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PhRMA

October 13, 2026

Mehmet Oz, M.D., M.B.A.
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human 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:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group established 20 years ago and comprising more than 150 institutions from across the health care spectrum to promote the understanding and adoption of personalized medicine concepts, services, and products, thanks the Centers for Medicare & Medicaid Services (CMS) for the opportunity to provide comments on the notice regarding the Regulatory Alignment for Predictable and Immediate Device (RAPID) coverage pathway.¹ PMC applauds your leadership in trying to improve patient access to certain Class II and Class III Breakthrough-designated Devices authorized by the U.S. Food and Drug Administration (FDA). We support the objective of the proposed RAPID pathway to facilitate greater coordination and efficiency between CMS and the FDA; however, we are concerned that the RAPID pathway as proposed could stifle the potential of personalized medicine at a time of rapid progress. PMC's comments urge CMS to remove its exclusion of diagnostic tests from RAPID pathway eligibility, to support RAPID with dedicated resources while strengthening its existing Medicare coverage infrastructure, and to provide a clear transition pathway for innovators experiencing changes resulting from RAPID's development.

PMC defines personalized medicine as an evolving field in which physicians use diagnostic tests and individual details about a person's health to determine which medical treatments will work best for each patient or use medical interventions to alter molecular mechanisms that impact health. By combining data from diagnostic tests with an individual's medical history, circumstances, and values, health care providers can develop targeted treatment and prevention plans with their patients.

Personalized medicine is helping to shift patient and provider experiences away from trial-and-error toward a more streamlined process for making clinical decisions, which will lead to improved patient outcomes, a reduction in unnecessary treatment costs, and better patient and provider satisfaction. PMC and its members are leading the way in personalized medicine and in developing evidence showing how patients and the health care system can benefit from appropriate testing and tailored treatment as soon as possible during their clinical experiences.

Unfortunately for areas of unmet medical need, the newness of a medical device and, in some cases, small patient population sizes can create challenges to gathering in a timely manner the clinical evidence needed for determining coverage and reimbursement for the innovative technologies that make personalized medicine possible. A survey conducted by the Stanford Byers Center for Biodesign found it takes an average of 5 years for medical devices to achieve nationwide coding, coverage, and payment.ⁱⁱ Technologies that receive breakthrough designation and marketing authorization from the FDA provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating diseases or conditions. Encouraging early discussion among CMS, FDA, and innovators could help reduce some of the historic delays between FDA market authorization and Medicare coverage that currently exist. The RAPID pathway represents an important step toward creating a process that allows for these communications to occur. With the improvements recommended below, we believe RAPID could provide timelier coverage for, and thus patient access to, technologies underpinning personalized medicine.

Statement of Neutrality

Many of PMC's members will present their own responses to CMS on the RAPID pathway notice and will actively advocate for those positions. PMC's comments are designed to provide feedback so that the general concept of personalized medicine can advance, and are not intended to adversely impact the ability of individual PMC members, alone or in combination, to pursue separate comments with respect to this proposed pathway or similar coverage modernization initiatives at CMS.

Expanding the scope of RAPID eligible technologies

PMC appreciates the dialogue we have had with CMS for several years as the agency shaped the development of a new coverage pathway for breakthrough devices, including the agency's Transitional Coverage for Emerging Technologies (TCET) pathway and the proposal preceding TCET, the Medicare Coverage of Innovative Technology (MCIT) pathway.^{iii iv} Under MCIT, PMC supported a pathway that would provide coverage to all breakthrough devices immediately upon FDA marketing authorization for up to 4 years. Because timely coverage of breakthrough devices can improve patients' access to these technologies and facilitate the post-market collection of any additional evidence needed to inform future coverage decisions, PMC still maintains that a voluntary pathway providing immediate coverage after FDA marketing authorization is the most expeditious approach. Such a pathway would have a transformational effect on the coverage environment for patients and manufacturers.

