



August 28, 2023

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Blvd.
Baltimore, MD 212441

Re: Medicare Program; Transitional Coverage for Emerging Technologies (CMS-3421-NC) and Coverage with Evidence Development Proposed Guidance Document

Dear Administrator Brooks-LaSure:

The Personalized Medicine Coalition (PMC), a multi-stakeholder group comprising more than 200 institutions from across the health care spectrum, appreciates the Centers for Medicare & Medicaid Services (CMS)' release of the proposed Transitional Coverage for Emerging Technologies (TCET) pathway.¹ We understand that the TCET pathway is an effort by CMS to expedite patient access to medical products designated as breakthrough devices and authorized by the U.S. Food and Drug Administration (FDA). We are concerned, however, that the limited number and scope of technologies eligible for the proposed TCET pathway could stifle the potential of personalized medicine to improve patient care at a time of rapid progress. We therefore urge CMS to accept more than five TCET pathway candidates per year and remove its limitation excluding the majority of diagnostic tests from eligibility. PMC's comments that follow also include suggestions on appropriate limits on the use of Coverage with Evidence Development (CED) to mitigate challenges to patient access from continued evidence collection.

PMC defines personalized medicine as an evolving field in which physicians use diagnostic tests 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 the 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's members are leading the way in personalized medicine and recommend that patients who may benefit from this approach undergo appropriate testing and tailored treatment as soon as possible during their clinical experiences.

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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 study by the Stanford Byers Center for Biodesign found it takes an average of five years for medical devices to achieve nationwide coding, coverage, and payment.ⁱⁱ Devices 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.

A new Medicare coverage pathway like TCET has the potential to mitigate the upfront evidence burden required to meet the current coverage standard while prioritizing patient access to tools that promise to address unmet medical needs. With the improvements recommended below, we believe TCET could provide timelier coverage for, and thus patient access to, certain diagnostic and other enabling technologies underpinning personalized medicine. As indicated above, our comments also address the implications of CMS' proposed guidance on CED.ⁱⁱⁱ

Statement of Neutrality

Many of PMC's members will present their own responses to CMS' proposed procedural notice on TCET, in addition to CMS' proposed guidance document on CED, 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 impact adversely the ability of individual PMC members, alone or in combination, to pursue separate comments with respect to these proposals or similar coverage modernization initiatives at CMS.

I.) Facilitating timelier Medicare coverage of more breakthrough devices

PMC appreciates the dialogue we have had with CMS for several years as the agency shaped the development of a new and distinct coverage pathway for breakthrough devices, including the agency's proposal preceding TCET, the Medicare Coverage of Innovative Technology (MCIT) pathway.^{iv} Under MCIT, PMC supported a pathway that would provide coverage to all breakthrough devices immediately upon FDA marketing authorization for up to four 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.

Under TCET, CMS proposes that manufacturers voluntarily submit a nomination for their technology to participate in the new coverage pathway approximately twelve months prior to an anticipated FDA decision on their submission as determined by the manufacturer. Unlike MCIT, TCET would provide coverage through a National Coverage Determination (NCD) for selected breakthrough device candidates within six months after FDA market authorization. The NCD would facilitate the generation of evidence with reconsideration in three to five years based on the date specified in an Evidence Development Plan (EDP). If CMS does proceed with finalizing this proposal, participation in **TCET should continue to be voluntary for breakthrough device manufacturers.** In Section D(2)(c), CMS seeks comments on whether coverage of similar devices through a TCET NCD would "establish a level playing field and

avoid delays in access that would occur if a separate NCD were required to ensure coverage,” rather than extending “privileged coverage status” only to the first device that achieves FDA market authorization. CMS proposes that similar devices be subject to the same coverage conditions, including a requirement to propose an EDP. **Recognizing an opportunity to avoid confusing providers and deterring clinical adoption, PMC would endorse this coverage-to-class approach to avoid inconsistent coverage policies for similar devices.**

We also believe it is important for TCET to foster alignment between CMS and FDA on evidence needs to help minimize the burden of post-market evidence collection on device manufacturers, clinicians, and patients. **In general, we appreciate CMS’ focus in TCET on opportunities to work with both manufacturers and FDA on the development and finalization of an EDP that meets both CMS’ evidence development and FDA’s post-market requirements [Section D(1)].**

