboard. September 2026. <https://www.cms.gov/files/document/ncddashboard.pdf>



NCDs that are currently on the Wait List and future non-RAPID NCD requestors who already face significant wait times. It is essential that RAPID includes adequate funding for CMS coverage work to avoid the potential for zero-sum resource prioritization determinations.

This is especially concerning for NCDs that pertain to IVDs. As noted above, there are certain categories of testing where Medicare coverage of IVDs is only enabled by the NCD process, including critical cancer screening tests, which leaves no other options for coverage. We are also aware of the impact this prioritization could have on NCD reconsideration requests that affect diagnostics. For example, we note that many stakeholders are in the process of engaging with CMS on the need to update NCD 90.2, which governs next generation sequencing (NGS) tests and provides important coverage for FDA-approved companion diagnostics tests for cancer patients. As of September 2026, NCD 90.2 is now on the NCD Wait List for reconsideration. Until CMS updates this NCD to align with current evidence, Medicare beneficiaries with cancer don't have access to some guideline-recommended testing.

At a minimum, prioritization of RAPID NCDs should not come at the expense of new NCDs or reconsideration requests where the NCD process is required to enable coverage. We urge CMS to support RAPID with sufficient resources that do not require diversion or divestment from non-RAPID coverage work. AdvaMed generally supports the NCD prioritization framework detailed in the Revised Process for Making National Coverage Determinations framework (78 FR 48164) in instances where resources are constrained and encourages CMS to review RAPID NCDs within those parameters rather than uniformly prioritizing NCDs based on their RAPID participation status. We reiterate our recommendations for additional CMS CAG resources to ensure timely and predictable coverage workflows. Furthermore, we request that CMS publicize its prioritization of NCDs on the NCD Wait List.

Additional Policy Considerations

Transparency

AdvaMed supports transparency within the RAPID pathway. As CMS and FDA prepare to accept applications and implement RAPID, we recommend that CMS balances transparency goals with appropriate safeguards. Specifically, CMS should not disclose specific technologies that have been accepted as RAPID participants. It is possible that the disclosure of specific technology and IDE study information may disadvantage applicants that withdraw from RAPID for any reason prior to receiving an NCD. We do support an approach similar to TCET, whereby CMS maintains a running list of clinical disease areas and the number of technologies participating in RAPID. We also recommend that CMS and FDA align with TCET and Parallel Review, which offer manufacturers the opportunity to voluntarily disclose their own participation.



Scope of Coverage Determinations Under RAPID

AdvaMed encourages CMS to use RAPID to establish coverage policies that extend beyond individual products whenever clinically appropriate. Device-specific determinations may limit the pathway's efficiency and create unnecessary variation in beneficiary access. Coverage policies based on a defined clinical indication, procedural class, or category of technologies would promote consistency, reduce administrative burden, and create a more predictable environment for innovation while preserving CMS's ability to apply appropriate safeguards and evidentiary standards. We encourage CMS to clearly define requirements for follow-on products in the same category of RAPID devices. It is presently unclear whether a follow-on device of a RAPID NCD that requires CED would automatically receive RAPID consideration, or how CED study design would be addressed for follow-on devices. Conversely, it is not specified if a follow-on device might be disqualified from RAPID because an NCD already exists. AdvaMed recommends that CMS consider RAPID eligibility for these scenarios when the modified or expanded technology continues to address an unmet need for Medicare beneficiaries and when early FDA and CMS alignment would meaningfully accelerate access to important innovations. AdvaMed requests CMS to provide detailed information for the consideration and treatment of follow-on devices.

We request similar clarification regarding the indications of a single device. This clarification is important for manufacturer lifecycle planning because many Breakthrough technologies evolve through iterative design, expanded indications, and new evidence generation after the original approval. As drafted, RAPID attaches to one device, one FDA marketing submission, and one indication, and the route into the pathway is dictated by eligibility criteria rather than by evidence. A manufacturer whose device already holds market authorization for one indication, and which is generating evidence in an adjacent indication, must currently route the new indication through Breakthrough designation, and potentially a new premarket submission to FDA. The resulting NCD would then apply only to that one indication, with no view of the indications the device already holds or is likely to pursue next.

To address concerns about inappropriately narrow coverage policies, AdvaMed recommends that CMS issue NCDs that enable coverage based on a device's FDA labeling. As a device matures and clinical practice evolves with potentially expanded future indications, it is important for NCDs to be issued in ways that do not require CMS to reissue coverage policies. Where clinically appropriate and consistent with Medicare's reasonable and necessary standard, CMS should structure RAPID NCDs to accommodate the scope of a device's FDA-authorized labeling and foreseeable label modifications without requiring unnecessary reopening of the NCD. Similarly, follow-on devices should not be required to participate in RAPID and pursue an



additional, separate NCD. Finally, we recommend that RAPID coverage policies for modified devices align with FDA's PMA and 510(k) modification guidance and do not require a new coverage determination when FDA does not require a new marketing submission. We believe this approach will alleviate resource constraints over time for all NCDs.

AdvaMed thanks CMS for its work on the RAPID coverage pathway. We appreciate the opportunity to share these comments and hope to continue to engage with the agency on critical coverage modernization issues. If you have any questions regarding these comments or require additional information, please contact Amber Stock (astock@advamed.org).

Sincerely,



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