Personalized medicines have now accounted for at least a quarter of new drug approvals for each of the last 10 years.^v Diagnostic tests play a critical role in helping patients and providers evaluate their treatment options, allow for earlier disease detection, and in some cases reduce the cost and complexity of care. Whereas MCIT would have applied to all devices that receive breakthrough designation, CMS proposes to exclude in vitro diagnostics (IVDs) from RAPID. Specifically, the RAPID pathway notice states that "IVD products will not be accepted into the RAPID coverage pathway." CMS describes IVDs as a highly specific area of coverage policy development and states that it has historically delegated review of many such products to specialized Medicare Administrative Contractors (MACs). The notice further states that most coverage determinations for breakthrough-designated IVDs should continue through existing MAC pathways. CMS notes that in cases where CMS and a manufacturer agree that a National Coverage Determination (NCD) is appropriate for an IVD, the manufacturer may still submit an NCD request through the conventional process (i.e., not through RAPID). We believe the proposed exclusion of diagnostics does not align with CMS' goals for the RAPID pathway and that the agency's own practices do not support delegating Breakthrough-designated IVD coverage decisions to the MACs. The agency has issued several NCDs that pertain to IVDs. Two technologies have completed FDA-CMS Parallel Review, a program created expressly to shorten the interval

between FDA authorization and national coverage. Both were IVDs – a colon cancer screening test^{vi} covered under NCD 210.3^{vii} and a next-generation sequencing-based IVD^{viii} covered under NCD 90.2^{ix}. Earlier this year, CMS updated NCD 210.3 and recently added NCD 90.2 to the reconsideration waitlist. These actions are difficult to align with the rationale used to exclude IVDs from the RAPID coverage pathway.

PMC’s membership includes diagnostics companies as well as clinical and academic laboratories whose innovations are essential to personalized medicine. For diagnostic tests underpinning personalized medicine, the lack of clarity and consistency of payer coverage policies within and between states and across clinical areas creates barriers for providers in adapting to new requirements, practices, and policies associated with advances in, for example, genomic testing.^x These technologies are often developed by teams that face the same coverage uncertainty as devices. The purpose of RAPID is to facilitate more expeditious national Medicare coverage for a unique class of devices that are likely to be highly relevant to the needs of the Medicare population. Excluding diagnostics from RAPID sends a signal that some of the most transformative technologies must continue navigating costly and fragmented processes. MAC-by-MAC coverage has produced multi-year delays and geographic variation in access – precisely the problems RAPID is intended to solve. These delays are structural rather than incidental. The MoDX program governs coverage of molecular diagnostics that are central to personalized medicine, and its policies apply across MACs representing more than half of the states. Its current backlog in Local Coverage Determinations (LCDs) produces multi-year delays, during which Medicare beneficiaries go without access to advances in care. Compounding this problem, MoDX does not allow tests to undergo the technical assessment (TA) process in the absence of an applicable LCD and as a result, there is no interim reimbursement mechanism analogous to the claim-by-claim adjudication that occurs in other circumstances and in other MAC jurisdictions. This results in multiple years of non-coverage for new, clinically meaningful tests if they do not fit under an existing LCD.

Medicare beneficiaries stand to benefit equally from diagnostic tests that receive breakthrough designation from FDA and from expedited national coverage under RAPID. In fact, CMS stated in the preceding MCIT proposal that diagnostic tests that receive breakthrough designation and fall within an existing benefit category would be eligible for expedited coverage. In addition, for several categories of diagnostics, the NCD process is not merely customary, but required, making delegation to MACs impossible. Coverage of additional preventive services that fall outside the regulatory definition of “preventive services” – a category that can include IVDs – may be added only through the NCD process following a recommendation from the U.S. Preventive Services Task Force.^{xi} Coverage for screening IVDs generally require an NCD rather than an LCD, and for NCD reconsiderations that pertain to IVDs, the national policy itself must be revised to expand coverage. Reliance on LCDs can impose undue burden by prolonging the coverage process and requiring multiple determinations to achieve national coverage, ultimately resulting in fragmented patient access based on geographic locality rather than whether the device satisfies applicable performance and medical necessity criteria. Given the foundational role of diagnostic testing to personalized medicine and the importance of diagnostics to patient care, we believe limiting diagnostic tests’ eligibility for RAPID significantly hinders the pathway’s ability to improve Medicare beneficiary access to important emerging technologies. **PMC strongly urges CMS to reconsider the proposed exclusion of diagnostics and specify that diagnostic tests that receive breakthrough designation from FDA are appropriate candidates for the RAPID pathway.** If necessary, the agency should create a tailored track or phased approach that clarifies evidence expectations and coverage timelines for diagnostics under RAPID.

