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August 28, 2023

Via Electronic Submission

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS–3421–NC
P.O. Box 8013
Baltimore, MD 21244–8013

RE: Transitional Coverage for Emerging Technologies (TCET) (CMS-3421-NC)

Dear Administrator Brooks-LaSure,

The Medical Device Manufacturers Association (MDMA), a national trade association representing the innovative sector of the medical device market, is submitting this letter in response to the notice and request for comment from the Centers for Medicare & Medicaid Services (CMS) establishing a subregulatory Transitional Coverage for Emerging Technologies (TCET) program (the "TCET Program") as part of the Coverage with Evidence Development (CED) pathway and national coverage determination (NCD) process (the "TCET Notice").[1]

For more than 30 years MDMA has advocated for policies that promote the development of innovative medical technologies that improve healthcare delivery and patient outcomes. MDMA's membership is broad and diverse, ranging from small start-ups to multinational medical device companies. It is a long and risky venture to develop novel medical devices and diagnostics, but medical technology innovation is essential to improving outcomes and quality of life for patients, including Medicare beneficiaries.

Introduction and Summary

We appreciate CMS' commitment to fostering innovation and accelerating access to novel medical devices and diagnostics for Medicare beneficiaries and their physicians, especially when other treatment options are unavailable or inadequate. Progress in improving the existing Medicare coverage pathways has been made over the past two decades through collaborative bipartisan

[1] Centers for Medicare & Medicaid Services, Medicare Program: Transitional Coverage for Emerging Technologies, 88 Fed. Reg. 41,633 (June 27, 2023).

efforts with Congress and successive administrations, the medical device sector and other stakeholders. Still, for a meaningful number of novel technologies, a significant amount of time elapses between marketing authorization by the U.S. Food and Drug Administration (FDA) and the issuance of coverage, coding and payment policies providing access for Medicare beneficiaries. Recent peer reviewed research from the Stanford Byers Center for Biodesign found that only 44% of novel technologies authorized by the FDA between 2016 and 2019 achieved nominal Medicare coverage by the end of 2022, and the median time to achieve this nominal coverage was actually 5.7 years.[2]

In addition to delaying access for beneficiaries and their physicians to new therapies and diagnostic technologies that are appropriate for their care—and, importantly, which the FDA has determined meet the standards for safety and effectiveness required for marketing in the U.S.—the uncertainty and unpredictability associated with Medicare coverage of novel medical technologies also acts as a disincentive to investment in medical technology development, as evidenced by findings from a previous peer-reviewed Stanford Biodesign study.[3]

Current Medicare coverage pathways have been insufficient to provide either timely access to new medical advances for Medicare beneficiaries whose medical needs are not adequately met by existing therapies or the predictability needed to support investment in innovative technologies. Recognizing stakeholder concerns about delays in access and the environment for medical technology innovation, CMS promulgated the Medicare Coverage for Innovative Medical Technologies (MCIT) final rule in 2020 and 2021.[4] That rule, which was similar to bipartisan legislation introduced in Congress going back to at least 2016,[5] would have granted temporary national Medicare coverage to novel technologies designated by the FDA as "breakthrough devices" for a period of four years following FDA marketing authorization. CMS repealed the MCIT rule prior to implementation after reconsidering several specific aspects of the rule, including the automatic extension of Medicare coverage based on FDA breakthrough status without a CMS determination that the technology is "reasonable and necessary" under the Act and the lack of a requirement that manufacturers collect evidence on real world use in the Medicare

[2] Sexton ZA, Perl JR, Saul HR, et al. Time From Authorization by the U.S. Food and Drug Administration to Medicare Coverage for Novel Technologies. *JAMA Health Forum.* 2023;4(8):e232260. doi:10.1001/jamahealthforum.2023.2260.

[3] Ruggles SW, Perl JR, Sexton ZA, Schulman K, Makower J. The Need for Accelerated Medicare Coverage of Innovative Technologies: Impact on Patient Access and the Innovation Ecosystem. *Health Management, Policy and Innovation* (www.HMPI.org). 2022; 7(1). ("For investors, the majority of investor respondents consider the reimbursement pathway to be the highest-impact external risk factor to an investment. Consequently, the uncertainty of the timelines to achieve coding, coverage, and payment create a much higher bar for investment in important clinical areas and a strong disincentive for investment in breakthrough products. As a result, these delays, and the lack of potential payment for breakthrough technologies, have a direct impact on patients who must go without leading-edge interventions.")

[4] Centers for Medicare & Medicaid Services, Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary", 86 Fed. Reg. 2,987 (Jan. 14, 2021) (final rule); Centers for Medicare & Medicaid Services, Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary", 85 Fed. Reg. 54,327 (Sep. 1, 2020) (proposed rule).

[5] *See, e.g.,* H.R. 5333, Ensuring Patient Access to Critical Breakthrough Products Act of 2019 (116th Congress); H.R. 5997, Ensuring Patient Access to Critical Breakthrough Products Act of 2019 (115th Congress); and H.R. 5009, Ensuring Patient Access to Critical Breakthrough Products Act of 2016 (114th Congress).

population during the temporary coverage period to help inform the development of permanent coverage policy.[6]

We were disappointed when CMS repealed the MCIT rule because we knew the repeal would result in a significant delay in implementing measures to speed access for Medicare beneficiaries to breakthrough innovations that promise improvement in their care. Despite our disappointment, in our comment letter responding to the proposed repeal, we acknowledged the operational challenges and other concerns raised by CMS.[7] We also noted our belief that CMS did not appear to be stepping back from the goals that prompted the development of the MCIT rule, and we expressed our strong commitment to working with the agency to develop a new proposal that would address those concerns, including developing a process and criteria for CMS to determine eligibility for transitional coverage, ensuring adequate engagement between the manufacturer of an eligible device and CMS prior to FDA market authorization, and ensuring the development of additional evidence relevant to the Medicare population during the transitional coverage period.

There have been at least six formal opportunities for the public to provide input on the MCIT rule and the development of the TCET Notice.[8] The overwhelming majority of commenters—including patient groups, research advocates, and providers in addition to medical technology innovators and investors—support a broad and robust program for accelerating coverage determinations on important emerging technologies. We believe that proposals to replace MCIT and otherwise improve Medicare coverage pathways should be evaluated with a simple question: would adoption of the policy likely result in a meaningful, positive impact on patient access to novel technologies and reduce the uncertainty around current Medicare reimbursement pathways that discourages investment in medical technology innovation?[9]

In the TCET Notice, CMS has proposed a number of reforms to enhance the existing CED pathway, many of which would be improvements. First and foremost, ***MDMA reiterates its strong support for the CED pathway.*** We believe that CED represents an appropriate use of the agency's authority under section 1862(a)(1)(E) of the Act[10]—*i.e.*, allowing CMS to cover an item or service provided in the context of a clinical research study conducted under separate authority granted to the Agency for Healthcare Research and Quality (AHRQ), even when CMS is unable to determine

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[6] Centers for Medicare & Medicaid Services, Medicare Program; Medicare Coverage of Innovative Technology (MCIT) and Definition of "Reasonable and Necessary", 86 Fed. Reg. 62,944 (Nov. 15, 2021). *See also*

[7] Letter from Mark Leahey, President and CEO, Medical Device Manufacturers Association, to Chiquita Brooks-LaSure, Administrator, Centers for Medicare & Medicaid Services, October 15, 2021, https://www.regulations.gov/comment/CMS-2020-0098-0643

[8] Opportunities for formal comment during the promulgation of MCIT included the proposed rule, interim final rule delaying the effective date, and proposed repeal. *Supra* notes 4 and 6. Opportunities since the MCIT repeal have included two CMS "listening sessions" prior to the issuance of the TCET Notice and a recent "stakeholder meeting" focused on the TCET Notice. Transcripts from the listening sessions and stakeholder meeting are available at https://www.cms.gov/outreach-education/partner-resources/cms-national-stakeholder-calls.