CMS proposes that candidates for TCET must be FDA-designated breakthrough devices determined to fall within a Medicare benefit category. Some breakthrough technologies, like tests used for preventive screening, novel digital health technologies, and artificial intelligence applications may not fall within a defined Medicare benefit category. CMS states it can only accept up to five TCET candidates annually “at present” due to resource constraints. With more than 19 breakthrough devices receiving FDA marketing authorization in 2022 and 15 in 2021,^v PMC is concerned that CMS’ initial cap of up to five candidates is too limited for the pathway to meaningfully improve beneficiary access to emerging personalized medicine technologies. Furthermore, CMS’ proposal to prioritize innovative medical devices based on their potential impact on the “greatest number” of Medicare beneficiaries creates challenges. For example, accepting applications on a rolling basis, as outlined in Section D(1)(b), would make it infeasible for CMS to compare the potential number of beneficiaries impacted by a technology across all applications received.

PMC acknowledges CMS’ resource constraints, but we urge CMS to increase the number of candidates accepted annually and to adopt a flexible approach in making benefit category determinations including all benefit categories under Medicare Parts A and B for consideration. We believe these changes are necessary to maximize the impact of this pathway. CMS should continue working with stakeholders to clarify how it can better prioritize candidate applications to serve those patients in need of more effective treatment for or diagnosis of life-threatening, irreversibly debilitating diseases or conditions.

II.) Expanding the TCET pathway to include diagnostics

Whereas MCIT would have applied to all devices that receive breakthrough designation, CMS proposes to exclude the majority of diagnostics from TCET. Specifically, CMS states in Section C that the “majority of coverage determinations for diagnostic tests granted Breakthrough Designation should continue to be determined by [Medicare Administrative Contractors, or MACs] through existing pathways” because CMS has historically delegated review of many of these tests to specialized MACs and because diagnostic laboratory tests involve “highly specific areas of coverage policy development.” We believe the proposed exclusion of diagnostics does not align with CMS’ goals for the TCET pathway. The scope of diagnostics’ exclusion from TCET is also unclear. Although CMS proposes to defer the “majority” of coverage

determinations to MACs, CMS does not articulate any criteria for determining which diagnostic tests would or would not be eligible for consideration under TCET.

According to CMS, the purpose of TCET 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. 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.^{vi}

Medicare beneficiaries stand to benefit equally from diagnostic tests that receive breakthrough designation from FDA and from more rapid national coverage under TCET. 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. 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 TCET 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 TCET pathway. If CMS decides to retain its proposed exclusion for the "majority" of diagnostics, we ask CMS to clearly define and publish the criteria it would use to decide whether certain diagnostic tests are eligible for the TCET pathway.**

III.) Mitigating challenges associated with the use of CED

To provide transitional coverage for breakthrough devices during post-market evidence generation, CMS proposes to leverage NCDs utilizing its existing CED mechanism. CMS uses CED to cover promising technologies with a limited evidence base on the condition that they are furnished to Medicare beneficiaries in a setting of approved clinical studies or ongoing data collection. Although this mechanism has been used for nearly two decades, it has been criticized for the lack of transparency in how it is applied and because CMS can require ongoing evidence collection without any specified time frame for retiring these requirements. Under TCET, CMS anticipates a transitional coverage period of three to five years as evidence is generated and proposes reconsideration of the related NCDs on a date specified in EDPs. **PMC believes specifying a date in the EDP to facilitate time limited CED under TCET may resolve some of the uncertainties created by CMS' historical use of CED. We also believe CMS should build flexibility into the TCET pathway for manufacturers to work with CMS to either speed up or slow down the date of this review based on the progress/challenges with evidence collection.**

CED has also been criticized for creating barriers that prevent wider access to medical breakthroughs, limiting data for research, and ultimately hampering innovation.^{vii} In some instances, for example, CED's questions may be too broad to be answerable within the context of certain CED studies. Patients also do not have a way to directly engage with the agency on the choice to apply CED requirements. **In the process of creating and conducting an EDP, PMC encourages CMS to work with manufacturers to consider and mitigate barriers that may arise in applying CED to ensure CED's questions are appropriate to the technology and answerable. CMS should also systematically consult patients on**

how CED might impact access to the technology, their health and outcomes (e.g., from delayed access to care), and caregiver experiences. If CMS determines that it will utilize CED, it should consult patients on study design protocols and outcomes of relevance to transitioning to full coverage for the technology.