Facilitating timelier Medicare coverage for more technologies

PMC strongly supports CMS’s goal of reducing the prolonged gap between FDA authorization and Medicare coverage for novel technologies; however, we are concerned about the effect that prioritizing RAPID NCDs could have on new NCD requests and reconsiderations for technologies that are not eligible for RAPID. Early FDA-CMS coordination, same-day proposed national coverage determinations, and greater transparency would be meaningful improvements to benefit patients, however, RAPID requires dedicated, stable coverage

resources to be successful. CMS estimates that approximately 40 devices would qualify initially, with about 20 more subsequently, and the agency acknowledges that it cannot run TCET and RAPID simultaneously. Prioritizing RAPID ahead of all other NCDs, including those on the existing NCD waitlist – where some devices have been pending for 5 or more years – risks widening disparities in patient access. If RAPID is supported by diverting resources from existing coverage work, the pathway may accelerate access for a narrow set of technologies while prolonging delays for others. Companies that do not qualify for RAPID could find themselves further back in the queue. This concern is compounded by the pathway’s own design. Because a device is ineligible for RAPID if it is already the subject of a controlling NCD, a categorical preference for RAPID NCDs would push every reconsideration behind every new RAPID request. Reconsideration is often the only means of lifting an outdated national non-coverage policy that current evidence no longer supports and can therefore carry urgent consequences for beneficiaries. **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. PMC urges CMS to support RAPID with dedicated resources while strengthening its existing coverage infrastructure, including regular reporting on the agency’s coverage capacity and timelines for coverage of RAPID and non-RAPID technologies.**

Furthermore, a coverage decision is only meaningful if beneficiaries can receive the technology. Clear transition mechanisms are necessary to navigate changes experienced as a result of the RAPID pathway’s development. For example, TCET is paused indefinitely and the RAPID pathway notice does not specify how TCET participants that built evidence programs around TCET can obtain expedited coverage consideration under RAPID. **We encourage CMS to establish a transition track into RAPID, a grandfathering mechanism, or a separate expedited pathway recognizing prior CMS engagement.** Importantly, physicians and facilities also need to be paid appropriately for offering services utilizing breakthrough technologies. PMC provided separate comments to CMS on its hospital inpatient prospective payment system (IPPS) and outpatient prospective payment system (OPPS) proposed rules for CY 2027.^{xii xiii} These proposed rules significantly shifted policies for add-on and pass-through payments for breakthrough devices that have helped bridge the gap between FDA authorization and early provider adoption of new and innovative technologies. CMS announced that the policy shifts to IPPS and OPPS were made to accommodate RAPID; however, they limited a critical pathway providers relied on for securing additional Medicare reimbursement for providing patients with access to breakthrough devices. **Given RAPID’s limited scope, we again urge CMS to reverse its IPPS and OPPS policies requiring breakthrough technologies to demonstrate substantial clinical improvement relative to existing technologies. Without this reversal the evidentiary burden for innovations that are not eligible for RAPID will be greater and providers will be required to somehow absorb the increased costs of providing patients with the cutting-edge care.**

Finally, coverage and payment for a new technology requires appropriate coding to describe it. The RAPID pathway notice outlines an accelerated coverage decision but does not address how a covered device or the associated clinical service will be reported on a claim. TCET was designed to coordinate benefit category determination, coding, and payment review together, and CMS should consider preserving that coordination under RAPID. A final NCD issued 60 to 90 days after FDA market authorization delivers limited practical benefit if physicians and facilities have no code to report the service. That result could reintroduce additional unpredictability at the claims level that RAPID is intended to remove. **PMC encourages CMS to explore coding solutions for technologies moving through the RAPID pathway. Early coordination on coding and payment would help ensure that accelerated coverage translates into more predictable access for Medicare beneficiaries and providers.**

Conclusion

PMC appreciates CMS’ attempts to foster innovation and ensure Medicare beneficiaries have access to breakthroughs that may improve their health outcomes. We look forward to working with you and your

colleagues at CMS to ensure the Medicare program facilitates patient access to personalized medicine and the emerging technologies enabling this approach to care. If you have any questions about the content of this letter, please contact me at 202-499-0986 or cbens@personalizedmedicinecoalition.org.
Sincerely,



Cynthia A. Bens
Senior Vice President, Public Policy

ⁱ Centers for Medicare & Medicaid Services. Medicare Program; Regulatory Alignment for Predictable and Immediate Device (RAPID) Coverage Pathway (CMS-3487-NC). August 11, 2026. <https://www.regulations.gov/document/CMS-2026-2674-0001>. (accessed October 6, 2026).

