



October 13, 2026

The Honorable Robert F. Kennedy, Jr.
Secretary
U.S. Department of Health and Human Services
200 Independence Avenue, SW
Washington, D.C. 20201

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

Re: CMS-3487-NC – Regulatory Alignment for Predictable and Immediate Device (RAPID) Coverage Pathway
91 Fed. Reg. 51710 (August 11, 2026)

Dear Secretary Kennedy and Administrator Oz:

The American Cancer Society Cancer Action Network (ACS CAN) appreciates the opportunity to comment on the Regulatory Alignment for Predictable and Immediate Device (RAPID) Coverage Pathway procedural notice. ACS CAN is making cancer a top priority for public officials and candidates at the federal, state, and local levels. ACS CAN empowers advocates across the country to make their voices heard and influence evidence-based public policy change, as well as legislative and regulatory solutions that will reduce the cancer burden. As the American Cancer Society's nonprofit, nonpartisan advocacy affiliate, ACS CAN is more determined than ever to end cancer as we know it, for everyone.

ACS CAN offers comments on the following policies:

- RAPID Coverage Pathway – An Opportunity to Accelerate Patient Access to Beneficial Medical Products
- Appropriate Candidates
- Procedures for the RAPID Coverage Pathway
- RAPID Coverage Pathway and Parallel Review
- RAPID Coverage Pathway Prioritization
- RAPID Coverage Pathway Transparency

II. PROVISIONS OF THE NOTICE WITH COMMENT PERIOD

A. RAPID Coverage Pathway – An Opportunity to Accelerate Patient Access to Beneficial Medical Products

The Centers for Medicare & Medicaid Services (CMS) proposes that under the RAPID coverage pathway, CMS and the Food and Drug Administration (FDA) will work together with manufacturers earlier in the device development process so that evidence generated during FDA investigational

device exemption (IDE) studies can be used for Medicare coverage decisions. CMS proposes that if the IDE study successfully demonstrates an improvement in the Medicare population's health outcomes, the agency will issue a proposed Medicare National Coverage Determination (NCD) on the same day as FDA market authorization and finalize it as early as 60 days later.

ACS CAN supports the development of the RAPID coverage pathway and efforts to develop timely pathways for Medicare coverage and reimbursement. Advances in medical devices have the potential to improve patient outcomes, reduce beneficiaries' overall cost of care, and lower potential costs to the Medicare program, and coverage policies and payment pathways play a critical role in shaping the availability and timeliness of beneficiaries' access to these advances. Medicare's current coverage determination processes can be ill-suited to keep pace with the fast-moving development of emerging technologies.

We support the aim of the RAPID coverage pathway, which is to improve evidence alignment between FDA market authorization and the NCD process to reduce time to Medicare coverage. However, we are concerned that CMS does not propose allocating additional funds to implement the RAPID coverage pathway. Without more resources, products that are not eligible for the RAPID pathway could experience even longer delays in receiving coverage determinations, as CMS would prioritize RAPID NCDs over non-RAPID NCDs. This prioritization could inadvertently disincentivize the development of promising new technology that can deliver critical clinical advancements to Medicare beneficiaries. We urge CMS to ensure that the agency is properly resourced to implement this new pathway to prevent unintended consequences for the approval of other products.

C. Appropriate Candidates

CMS proposes to limit pathway eligibility to some, but not all, FDA Breakthrough Devices by establishing eligibility criteria related to FDA review status, Medicare coverage, and payment considerations. CMS also proposes that in vitro diagnostic (IVD) products would be ineligible, noting that coverage of these products is a highly specific area of policy development and that CMS has historically delegated the review of many of these products to specialized Medicare Administrative Contractors (MACs). CMS also proposes that devices that are beyond the IDE presubmission stage would be excluded from the RAPID coverage pathway and seeks comment on this approach.

ACS CAN supports the development of the RAPID coverage pathway because it has the potential to accelerate beneficiary access to innovative devices. We urge CMS to continue to refine and expand RAPID after implementation to include certain devices that do not have a Breakthrough Device designation but still can confer clinically meaningful benefits to patients, including devices that save and extend lives, and those that address unmet patient needs. We are also concerned that some of the requirements for Class II devices, particularly committing to submit a De Novo request within 18 months, could be overly restrictive. Several of the existing coverage pathways aiming to reduce time between FDA approval and Medicare coverage have had limited uptake, and as such, we are concerned that overly onerous requirements for manufacturers could limit participation and impact the RAPID coverage pathway's success.

ACS CAN is concerned that CMS proposes to exclude IVDs from the RAPID coverage pathway and urges the agency to reconsider. IVDs are not the only category of devices which has historically relied on local

coverage decisions jurisdictions of MACs, yet they are the only one that is categorically excluded from the RAPID pathway. Relying on MACs can result in a patchwork of coverage, meaning that beneficiary access to new technologies will vary depending upon the geographic area in which the beneficiary resides. We are also concerned that this policy could negatively impact access to biomarker testing, which helps physicians tailor their care plan and can provide patients with access to life-saving treatments. We urge CMS to make these crucial devices eligible for consistent Medicare coverage through the RAPID coverage pathway.