In conjunction with the notice for comment on TCET, CMS also proposed updated guidance for CED to facilitate a broader range of fit-for-purpose study designs. CMS' intention in revising the guidance, last updated in 2014, is to move towards a more transparent and predictable evidence-generation framework to facilitate Medicare coverage. Although we appreciate CMS' focus on fit-for-purpose evidence development for TCET, PMC believes the draft guidance on CED does not adequately address existing problems with the mechanism. For example, even though CMS acknowledges CED should "not last indefinitely," CMS only suggests sponsors communicate interim results and CED be time-limited "if evidence supports a favorable coverage." **As with TCET, we believe incorporating flexible time-limits for the conclusion of CED study requirements and incorporating processes for CMS to work with manufactures to ensure CED's questions are appropriate and answerable to the technology would help CMS move towards a more transparent and predictable approach for evidence development.**

PMC is also concerned that the proposed CED guidance includes language that would further expand the applicability of CED to drugs and biologicals where there is no precedent for CED, thereby complicating existing coverage policies. As proposed, CMS' revised CED guidance would create new coverage standards for drugs that receive accelerated approval using surrogate endpoints and for the generalizability of evidence on outcomes data for drugs to the Medicare population. Medicare coverage policy for drugs and biologicals has been effective in ensuring Medicare beneficiaries have access to innovative drugs and biologicals without creating undue burden on the Medicare program itself or manufacturers of drugs and biologicals. Unlike drugs and biologicals, devices face greater coverage scrutiny and do not have the same statutory protections. **In keeping with CMS' stated intention to use CED to generally expand access to medical technologies, we urge CMS to refrain from expanding the scope of CED for drugs and biologicals and to focus instead on making improvements to CED limited to devices.** Implementing TCET and related policy changes to establish this pathway, such as to CED, should not extend to changing coverage policies for drugs and biologicals, which could adversely impact patient access to personalized medicine where the path to coverage may already be smooth and well-understood.

VI.) 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 PMC's comments, please contact me at 202-499-0986 or cbens@personalizedmedicinecoalition.org, or David Davenport, PMC's Manager of Public and Science Policy, at ddavenport@personalizedmedicinecoalition.org or 804-291-8572.

Sincerely,



Cynthia A. Bens
Senior Vice President, Public Policy

ⁱ Centers for Medicare & Medicaid Services. *Medicare Program; Transitional Coverage for Emerging Technologies*. June 27, 2023. <https://www.federalregister.gov/documents/2023/06/27/2023-13544/medicare-program-transitional-coverage-for-emerging-technologies>

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 May 22, 2023.)

ⁱⁱⁱ Centers for Medicare & Medicaid Services. *Coverage with Evidence Development Proposed Guidance Document*. June 22, 2023. <https://www.cms.gov/medicare-coverage-database/view/medicare-coverage-document.aspx?mcdid=35#:~:text=CED%20will%20require%20the%20generation,%2C%20biological%20products%2C%20and%20devices>.

^{iv} Personalized Medicine Coalition. *Comment Letter on Medicare Program; 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

^v U.S. Food and Drug Administration. *Breakthrough Devices Program*. <https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program>. (Accessed August 22, 2023.)

^{vi} Personalized Medicine Coalition. *Understanding Genomic Testing Utilization and Coverage in the US*. June 2020. https://www.personalizedmedicinecoalition.org/Userfiles/PMC-Corporate/file/PMC_Understanding_Genomic_Testing_Utilization_and_Coverage_in_the_US2.pdf

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^{vii} Grogan, Joe. “Medicare’s ‘Coverage With Evidence Development’: A Barrier To Patient Access And Innovation.” *Health Affairs Forefront*. May 1, 2023. <https://www.healthaffairs.org/content/forefront/medicare-s-coverage-evidence-development-policy-barrier-patient-access-and-innovation>. (Accessed May 22, 2023.)