[9] *See* Tunis S, Neumann P, Chambers J, Jenkins N. Medicare Coverage of Emerging Technologies: Challenges and Opportunities. October 2022. Tufts Center for the Evaluation of Value and Risk in Health. https://cevr.tuftsmedicalcenter.org/publications/medicare-coverage-of-emerging-technologies-challenges-and-opportunities. ("As stakeholders consider alternative approaches that exclude an automatic link between FDA approval and coverage, policy makers need to reflect on whether proposed changes will provide sufficient confidence and certainty for innovators and investors to develop novel technologies for which the pathway to reimbursement is not clearly defined.")

[10] 42 U.S.C. § 1395y(a)(1)(E).

that the item or service is "reasonable and necessary for the treatment of illness or injury or to improve the functioning of a malformed body member."[11] Collaboration between CMS and AHRQ on CED policies permits access to such items and services for some beneficiaries and their physicians, with appropriate beneficiary protections, and also supports collection of additional clinical evidence sufficient to support a future "reasonable and necessary" coverage determination. It provides an alternative to a finding of noncoverage, which would foreclose such access and hamper ongoing development of clinical evidence within the Medicare population.

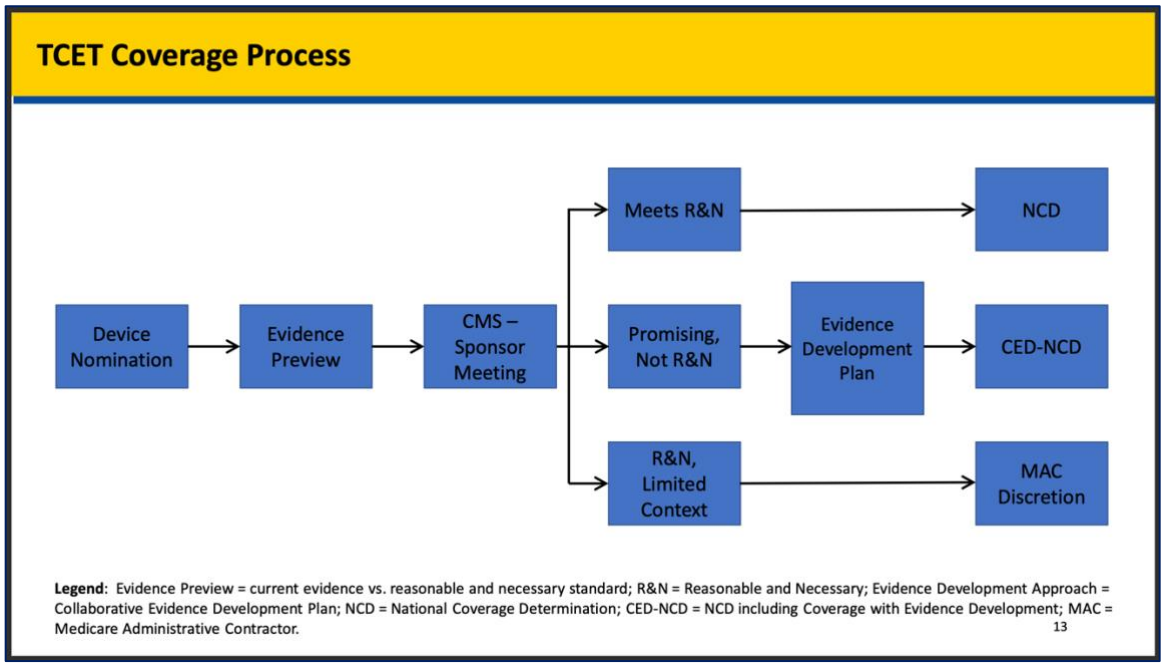
MDMA appreciates the work that CMS has put into developing a proposal to accelerate national coverage determinations (NCDs) that are made under the CED pathway for certain devices. Part I of this comment letter includes specific feedback and recommendations for improvement of that proposal, which we refer to as the "TCET-CED Pathway." ***We believe that the proposed TCET-CED Pathway, with the improvements and clarifications recommended in this letter, would represent a positive, incremental step toward achieving the objectives underlying TCET and we urge CMS to move forward quickly with its implementation.*** Anything that reduces the "valley of death" that exists between receiving FDA marketing authorization for novel medical technologies and establishing Medicare beneficiary access with appropriate coverage and reimbursement will improve the climate for investments in the cures, therapies and diagnostics of tomorrow, and MDMA looks forward to continuing to work with CMS to improve CED.

While we support moving forward with finalizing the TCET-CED Pathway, we also strongly believe that the TCET Notice does not leverage the full range of CMS coverage authorities to meaningfully accelerate beneficiary access and foster innovation. To achieve such impact and create the robust TCET program envisioned by stakeholders, CMS should build on this Notice by creating a new coverage pathway separate from CED for appropriate technologies.

The limited scope of the TCET Notice is clearly illustrated by a graphic that CMS officials have used frequently to describe the proposed TCET coverage process. (See Fig. 1.) That graphic, which is streamlined but otherwise consistent with the proposal outlined in the TCET Notice, divides items and services into three categories: first, those that clearly meet the reasonable and necessary criteria under general conditions of use and are therefore appropriate subjects for an NCD; second, those that are promising, but for which there are gaps in evidence relevant to the Medicare population that are significant enough that it does not meet the "reasonable and necessary" standard, and thus can only be covered under CED; and, finally, those that are reasonable and necessary, but for which there is "limited context", meaning that additional data from real world use of the technology is needed to formulate a long term national coverage policy.

[11] Id. § 1395y(a)(1)(A).

Fig. 1. CMS graphic illustrating the TCET coverage process.[12]



The graphic shows the proposed nomination process, Evidence Preview (EP), CMS-sponsor engagement, creation of an Evidence Development Plan (EDP), and potential provision of coverage through an NCD-CED policy. What is notable, however, is that CMS has not proposed to take any steps to accelerate access to technologies in the "R&N, Limited Context" category. CMS will continue to delegate coverage decision making on items and services in this category to its local Medicare Administrative Contractors (MACs). Unfortunately, many of these technologies, despite meeting the "reasonable and necessary" threshold, languish for years as manufacturers (especially small, innovative companies that comprise the majority of MDMA's membership[13]) struggle to navigate the opaque, inconsistent and undefined procedures that the MACs use to make coverage decisions.