ACS CAN is also concerned that as proposed, there is no temporary pathway for devices already undergoing the IDE process to become eligible for the RAPID coverage pathway. Without a temporary bridge, it could take years longer for these devices, including those important for the treatment of cancer, to reach patients. We support the establishment of a temporary process to include devices that are already undergoing IDE studies.

D. Procedures for the RAPID Coverage Pathway

1. IDE Presubmission

CMS proposes that entry into the coverage pathway is voluntary. FDA would make an initial determination of whether a device meets the criteria to be included in the pathway, and if so, would confirm with CMS and consult to discuss the protocol. Prior to the RAPID kickoff meeting, CMS proposes that it would initiate a preliminary benefit category assessment if all other pathway criteria have been met.

ACS CAN supports CMS being involved during the presubmission process to help reduce barriers to innovative devices gaining Medicare coverage. The rapid development of technologies is an impactful opportunity for people with serious conditions like cancer; however, the current path to Medicare coverage – and access for beneficiaries – often is uncertain, even for new technologies that receive FDA approval. As proposed, RAPID would allow for the most collaboration between FDA and CMS of any pathway, significantly improving evidence alignment between FDA and CMS and accelerating access to innovative devices. We encourage CMS to further clarify the process for determining Medicare benefit categories, coding, and payment and CMS' timeline for these processes.

2. Formal IDE Submission to FDA and CMS

CMS proposes that the FDA would review the IDE application and inform the manufacturer of any study design considerations (SDCs). FDA would then share the letter with CMS, after which CMS would communicate with the manufacturer about the SDCs that must be addressed. If the criteria are addressed, CMS would notify the manufacturer of approval and list the approved IDE study on the CMS website.

ACS CAN supports efforts to inform manufacturers early on of any criteria that need to be addressed for continuing in the pathway. It is crucial that throughout the IDE process, CMS and FDA keep manufacturers updated on requirements so as not to slow down the FDA approval or NCD coverage process. When implemented effectively, this pathway has the potential to bring faster innovations to patients by accelerating review timelines and improving the frequency and timeliness of communication between manufacturers and regulators.

3. Transition from IDE to Coverage

CMS proposes that the process for Medicare coverage under the RAPID coverage pathway would generally follow the NCD statutory timeframes. The agency outlines that its 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. There would be a 30-day public comment period on the proposed NCD.

ACS CAN supports CMS finalizing NCDs as early as 60 days following FDA market authorization. However, we urge CMS to establish a clear, predictable timeline by which it will finalize RAPID NCDs beyond statutory requirements. Although “as early as” 60 days following FDA market authorization is an important step towards accelerating patient access, the phrase “as early as” does not provide stakeholders with necessary certainty regarding the timing of coverage decisions. Establishing a transparent and consistent time standard for RAPID NCDs, beyond what is required for all NCDs by statute, would promote predictability and more timely access to innovative devices for Medicare beneficiaries.

F. RAPID Coverage Pathway and Parallel Review

CMS proposes that it would work with FDA to consider updates to the Parallel Review program.

ACS CAN supports the agency’s efforts to ensure that these coverage pathways are streamlined to reduce redundancy and promote program uptake, which has been a challenge for the Parallel Review program.¹ We urge CMS to explicitly outline the changes that it is considering and to ensure that any changes to the Parallel Review program are communicated clearly to manufacturers, and beneficiaries as necessary, to prevent disruptions in access.

H. RAPID Coverage Pathway Prioritization

CMS proposes to prioritize the review of RAPID NCDs over non-RAPID NCDs from the NCD Wait List.

ACS CAN is concerned that some devices, including lab tests, are excluded from the coverage pathway and could be deprioritized during the NCD-review process, and experience delays in coverage as a result. As CMS notes, there is already an NCD Wait List, and prioritizing RAPID NCDs over non-RAPID NCDs could lead to delays in coverage for non-RAPID eligible products. We urge CMS to ensure that RAPID NCDs are not prioritized over non-RAPID NCDs on the NCD Wait List. Additionally, we encourage CMS to dedicate additional resources to expand the agency’s capacity to review NCDs so that Medicare beneficiaries do not face avoidable delays in accessing innovative devices.

I. RAPID Coverage Pathway Transparency

CMS proposes to make the identity of specific manufacturers and devices in the RAPID coverage pathway publicly available.

ACS CAN supports transparency in making the identity of the participating manufacturers and devices public. In addition to identifying participants, we urge CMS to publicly track and report the number of requestors and number accepted into the process each year so that stakeholders can track program

¹ Tunis, S. R., Neumann, P. J., Chambers, J. D., & Jenkins, N. B. (2022, October 13). *Improving Medicare coverage of innovative technologies*. *Health Affairs Forefront*. <https://doi.org/10.1377/forefront.20221013.475887>

uptake. We also encourage CMS to provide greater transparency regarding the selection process to enable stakeholders to understand why certain devices are approved and to improve the development of future IDE studies.

CONCLUSION

Thank you for the opportunity to comment on the RAPID Coverage Pathway procedural notice. If you have any questions, please feel free to contact me or have your staff contact Allie Babyak, Public Policy Fellow, Access to Care at Allie.Babyak@cancer.org.

Sincerely,

A handwritten signature in black ink, appearing to read "Lisa A. Lacasse". The signature is fluid and cursive, with the first name "Lisa" being the most prominent.

Lisa A. Lacasse, MBA
President
American Cancer Society Cancer Action Network