



Chris Klomp, Director
Center for Clinical Standards and Quality
Centers for Medicare & Medicaid Services
P.O. Box 8010
Baltimore, MD 21244

October 13, 2026

Re: Medicare Program; Regulatory Alignment for Predictable and Immediate Device (RAPID) Coverage Pathway - Notice with Comment Period (CMS-3487-NC; 91 FR 51710)

Dear Director Klomp,

The Alzheimer's Association and the Alzheimer's Impact Movement (AIM) appreciate the opportunity to respond to the Notice with Comment Period on the Regulatory Alignment for Predictable and Immediate Device (RAPID) Coverage Pathway.

The Alzheimer's Association is the leading voluntary health organization in Alzheimer's and dementia care, support, and research. The Alzheimer's Impact Movement, a separately incorporated advocacy affiliate, is a nonpartisan, nonprofit organization and works to make Alzheimer's and dementia a national priority.

Today there are an estimated 8.6 million Americans with the biomarkers of Alzheimer's disease and symptoms, including 4.4 million Americans with dementia due to Alzheimer's and 4.2 million with mild cognitive impairment (MCI) due to Alzheimer's.¹ Fewer than 1 in 10 people with MCI receive a diagnosis. In a study of about 40 million Medicare beneficiaries, fewer than 8% of expected cases had been diagnosed. Timing matters. People get the most benefit from today's treatments when they start at the first signs of mild cognitive impairment due to Alzheimer's disease. That's why early detection and diagnosis is essential.

The Alzheimer's Association and AIM commend the Centers for Medicare & Medicaid Services (CMS) for pursuing a more predictable and timely national coverage pathway for innovative devices. Medicare beneficiaries living with Alzheimer's and other causes of cognitive impairment and dementia are disproportionately affected by delays between market authorization and coverage, because many are simultaneously managing multiple chronic conditions and have historically been underrepresented in device trials. We offer the following comments and recommendations.

General Support for the RAPID Framework

¹ Alzheimer's Association. (2026). *2026 Alzheimer's Disease Facts and Figures*.

We support CMS's goal of aligning the Food and Drug Administration (FDA) and CMS evidence expectations earlier in the development lifecycle so that a single body of evidence can support both market authorization and coverage. This is particularly important for the mild cognitive impairment and dementia field, where blood tests, digital cognitive assessment tools, and other Breakthrough-designated technologies are increasingly reaching the market. Reducing the historical lag between FDA authorization and Medicare coverage can materially improve access for people living with cognitive impairment, for whom even short delays can mean the loss of a window in which an intervention is most beneficial.

Eligibility Criteria and IVD Exclusion (Section II.C)

We appreciate CMS's clarification of the eligibility criteria for the RAPID pathway. However, we are concerned about the categorical exclusion of in vitro diagnostic (IVD) products, including diagnostic laboratory tests, from the pathway. The dementia field is in the midst of a rapid expansion of blood-based biomarker tests and other diagnostic tools to identify disease that meet FDA's Breakthrough Device criteria and that could meaningfully shorten the diagnostic journey for patients and families with neurodegenerative diseases where time is brain. Excluding this entire category from RAPID's accelerated timeline risks perpetuating the coverage lag, RAPID is otherwise designed to solve, precisely for the technologies most likely to improve early and accurate diagnosis in the Medicare population. CMS suggests continuing diagnostic coverage through Medicare Administrative Contractors (MACs). Pursuing coverage through MACs involves limitations in geography which could adversely impact beneficiaries' equitable and timely access to the latest FDA-authorized diagnostic innovations. We urge CMS to reconsider the blanket IVD exclusion so people have timely access to FDA-authorized diagnostics for neurodegenerative diseases like Alzheimer's disease, frontotemporal dementia, and Lewy body dementia.

Transition process for devices already under an Active Investigational Device Exemption (IDE) (Section II.C)

CMS specifically asks whether it should establish a temporary process allowing devices that have already progressed beyond IDE pre-submission, and are currently being studied under an active IDE, to become eligible for RAPID, and if so, for how long. We support establishing such a process. A number of disease that cause dementia-related devices are currently enrolled in IDE studies that began before RAPID existed as an option; without a transition mechanism, manufacturers who would otherwise have chosen RAPID will be ineligible purely for timing, and Medicare beneficiaries enrolled in those very studies will be denied the accelerated coverage benefit RAPID is meant to provide. We urge CMS to establish a proposed temporary transition process for devices already under an active IDE. A transition process will ensure seniors will gain timely access to innovation caught in the coverage gaps during the transition from the Transitional Coverage for Emerging Technologies (TCET) pathway to RAPID.