The TCET Notice does not address the "R&N, Limited Context" category, as the proposal is built on the CED pathway that is intended only for technologies for which evidence is insufficient to support a reasonable and necessary determination for any delineable portion of the Medicare population. ***CMS could further (and likely more meaningfully) improve timely beneficiary and physician access to promising new technologies by creating a similar but separate pathway for technologies that meet the reasonable and necessary threshold, but with limited context on real world use in the Medicare population.*** Adopting a temporary, transitional national coverage policy for important new technologies in this category would have dual benefits: accelerating

[12] Steve Farmer, MD, PhD, Chief Strategy Officer, Coverage and Analysis Group, Center for Clinical Standards and Quality, Centers for Medicare and Medicaid Services. Transitional Coverage for Emerging Technologies (TCET). Presentation to Duke Margolis Center for Health Policy, Aug. 3, 2023.

[13] *See* Sexton et al., *supra* note 2, at 6. ("This study also found considerable variability in time to coverage milestone achievement. Among 3 hypothesized factors for such variability, manufacturer size showed the most striking difference and suggests a disproportionate burden for small manufacturers.")

access and, when necessary, organizing the collection and evaluation of additional real world evidence (RWE) to support development of a permanent coverage policy. Part II of this comment letter will discuss how we believe CMS can build on the TCET Notice to create a separate, non-CED pathway as part of a comprehensive TCET Program.

Part III of our comment letter provides feedback on resources for Medicare coverage decision making and next steps to advance the TCET Program and successfully achieve its objectives.

I. Recommended Improvements to the Proposed TCET-CED Pathway

As stated above, MDMA strongly supports an efficient CED coverage pathway as an appropriate exercise of CMS' statutory authority to establish Medicare coverage policies for medical devices and diagnostics.[14] ***MDMA generally supports the process and timeframes proposed for the TCET-CED Pathway. We recognize a number of other positive aspects of the proposal, such as the acknowledgement by CMS that it can accept technologies into the TCET Program based upon a preliminary benefit category determination, and the goal of reaching agreement between the manufacturer, CMS and AHRQ on a fit-for-purpose EDP in advance of issuing a proposed CED coverage policy for public comment.***

With regard to that last point, we believe that one of CMS' primary objectives for the current TCET Notice is to address a key challenge related to the CED pathway. That challenge arises from the fact that CED is usually an *outcome* of a national coverage analysis, but not the *initial objective*. The process starts as a typical national coverage analysis, but along the way CMS determines that the available evidence does not support a finding that the item or service is reasonable and necessary for any delineable population of Medicare beneficiaries, leaving the agency with only two options—to issue a non-coverage decision based on available evidence, or to permit coverage under CED. This illustrates the important role that CED plays in providing beneficiary access and supporting ongoing evidence development for an item or service that otherwise doesn't meet the reasonable and necessary standard; however, at that point the statutorily-mandated nine-month clock for completing the national coverage analysis is already running. CMS officials have indicated that it is extremely difficult to define the specific evidence gaps and develop a corresponding evidence development plan within that timeframe, especially in a collaborative process involving the manufacturer.

Again, MDMA believes that the TCET-CED Pathway represents a positive, incremental step toward achieving the objectives of TCET, and we urge CMS to move forward quickly with its implementation with the following improvements and clarifications:

a. CMS should expand the scope of technologies eligible for participation.

1. The TCET Program should be open to technologies that have not received a breakthrough designation from the FDA. In the preamble to its repeal of the MCIT rule, CMS stated that limiting MCIT to only devices with breakthrough designation was "concerning" and "uneven" and suggested that devices beyond those with breakthrough designation could

[14] MDMA takes no position on the use of CED for products that are not authorized by FDA as medical devices or diagnostics.

benefit from participating in a separate pathway establishing Medicare coverage for novel devices.[15] We believe that the same reasoning applies to the TCET Program and the TCET-CED Pathway. There are a variety of reasons why a manufacturer might choose not to request breakthrough designation from the FDA, and we believe there are many technologies without breakthrough designation that have the potential to significantly improve clinical outcomes for Medicare beneficiaries or produce other benefits for the Medicare program.

2. CMS should clarify that there is no blanket exclusion of diagnostic devices and eliminate the blanket exclusion of devices that are the subject of an existing NCD. In the TCET Notice, CMS states that "[d]iagnostic lab tests are a highly specific area of coverage policy development, and CMS has historically delegated review of many of these tests to specialized MACs", and "the *majority* of coverage determinations for diagnostic tests granted Breakthrough Designation should continue to be determined by the MAC through existing pathways."[16] We agree that there are differences between the traditional process used for coverage determinations for lab tests compared to other items and services and also acknowledge that some research suggests coverage determinations for lab tests in general might be more timely.[17] While the existing process likely remains appropriate for the majority of lab tests, CMS should confirm that it will consider nominations of lab tests and other diagnostic technologies when consideration for coverage under the TCET Program would be helpful to provide timely beneficiary access and foster the development of additional clinical evidence. We encourage CMS to consider how collaboration with the specialized MACs could provide expertise and resources needed to develop a TCET-CED policy for a particular diagnostic technology.

In addition, we urge CMS to eliminate the requirement that limits eligibility for the Program to devices that are "not already the subject of an existing Medicare NCD."[18] We are specifically concerned about situations where an NCD is broadly written and the product is not explicitly mentioned, which could lead to rejection of a nominated device on the basis of a loosely applicable NCD. We are also concerned that the exclusion could limit the use of THE TCET-CED Pathway even when the novel technology represents an advancement over existing technology that is directly relevant to coverage limitations in the existing NCD, as well as its use to provide coverage for an expanded indication of a device that may be excluded from coverage under an NCD adopted prior to the FDA approval or clearance of the new indication. The blanket exclusion of devices that are the subject of NCD has the potential for significant negative impact on such devices, even when those devices are clearly addressing an unmet medical need for Medicare beneficiaries.

3. CMS should open the TCET Program to technologies that are currently under review by the FDA, regardless of the projected timeframe for marketing authorization. CMS should also permit the nomination of currently marketed devices or, at a minimum, establish a "look back period" that would allow the nomination of technologies that received FDA marketing authorization within a set period prior to the finalization of the Program.

[15] 86 Fed. Reg. at 62,949.
[16] 88 Fed. Reg. at 41,639 (emphasis added).
[17] *See* Sexton et al., *supra* note 2, at 6.
[18] 88 Fed. Reg. at 41,639.