ⁱⁱ Stanford Byers Center for Biodesign and Duke-Margolis Center for Health Policy. *The Need for Transitional Coverage for Emerging Technologies*. March 28, 2022. https://healthpolicy.duke.edu/sites/default/files/2022-04/TCET%20Webinar_Slides%203.28.22.pdf. (accessed October 6, 2026).

ⁱⁱⁱ Personalized Medicine Coalition. Comment letter on Medicare Transitional Coverage for Emerging Technologies (CMS-3421-NC) and Coverage with Evidence Development Proposed Guidance Document. August 23, 2023. <https://www.personalizedmedicinecoalition.org/wp-content/uploads/2023/08/comment-letter-3.pdf> (accessed October 6, 2026).

^{iv} Personalized Medicine Coalition. Comment Letter on Medicare Coverage of Innovative Technology (MCIT) and Definition of “Reasonable and Necessary” (CMS-3372-P2). October 15, 2021. https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PMC_Comments_MCIT-Proposed-Repeal.pdf. (accessed October 6, 2026).

^v Personalized Medicine Coalition. Personalized Medicine at FDA: The Scope and Significance of Progress in 2025. May 2026. https://www.personalizedmedicinecoalition.org/wpcontent/uploads/2025/06/PMC_PM_at_FDA_The_Scope_Significance_of_Progress_2024_1.pdf (accessed October 6, 2026).

^{vi} U.S. Food and Drug Administration. Pre-Market Approval Cologuard. Decision Date August 11, 2014. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=p130017>. (accessed October 12, 2026).

^{vii} Centers for Medicare & Medicaid Services. National Coverage Determination Colorectal Cancer Screening Tests. Effective Date June 8, 2026. <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=281>. (accessed October 12, 2026).

^{viii} U.S. Food and Drug Administration. Pre-Market Approval FoundationOne CDx. Decision Date November 30, 2017. <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=p170019>. (accessed October 12, 2026).

^{ix} Centers for Medicare & Medicaid Services. National Coverage Determination Next Generation Sequencing (NGS). Effective Date of this Version January 27, 2020. <https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=372>. (accessed October 12, 2026).

^x Personalized Medicine Coalition. Understanding Genomic Testing Utilization and Coverage in the US. June 2020. https://www.personalizedmedicinecoalition.org/Userfiles/PMCCorporate/file/PMC_Understanding_Genomic_Testing_Utilization_and_Coverage_in_the_US2.pdf (accessed October 6, 2026).

^{xi} 42 CFR 410.64. Code of Federal Regulations Title 42 Chapter IV Subchapter B Part 410 Subpart B § 410.64. August 29, 1997. <https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-410/subpart-B/section-410.64> (accessed October 12, 2026).

^{xii} Personalized Medicine Coalition. Comment letter on Medicare Program; Hospital Inpatient Prospective Payment Systems for Acute Care Hospitals and the Long-Term Care Hospital Prospective Payment System and Policy Changes and Fiscal Year 2027 Rates; Requirements for Quality Programs; and Other Policy Changes (CMS-1849-P) Proposed Rule. June 9, 2026. https://www.personalizedmedicinecoalition.org/wp-content/uploads/2026/06/PMC_IPPS_FY_2027_06092026-FINAL.pdf (accessed October 6, 2026).

^{xiii} Personalized Medicine Coalition. Comment letter on Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems; and Quality Reporting Programs; including the Hospital Outpatient Quality Reporting Program and Ambulatory Surgical Center Quality Program Proposed Rule for Calendar Year 2027 (CMS-1850-P). August 31, 2026. <https://www.personalizedmedicinecoalition.org/wp-content/uploads/2026/08/PMC-Comments-to-CMS-on-2027-OPPS-Proposed-Rule-FINAL-08312026.pdf> (accessed October 6, 2026).