CED-Based RAPID NCDs should be narrowly tailored, should not restrict access, and should have a defined, predictable end point

The Alzheimer's Association and AIM have consistently held that Coverage with Evidence Development (CED) should not operate as a barrier to care for people living with a progressive, fatal disease. Where CED is used, it should generate confirmatory evidence in a timeframe and manner that meaningfully informs near-term decisions by policymakers, payers, clinicians, and families, and it should not restrict access for the population the FDA-reviewed evidence supports.

We appreciate the notice's explicit statement that CED is not meant to provide indefinite coverage. The notice describes CED cycles as time-limited, intended to produce the evidence needed to support a full coverage determination under section 1862(a)(1)(A), and complete only once CMS reconsiders the decision and removes the study-participation requirement. We support that principle and ask CMS to operationalize it within the RAPID context.

The notice explains that higher-risk devices are more likely to have remaining evidence gaps at the time of FDA authorization, and therefore more likely to be covered through a RAPID National Coverage Determination (NCD) with CED. Many diseases that cause dementia-related technologies now advancing through the Breakthrough Devices Program, including implantable neurostimulation devices and other higher-risk interventions, are likely to fall into this category. For people with a progressive disease, each day matters. Open-ended or loosely bounded CED cycles are not a neutral default. Every additional month a device remains in conditional, study-contingent coverage is a month in which beneficiaries who are not enrolled in the CED study, or cannot reach it, go without coverage. This is true even though the device has already cleared FDA's bar and shown promising Medicare-relevant outcomes in the qualifying IDE study.

As currently described, RAPID NCDs issued under CED state only that coverage lasts "until reconsidered." Reconsideration is available to any member of the public, but no default timetable applies. We ask CMS to build predictability into this step so that beneficiaries, caregivers, clinicians, and manufacturers are not left to guess when a CED cycle will close. Additionally, we urge CMS to make CED the exception, not the default, and evaluate each product on its own evidence, and to ensure that CED does not restrict access. CMS should commit to initiating a reconsideration promptly once the study reaches its specified endpoint and not wait until a request to reopen before it acts.

RAPID NCD Prioritization (Section II.H)

In the notice, CMS proposes to prioritize RAPID NCDs over non-RAPID NCDs. We understand CMS's rationale for prioritizing RAPID NCDs to meet its same-day posting commitment. However, such prioritization could delay patient access to technologies that can obtain coverage only through the NCD process. Additionally, if CMS finalizes the exclusion of IVDs in the RAPID program, Medicare beneficiaries will have an even longer wait time for access to new and innovative products if non-RAPID NCDs are deprioritized. We therefore ask CMS to commit that prioritizing RAPID NCDs will not extend timelines for non-RAPID NCDs, and to explain how it will allocate resources to that both pathways meet their timeframes.

Conclusion

We appreciate CMS's continued efforts to modernize Medicare's coverage processes for innovative technologies and welcome the opportunity RAPID presents to accelerate access for people living with Alzheimer's and other dementia. We urge CMS to address the IVD exclusion, adopt a transition process for in-flight IDE studies, ensure that qualifying outcomes reflect patient- and caregiver-meaningful benefit, ensure that any use of CED is narrowly tailored, does not restrict access, and has a definite and predictable end point, and mitigate the downstream effects of NCD prioritization as it finalizes this pathway.

Thank you for the opportunity to comment. The Alzheimer's Association and AIM would be glad to serve as a resource to CMS as it considers these important issues and how they relate to individuals living with Alzheimer's and related dementia. Please contact Laura Thornhill, Director, Regulatory Affairs, at 202-638-7042 or lthornhill@alz-aim.org if you have questions or if we can be of additional assistance.

Sincerely,

A handwritten signature in black ink, appearing to read 'RE', with a long horizontal flourish extending to the right.

Robert Egge
Chief Public Policy Officer, Alzheimer's Association
President, Alzheimer's Impact Movement