As specifically stated in the TCET Notice, "CMS' goal is to finalize an NCD for technologies accepted into and continuing in the TCET pathway, within 6 months after FDA market authorization."[19] CMS also states in the Notice that "[t]he appropriate timeframe for manufacturers to submit TCET pathway nominations to CMS is approximately 12 months prior to anticipated FDA decision on a submission as determined by the manufacturer."[20]

We understand and acknowledge that a key measure of success that CMS has set for the TCET Program is to reduce the time between FDA authorization of important emerging technologies and the implementation of Medicare coverage and reimbursement, and we appreciate CMS stating its goal for establishing reimbursement for *premarket* emerging technologies with such precision. Overall, MDMA agrees with CMS that manufacturers of *premarket* technologies should self-nominate about a year before an anticipated FDA decision if possible. We believe that some manufacturers may even aim to self-nominate earlier in the process, especially if they are seeking to meet with CMS during the clinical trial design phase in order to increase the likelihood that their clinical trials meet the needs of both CMS and FDA. That said, the TCET Program should not be restricted to premarket technologies or only to those that are more than 12 months away from FDA marketing authorization. We believe there are important technologies that have recently received FDA approval or clearance that would be appropriate candidates for TCET. The same can be said of other technologies that are under active FDA review and likely to receive marketing authorization in the coming months. By allowing these technologies to apply for TCET, CMS would be better able to meet its goal of fostering innovation while ensuring people with Medicare have faster and more consistent access to emerging technologies that will improve health outcomes. Obviously, submission of a nomination later in the FDA review process or following marketing authorization would probably make it impossible to have coverage in place within six months of market introduction, but the inability to achieve that general program goal should not prevent the inclusion of a novel technology that is otherwise a good fit for the program.

MDMA urges CMS not to set rigid deadlines and to be flexible with respect to the timing of self-nominations, focusing on the nature of the specific device and its clinical evidence as well as the importance of ensuring Medicare beneficiary access to it.

4. CMS should provide additional detail on the factors that will be used for evaluating nominations and selecting devices for the TCET Program.

CMS has proposed a "nomination" process and has indicated that it does not expect that it will be able to accept all qualified nominees into the TCET Program due to resource constraints;[21] however, CMS has provided very little detail on how it will evaluate the relative merits of nominees and select technologies for the limited number of Program slots. The TCET Notice

[19] *Id.* at 41,638.
[20] *Id.* at 41,639.
[21] *Id.* at 41,644. ("Based on our initial assessment of Breakthrough Devices applying the characteristics we list in II.C. of this notice with comment period regarding appropriate candidates for the TCET pathway, we anticipate that we will receive approximately eight nominations for the TCET pathway per year. Due to current CMS resource constraints, we do not anticipate the TCET pathway will accept more than five candidates per year.")

states only that "CMS intends to prioritize innovative medical devices that, as determined by CMS, have the potential to benefit the greatest number of individuals with Medicare."[22]

MDMA urges CMS to establish clearly defined and transparent criteria for evaluating nominations and selecting devices for the TCET Program. We believe the relative benefit to individuals with Medicare is an important factor to consider; however, CMS should reconsider how it will measure potential benefit. Comparing raw numbers of beneficiaries could eliminate technologies that target diseases or conditions for which the impact on affected individuals or the Medicare program is disproportionally large relative to the prevalence in the population. With regard to other potential factors, while we are recommending that CMS open the program to technologies that have not received a breakthrough device designation from FDA, CMS could give additional weight to an FDA breakthrough designation in its review and prioritization of TCET nominations. It could also use some or all of the same criteria for the purpose of evaluating nominations that do not have an FDA designation.[23] In addition, other stakeholders and experts have suggested potential criteria for selecting Program participants. For example, researchers at the Tufts Center for the Evaluation of Value and Risk in Health suggested that CMS could consider, among other things, whether "the technology is unlikely to fit into an existing payment pathway"; whether "the target clinical condition is serious, life-threatening, and/or a cause of substantial morbidity and/or mortality in the Medicare population"; or if "available clinical options are limited and inadequate" or "the technology represents a novel approach to patient care than current options.[24]

b. CMS should begin discussions with the manufacturer regarding the alignment of coding and payment as soon as a technology is accepted into the Program. Moreover, CMS should actively coordinate coding and payment activity to ensure that MACs and Medicare Advantage plans can process claims as of the effective date of the CED coverage policy and, additionally, that applicable payment programs for new technologies are fully utilized.

We appreciate that CMS has recognized that coverage is only one leg of the reimbursement "stool" that supports beneficiary access to innovative new technologies. Many devices and diagnostics also require changes to coding systems and the assignment of an initial payment, and the processes and the decision makers involved in coding and payment determinations vary depending on the benefit category, setting of use, and other factors. CMS states that "the TCET pathway aims to coordinate benefit category determination, coding, and payment reviews," and goes on to describe the lack of such coordination as a shortcoming of the MCIT rule, noting that

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[22] *Id.*

[23] To qualify for FDA breakthrough device designation, a device must "provide for more effective treatment or diagnosis of life-threatening or irreversibly debilitating human disease or conditions" and meet at least one of the following four additional criteria: "represents breakthrough technology"; "no approved or cleared alternatives exist"; "offers significant advantages over existing approved or cleared alternatives"; or "device availability is in the best interest of patients." Food and Drug Administration, Breakthrough Devices Program, https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program#s3 (content current as of July 12, 2023).

[24] Tunis et al., *supra* note 9, at 23-24. This reference is offered as an example and is not an endorsement of specific criteria. We are requesting additional clarity on the range of factors CMS will use in reviewing, prioritizing and accepting nominations rather than exclusionary criteria.

> One of the issues identified in the prior rulemaking was that the agency did not adequately address how certain steps, which are necessary to implement national coverage determinations for a new item or service, would be accomplished in a timely manner. Specifically, under the Medicare program an item or service must fall within the parameters of a benefit category that is within the scope of Part A or Part B. Commenters have requested that CMS explain how benefit category determinations (BCDs) will be made in connection with emerging technology. CMS was also encouraged to align coding and payment processes to facilitate coverage and payment for new or emerging technologies.[25]

If appropriate coding and payment are not aligned at the same time as coverage, beneficiary access and evidence collection will be delayed substantially and the 3-5 years of the anticipated data collection period will be whittled away. We appreciate that CMS has acknowledged the importance of alignment of coding and payment to operationalize coverage, but also note that the TCET Notice similarly lacks detail regarding how that alignment will be accomplished. It would be helpful for CMS to provide additional information and details regarding how such coordination will occur and the role of external stakeholders such as other medical device companies, the American Medical Association (AMA), and others. We believe these additions can be made without delays in implementing the Program, as CMS can leverage existing mechanisms to ensure coding and payment systems are ready at the beginning of the TCET coverage period. We also offer the following specific process recommendations:

1. ***CMS should offer manufacturers a "System Readiness Meeting" within 45 days of notifying the manufacturer that its technology has been selected for the Program.*** The meeting would be attended by appropriate CMS officials with responsibility for coverage, coding and payment, depending on the benefit category and setting of use. The purpose of this meeting would be to discuss the specific benefit category, coding and payment determinations applicable to the technology—including eligibility for and timing of any relevant new technology payment programs—and opportunities to achieve the objective of aligning those determinations with the issuance of the final coverage policy. It should also specifically include coverage, coding and payment alignment for drugs, radiopharmaceuticals, procedures, and other items and services necessary to ensure patient access to the full treatment with the technology.

2. ***CMS should schedule a second "System Readiness Meeting" following the EP Meeting and the manufacturer's decision to continue with the TCET Program.*** The timing of this meeting could vary based upon the manufacturers progress on preparing a proposed EDP and the projected date for FDA market authorization and the start of the NCD process. Acknowledging that "system readiness" is a joint responsibility, this meeting also would provide an opportunity for the manufacturer and CMS to discuss actions by the manufacturer required to successfully launch and complete any necessary EDP.

We ask that CMS add these System Readiness Meetings to ensure the setup of proper coding and payment decisions without compromising the timelines targeted in the Notice.

[25] 88 Fed. Reg. at 41,634.

Finally, our members report significant confusion among Medicare Advantage (MA) plans regarding coverage pathways that are associated with clinical research or other evidence development, including CED, coverage of devices under an FDA Investigation Device Exemption (IDE), and coverage for clinical trial participation. CMS should clarify that transitional coverage policies adopted under the TCET Program are national coverage policies that MA plans are obligated to follow. CMS should also consider providing additional guidance to MA plans clarifying the different coverage policies involving clinical research or data collection.

c. CMS should clarify the scope of the EP and move evaluation of evidence gaps specific to the subject technology to the EDP stage.

There is significant confusion regarding the scope of the EP document. It is described in the TCET Notice as "a systematic literature review that would provide early feedback on the strengths and weaknesses of the publicly available evidence for a specific item or service . . . that will help CMS identify any material evidence shortfalls."[26] Because most of the devices that will be accepted into the Program are likely to be premarket, first-of-their-kind technologies, there may be little to no publicly available evidence specific to the technology until data from their FDA approval trials is published. In addition, the description also indicates that the EP is intended to "*help CMS* identify any material evidence shortfalls," suggesting separation between the EP (which will be conducted by a contractor) and the evidence gap analysis. That said, the description also refers to "evidence for a specific item or service", the discussion of the EDP phase of the process starts with the phrase "[i]f evidence gaps are identified by CMS and/or AHRQ during the Evidence Preview,"[27] and discussions with CMS officials suggest that the gap analysis will be part of the EP document.

The scope of the EP is a critical issue for manufacturers who might consider applying for the TCET Program. That is because CMS plans to distribute the EP to MACs in the event that a manufacturer decides to withdraw from the Program at this stage.[28] If the EP includes discussion of evidence gaps specific to the novel technology on endpoints identified by CMS as relevant to a determination of coverage, providing the EP to the MACs could reasonably be expected to be interpreted by them as an implied conclusion by CMS that the technology is not reasonable and necessary and, therefore, not eligible for coverage. MACs also might assert that a manufacturer's voluntary pursuit of coverage through the TCET Program itself suggests an acknowledgement by the manufacturer that the technology is not reasonable and necessary, given that the CED pathway is specifically intended for items and services that cannot meet the normal reasonable and necessary threshold for coverage. This would likely affect both case-by-case determinations of medical necessity and the development of local coverage determinations (LCDs) following FDA marketing authorization. We believe this risk will result in most manufacturers forgoing the opportunity to participate in the Program, further reducing the potential for the Program to achieve the TCET goals of accelerating access and fostering innovation.

We recommend that CMS clarify that the EP is a summary of the published peer-reviewed literature in the relevant clinical space, and an examination of the outcomes of interest to CMS, associated endpoints and clinically meaningful differences for the target disease or condition.

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[26] *Id.* at 41,640.
[27] *Id.* at 41,641.
[28] *Id.*

The EP should not extend to include an analysis of the evidence gaps associated with the nominated technology. The EP also should explicitly state that the document is not a coverage determination and should not be interpreted to represent a finding regarding whether any specific item or service is reasonable and necessary. We believe that the proposed osteoarthritis guidance issued by CMS as part of the TCET announcement is a good model for the EP. We note that guidance appears to represent the first of what CMS officials have previously referred to as "Medicare Evidence Development and Coverage Advisories," which are intended to "provide more guidance to manufacturers about the clinical outcomes the agency will be looking for when reviewing studies, as well as the clinical differences that will be considered meaningful."[29]

For manufacturers who elect to stay in the Program at this stage, the EP would then become the basis for CMS and the manufacturer—presumably with the involvement of AHRQ and the contractor who conducted the EP as appropriate—to discuss the evidence gaps as the first step in the next stage of the process: the creation of a proposed EDP. If CMS has already developed a clinical endpoints guidance document relevant to the specific disease or condition, that would significantly reduce and potentially eliminate the time and expense associated with producing an EP. The process could potentially move directly from Program acceptance to the discussion of an EDP, depending on the age of the relevant EP.

It is also crucial that the EP meeting avoid bias toward additional data collection under an EDP, especially in cases where a device has robust pre-market clinical evidence. Under this circumstance, CMS should fast-track non-CED national coverage for these devices, which would facilitate timely access to innovative and clinically sound technologies that meet the "reasonable and necessary" threshold.

Limiting the scope of the EP as described above should resolve concerns about providing the document to MACs in the event the manufacturer withdraws from the Program. ***Should CMS decide to include the gap analysis for the TCET technology in the EP, MDMA urges CMS to eliminate the planned distribution to MACs or distribute only those portions of the EP that do not relate to the specific technology.***

d. CMS should clarify the process and timeframe for updating criteria for CED studies to incorporate "fit-for-purpose" study designs and ensure that the criteria and review of proposed EDPs weigh the cost/burden and appropriateness of different data collection models.

MDMA is encouraged by CMS' intent to incorporate fit-for-purpose (FFP) evidence development into the CED program. CMS has defined FFP studies as those "where the study design, analysis plan, and study data are appropriate for the question the study aims to answer. FFP study designs scale sample size, duration, and study type, etc., based off of the utilization and risk profile of the item or service." The agency also states in the TCET Notice that it is "partnering with AHRQ to consider how to incorporate greater flexibility into the CED paradigm by allowing FFP evidence study designs that meet rigorous CMS evidence requirements" and that "updates will be

[29] Fleisher LA and Blum JD. A Vision of Medicare Coverage for New and Emerging Technologies—A Consistent Process to Foster Innovation and Promote Value. *JAMA Internal Medicine.* Oct. 12, 2022 (online). doi:10.1001/jamainternmed.2022.5085.

communicated in guidance documents and potential rulemaking as applicable and will include an opportunity for public comment."[30]

Clarity on acceptable FFP study designs is critical to the success of the TCET Program, as it will provide the basis on which the manufacturer, CMS and AHRQ will reach agreement on the EDP prior to the start of the NCD process—a primary objective of the Program. It is also key to fulfilling one of the four principles that CMS has set for TCET—that "[i]f CMS determines that further evidence development is the best coverage pathway, the agency would explore how to reduce the burden on manufacturers, clinicians, and patients while maintaining rigorous evidence requirements."[31]

It is unclear from the TCET Notice whether the draft guidance document on CED that was released at the same time as the TCET Notice will require additional updates to incorporate the flexibility needed for FFP study designs. As described in that document, the process for developing the currently proposed revisions to the criteria for CED studies has taken more than a year—including the development and issuance of a draft report with updated criteria that was released by AHRQ for public comment in September 2022, the release of the final AHRQ report in November 2022, and a two-day public meeting of the Medicare Evidence Development & Coverage Advisory Committee (MEDCAC) in February 2023 to review the report, followed by evaluation of the subsequent MedPAC recommendations and additional revisions by AHRQ and CMS, resulting in the proposed criteria contained in section VII of the draft guidance.[32] If additional updates are needed to allow for FFP study designs, we are concerned about the lack of specific details regarding the process and expected timeframe.

e. CMS should start the NCD process with the issuance of the proposed CED policy and EDP along with the EP.

The TCET Notice indicates that during the EDP stage of the TCET-CED Pathway, CMS and AHRQ will work with the manufacturer to reach agreement on an EDP, which will subsequently be published by CMS for public comment along with the proposed CED coverage policy. The Notice goes on to describe the NCD process as follows:

> The process for Medicare coverage under the TCET pathway would follow the NCD statutory timeframes in section 1862(l) of the Act. CMS would start the process by posting a tracking sheet and elements of the finalized Evidence Preview, specifically the non-proprietary information, which would initiate the start of a 30-day public comment period. Following further CMS review and analysis of public comments, CMS would issue a proposed TCET NCD and EDP within 6 months of opening the NCD. There would be a 30-day public comment period on the proposed TCET NCD and EDP

[30] 88 Fed. Reg. at 41,641.
[31] *See, e.g.*, Fleisher LA and Blum JD, *supra* note 29.
[32] Centers for Medicare & Medicaid Services, Coverage with Evidence Development: Proposed Guidance Document, June 22, 2023, 5.

> and a final TCET NCD would be due within 90 days of the release of the proposed TCET NCD.[33]

We recommend that CMS not begin the NCD process until the agency, AHRQ and the manufacturer have reached agreement on the EDP that will accompany the proposed coverage policy. The initial 30-day comment period on the tracking sheet is not required by statute—only the 30-day comment period following the issuance of a proposed coverage policy is required.[34] By issuing the proposed EDP and coverage decision along with the tracking sheet and the EP, similar to the Parallel Review program, CMS would eliminate the need for the initial comment period, which would expedite the NCD timeline.

f. CMS should allow extension of the primary data collection period and review timeframe when appropriate, and clarify that coverage of the technology continues after the primary data collection and review period until reconsideration of the original CED policy is complete.

The specific duration of the coverage period under the TCET-CED is another area of the TCET Notice that requires clarification. The TCET Notice suggests that the duration of coverage is tied to the EDP and that a review date that will be specified in the EDP (set at the end of the evidence collection period plus an additional one year), going on to state that "we anticipate this transitional coverage period would last for a period of 3 to 5 years as evidence is generated to address evidence gaps identified in the Evidence Preview."[35] In addition, the "TCET Proposed Pathway/Timeline" graphic included in the TCET Notice indicates that "CED Stops" prior to the "Transition to Post TCET Coverage" stage of the process.[36] On the other hand, the proposed CED guidance document states that "[a] CED cycle is considered completed when CMS *completes a reconsideration of the CED coverage decision* and removes the requirement for study participation as a condition of coverage."[37] Furthermore, in the section describing the development of the EDP, CMS advises that "[m]anufacturers should conceive a continued access study that maintains market access between the period when the primary EDP is complete, the evidence review is refreshed, and a decision regarding post-TCET coverage is finalized"[38]—suggesting that CED coverage does not end until a reconsideration of the original CED policy is final.

MDMA recommends that CMS work closely with the device manufacturer to establish a reasonable, mutually agreed upon data collection and review period in the EDP, appropriate for the disease and stage of disease that the technology is designed to treat—but that the agency be flexible in extending it. Generally, we believe 3-5 years should be sufficient for most manufacturers to generate meaningful evidence and publish it, and that CMS should be open to extending the time period if the manufacturer is acting in good faith or if there is some other unanticipated delay.

MDMA urges CMS to clarify that coverage should continue (under modified data collection if specified in the EDP) until the Transition to Post TCET Coverage stage is complete and an NCD

[33] 88 Fed. Reg. at 41,642.
[34] *See* 42 U.S.C. §1395y(l)(3).
[35] 88 Fed. Reg. at 41,642.
[36] *Id.* at 41,643.
[37] Coverage with Evidence Development: Proposed Guidance Document, *supra* note 32, at 12.
[38] *Id.* at 41,641.

redetermination is finalized. In addition, we recommend that CMS look for opportunities to streamline the reconsideration process to preserve resources and allow more technologies to be considered under the TCET Program. For example, CMS could eliminate the initial 30-day comment period by moving directly to publication of a revised coverage policy along with the tracking sheet, as we recommend above for the original CED coverage policy. CMS could also consider including in the original CED, when appropriate, an automatic termination of evidence collection requirements and conversion of the policy to a regular NCD in situations where all endpoints are met and there are no serious adverse events or other major problems during the CED study.

g. MDMA supports the general policy proposed by CMS with regard to similar (i.e., "follow-on") devices, but recommends that the agency provide additional clarity as the Program develops.

Today most NCDs with CED are for procedures and/or device categories and do not limit coverage to a particular manufacturer's device. In addition, in recent NCDs extending coverage under CED to medications intended for the treatment of Alzheimer's disease, CMS has developed a framework that allows for coverage of newly approved products based upon the review and approval of an evidence collection model by CMS for a new product without requiring a full national coverage analysis and new or revised NCD.

MDMA generally believes that a similar framework should allow for the extension of coverage to follow-on devices that fit within the same device category as a device covered under a CED policy developed through the TCET-CED Pathway. We also agree, as indicated in the TCET Notice, that any post-TCET national coverage determination for the first device should apply to other medical technologies within the same coverage category.[39]

While some work will be required to conduct the review and approval of the EDPs for follow-on devices, given the efficiencies gained from this approach, we think that CMS should not count coverage that is extended to the follow-on devices against the agency's proposed five applicants that are accepted into the TCET-CED Pathway annually.

II. Recommendations for a Dedicated TCET Coverage Pathway

As stated in the Introduction and reflected in our Part I feedback above, we support actions to improve CED and urge CMS to implement the TCET-CED Pathway. At the same time, by limiting the scope of the TCET Program to solely that pathway, we believe CMS is missing a significant opportunity to accelerate beneficiary access to novel technologies and foster innovation. ***To realize the robust TCET Program envisioned and hoped for by patients and other stakeholders, CMS should build on this proposal by creating a new coverage pathway separate from CED for appropriate technologies.***

CED was created under CMS' statutory authority to cover items and services that do not meet the threshold of being "reasonable and necessary" for diagnosis or treatment of any discernable population of Medicare beneficiaries, but are reasonable and necessary to carry out certain research

[39] *Id.* at 41,642.

projects.[40] We acknowledge that evidence gaps are likely for many novel technologies at the time they are introduced to market due to the difference between the statutory standards for FDA marketing authorization and CMS coverage, the nature of how premarket clinical trials are designed, and the difference between utilization of medical devices in the controlled setting of a clinical trial as compared to "real world" use following FDA marketing authorization. We believe, however, that ***the mere existence of evidence gaps does not (and should not) mean that a new technology is "not reasonable and necessary" for certain patients.*** To conclude otherwise would lead to an illogical policy result—the technology would not be coverable by MACs, who have no mechanism like the proposed TCET-CED Pathway to cover items and services that are not reasonable and necessary; and that would severely curtail access to devices that FDA has concluded provide a reasonable assurance of safety and effectiveness for beneficiaries who need them and severely hinder the development of evidence on real world use in the Medicare population that could help CMS refine appropriate coverage policy over the lifecycle of the technology.

We believe CMS recognized that not every evidence gap should lead to a "not reasonable and necessary" determination when coverage officials identified the "R&N; Limited Context" category of devices shown in the TCET process graphic provided as Figure 1; however, in leaving coverage determinations for such devices solely to MAC discretion, the agency is failing to take any steps to accelerate access for those technologies or to use its coverage authority to incentivize and organize the collection of real world evidence (RWE). Engaging with multiple MACs on either claim-by-claim adjudication or LCD development is time-consuming and requires significant resources that small medical device companies (the source of most new device innovations) often do not have. This is especially true in the case of denials that must be appealed, often repeatedly for the same device.

We understand and appreciate that for an "R&N, Limited Context" device, the evidentiary record might not be "ripe" for a long term, national coverage policy. But for important technologies, CMS could help accelerate the "ripening" by extending coverage for a temporary period to facilitate the collection of additional evidence generated from real world use. This temporary, transitional NCD would not rely on CED authority (section 1862(a)(1)(E) of the Act); it would cover these technologies under section 1862(a)(1)(A). As a result, data collection would not need to comply with CED study requirements as established by AHRQ, giving CMS even greater opportunity to use FFP models, including primary use of RWE collection. This is consistent with CMS' principles governing the application of CED—specifically, that "CED will not be used when less restrictive coverage is justified by the available evidence."[41] ***We strongly agree that unnecessary use of CED should be avoided because, by its nature, CED imposes additional burdens and reduces access for beneficiaries and requires more resources to administer, not only by CMS and AHRQ, but also by manufacturers and providers.***

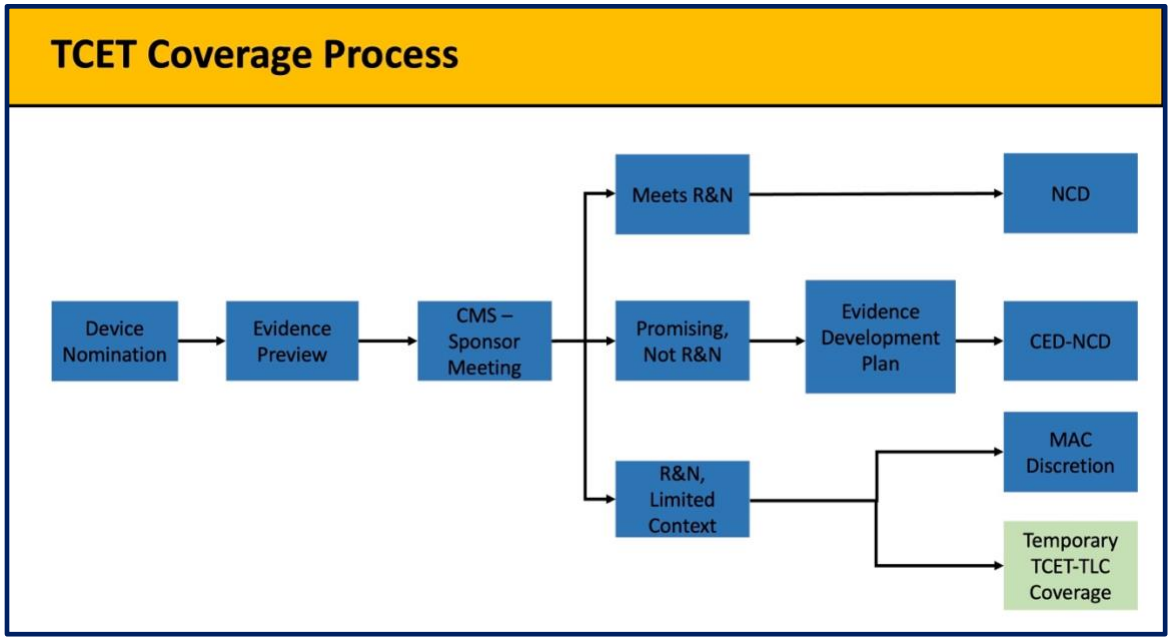
The final report released by AHRQ related to requirements for CED clinical studies includes a review of the history of CED, and briefly mentions two subtypes of CED—Coverage with Appropriateness Determination (CAD), and Coverage with Study Participation (CSP)—describing

[40] For a discussion of the history and statutory basis for CED, *see* Coverage with Evidence Development: Proposed Guidance Document, *supra* note 32, at 3-7.
[41] *Id*. at 7.

CAD as applicable when "CMS agrees that an item or service is reasonable and necessary but requests clinical data that are not generally available in claims to ensure appropriate use."[42] The report goes on to note that CMS no longer differentiates between the two subtypes, but MDMA believes that the CAD concept could be adapted to create a TCET pathway dedicated to coverage for select "R&N, Limited Context" and separate from CED.

We believe such a "TCET-Temporary Limited Context" (TCET-TLC) Pathway could work similarly to the proposed TCET-THC Pathway, with recommendations included in our comments above also applied as relevant. In fact, the two TCET pathways could potentially share a common nomination and selection process, with pathways diverging after the EP meeting at which CMS and the manufacturer "discuss the strengths and weaknesses of the evidence and discuss the available coverage pathways."[43] The difference would be that instead of being limited to "seeking coverage decisions made by a MAC",[44] CMS could offer manufacturers of "R&N, Limited Context" technologies another option—a temporary period of TCET coverage—as illustrated by the addition to the CMS TCET Coverage Process graphic shown in Figure 2.

Fig. 2. TCET coverage process with additional "non-CED" TCET pathway.



Again, because this temporary transitional coverage would not rely on CMS' CED authority (section 1862(a)(1)(E)), data collection would not need to comply with CED study requirements as established by AHRQ, giving CMS even greater opportunity to use FFP models, including the primary use of RWE collection. ***We support the recommendation that CMS develop and publish additional guidance on the use of RWE to support coverage determinations as part of its TCET***

[42] Agency for Healthcare Research and Quality, Analysis of Requirement for Coverage With Evidence Development (CED) – Topic Refinement, AHRQ Publication No. 23-EHC003, November 2022, 5, https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/ta/topicrefinement/ced-topic-refinement.pdf.
[43] 88 Fed. Reg. at 41,641.
[44] *Id.*

effort. We agree with the team of researchers and policy experts from the Tufts Center for the Evaluation of Value and Risk in Health, including a former Director of the Center for Clinical Standards and Quality and Chief Medical Officer at CMS, who wrote,

> While CMS has considered RWE in past coverage decisions, the Agency has not yet developed clear guidance or a general framework of how this evidence is assessed. Furthermore, the experience to date with clinical registry data in the context of CED policies has highlighted the significant cost, time and resources associated with this specific type of RWD [real world data]. Transitional coverage of emerging technologies is likely to be associated with increased reliance on RWD studies to inform future coverage decisions. For these reasons, it will be valuable for CMS to work with external experts and stakeholders to develop a framework that articulates how the Agency will assess the quality and relevance of RWE in making national coverage decisions. Ideally this framework would be communicated in the form of one or more guidance documents, similar to those that have been developed by the FDA in the context of their detailed exploration of the role of RWE in regulatory decision making. This guidance should address the potential use of data from claims, electronic health records, patient-reported data, digital biomarkers and other forms of RWD.[45]

Finally, with regard to process, we acknowledge that a TCET-TLC Pathway as envisioned by our comments likely falls within the statutory definition of a "national coverage determination,"[46] which means that statutory requirements related to the NCD process apply. We would urge CMS to take all possible steps in designing the TCET-TLC Pathway and reviewing specific technologies to ensure that all TCET NCDs are completed as quickly as permitted in accordance with those requirements.

In addition, while finalizing either a TCET-CED or TCET-TLC coverage policy might require use of the statutory NCD process, because the TCET-CED Pathway and the TCET-TLC Pathway would be based on different statutory coverage authorities, we believe CMS could choose different approaches to the duration of the temporary coverage and the "Transition to Post TCET Coverage." Under the MCIT framework, the temporary national coverage would have ended after four years, with coverage determinations defaulting to MAC discretion (exercised either through claim-by-claim adjudication or an LCD) unless and until CMS adopted an NCD providing coverage criteria or terminating coverage.[47] CMS could potentially take the same approach for TCET-TLC coverage policies, sunsetting the policy and returning coverage to MAC discretion without requiring reconsideration of the NCD. Reducing the number of formal NCD reconsiderations associated

[45] Tunis et al., *supra* note 9, at 23-24.
[46] 42 U.S.C. § 1395y(l)(6)(A). ("The term 'national coverage determination' means a determination by the Secretary with respect to whether or not a particular item or service is covered nationally under this subchapter.")
[47] *See* 86 Fed. Reg. at 2,993.

with devices receiving TCET coverage would help CMS in the management of the resources required for administering the national coverage process.

III. Additional Comments

We hope CMS will act quickly to respond to public comments received on the TCET Notice and finalize the TCET-CED Pathway, and will begin accepting nominations for technologies from interested manufacturers. We also urge CMS to develop and issue a second notice expanding the TCET Program to include the separate TCET-TLC Pathway for R&N, Limited Context devices. Both pathways are needed to meaningfully accelerate access for Medicare beneficiaries to novel technologies that address unmet needs across a wide range of diseases and conditions, and to incentivize investment in breakthrough technology development and post-market data collection.

We share the concern of many stakeholders that the scope of the TCET Program has been arbitrarily limited to a subset of eligible technologies. The TCET Notice specifically ties the proposal to limit the program to five candidate technologies each year to "CMS resource constraints."[48] We understand that the pace of innovation has accelerated and the complexity of new technologies has increased. We appreciate that this has increased demands on CMS policy development systems and personnel, both in terms of capacity and required expertise; but the potential that a technology that meets criteria for participation will not be selected, along with the fact that the Program is being established through subregulatory guidance as compared to a regulation, negatively impacts the predictability that is needed to incentivize investment in breakthrough medical devices and diagnostics.

Coverage policy making is a core function of management of the Medicare program, and it is critical that the Medicare program keep pace with the development of new innovations that improve outcomes and quality of life for beneficiaries. Beyond the direct interest of beneficiaries and their providers in having access to the full range of options for their care, the sheer scope of the Medicare program—which is the largest single purchaser of healthcare and covers nearly 18% of the U.S. population, including nearly all individuals aged 65 and older[49]—means that CMS and Congress must recognize and accept the role the program plays in either supporting or hindering the development of innovative devices and diagnostics, not only for that population but the entire U.S. healthcare system. In short, a system that efficiently establishes coverage, coding and payment policies for new technologies is a "must have", not a "nice to have."

MDMA is committed to working with CMS and Congress to support an efficient system for reimbursement policy development. We believe that the expanded TCET Program illustrated in Figure 2—aligned with the assignment of initial coding and payment and other "System Readiness" activities—is achievable for a reasonable investment of resources. In terms of the capacity needed for the TCET Program, we note that the Stanford Biodesign study identified

[48] 88 Fed. Reg. at 41,644.

[49] *See* Cha AE and Cohen RA, Centers for Disease Control and Prevention. Demographic Variation in Health Insurance Coverage: United States, 2021. November 3, 2022. https://www.cdc.gov/nchs/data/nhsr/nhsr177.pdf; Keisler-Starkey K and Bunch LN, U.S. Census Bureau. Health Insurance Coverage in The United States: 2020. September 2021. https://www.census.gov/content/dam/Census/library/publications/2021/demo/p60-274.pdf.

approximately 16 novel technologies per year (with and without FDA breakthrough designation) that were deemed to be seeking new coverage or codes to support reimbursement and patient access, which suggests a manageable number of candidate technologies. We are also supportive of CMS' efforts to enhance the scope of clinical and technological expertise provided both by CMS staff and available to the agency from third party contractors.

To facilitate productive discussions between the agency, the Administration, Congress and stakeholders about the appropriate level of resources allocated to CMS for national coverage policy making, we urge CMS improve its performance in providing timely and comprehensive information to Congress and the public about its coverage activities. First, as has been repeatedly requested by stakeholders and Congress, CMS should immediately and regularly update the "NCD Wait List" dashboard,[50] which has not been updated since September 2020. Second, we urge CMS to broaden the scope of quantitative and qualitative information regarding the national coverage program that is included in its statutorily mandated annual report to Congress,[51] including information specific to the TCET coverage pathways.

Conclusion

MDMA appreciates this opportunity to comment on the TCET Notice, and we look forward to working with CMS toward a comprehensive, robust and meaningful TCET program that includes both CED improvements and a separate, non-CED coverage pathway. If we can provide any additional information, please contact Dan Waldmann, EVP of Health Policy and Reimbursement, at dwaldmann@medicaldevices.org or (202) 354-7171.

Sincerely,

Mark Leahey
President and CEO
Medical Device Manufacturers Association

[50] *See* https://www.cms.gov/medicare/coverage/determinationprocess.
[51] *See* https://www.cms.gov/medicare/coverage/infoexchange/reports; 42 U.S.C. § 1395ff(f)(7).