



Catalyzing Innovation for Healthy Aging

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August 28, 2023

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### **RE: Transitional Coverage for Emerging Technologies Notice (CMS-3421-NC)**

The Alliance for Aging Research (“the Alliance”) appreciates the opportunity to offer comments to the Centers for Medicare & Medicaid Services (“CMS”) regarding its notice, “Medicare Program; Transitional Coverage for Emerging Technologies” (the “Notice”).

The Alliance is a leading nonprofit organization dedicated to accelerating the pace of scientific discoveries and their application to vastly improve the universal human experience of aging and health. We believe that advances in research help people live longer, happier, more productive lives and reduce healthcare costs over the long term.

We serve as a patient-centered voice in policy development, including for medical device coverage. Among our other efforts, we served as the founding convener for the *Heart Valve Disease Task Force*, which convenes patient advocacy organizations to improve access, research, and awareness of heart disease detection and treatment. We are also engaged as a stakeholder in medical device priorities with the Food and Drug Administration (“FDA”), including multiple reauthorization cycles for the Medical Device User Fee Act.

**We oppose CMS’s current proposal of the TCET pathway.** While we appreciate CMS’s efforts to bring transparency, predictability, and expedited national coverage for eligible Breakthrough Devices, the proposed TCET pathway will not achieve those goals as its end result will restrict rather than facilitate Medicare beneficiaries’ long-term access to innovative technologies. Instead, we urge CMS to restore the prior Medicare Coverage of Innovative Technology (“MCIT”) final rule and presumptively cover eligible Breakthrough Devices for a period of four years (subject to the limitations of the prior final rule). We outline our feedback on the proposed implementation of the TCET pathway, below.

#### **I. CMS Continues to Deploy the Extralegal, Flawed CED Paradigm with the Potential for Disastrous Consequences**

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The Alliance opposes the evolution and CMS’s current application of Coverage with Evidence Development (CED) in the National Coverage Determination (NCD) process.<sup>1</sup> The pathway, originally intended to expedite access to devices and diagnostics, has failed to live up to that aim. The Alliance has not always opposed the use of CED<sup>2</sup> for devices; however, the shortcomings and harmful impacts of CMS’s application of CED have become difficult to ignore necessitating a new approach. Products subject to NCD with CED are often under restrictions for a decade or more, if not indefinitely.<sup>3</sup> Further, CMS has extended its use of CED to drugs and biologics. Through the CED and National Coverage Analysis (NCA) guidance documents co-released with the TCET notice, CMS signaled an intention to use CED more often due to “products now coming to market with limited evidence,” despite these products receiving approval from FDA as being safe and effective.

We have extensively presented the facts and arguments concerning CMS’s use of CED, including to CMS directly. We have, among other things, questioned CMS’s reliance upon uncertain legal grounds for utilizing CED and highlighted the deficiencies with the CED model that lead to inequitable access, fundamental challenges in collecting data to inform beneficiary decision-making, and indeterminable criteria that perpetuate coverage restrictions. We are concerned that CMS’s continued and expanded use of CED will potentially lead to disastrous consequences such as the denial of beneficiary access to innovative therapies.

We incorporate by reference the positions we have articulated in our: (i) comment to CMS’s proposed National Coverage Determination (“NCD”) with CED for “Monoclonal Antibodies Directed Against Amyloid for the Treatment of Alzheimer’s Disease;”<sup>4</sup> and (ii) white paper, “Façade of Evidence: How Medicare’s Coverage with Evidence Development Paradigm Rations Care and Exacerbates Inequity.”<sup>5</sup> Notwithstanding our opposition to CMS’s use of CED, generally, we have additional concerns related to the proposals and rationales presented for the TCET pathway in the Notice.

**II. CMS Undermines FDA’s Breakthrough Devices Program and Post-Market Requirements**

**A. Undermining FDA’s Breakthrough Devices Program**

The proposed TCET pathway will undermine Congress’s goal, enacted in the 21<sup>st</sup> Century Cures Act (“Cures Act”), to bring innovative technologies to patients sooner through the FDA’s

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<sup>1</sup> The Agency claims that it will establish the TCET pathway, which leverages the National Coverage Determination and CED processes, from its “existing authorities.” 88 Fed. Reg. 41633, 41637 (June 27, 2023).

<sup>2</sup> See generally Comment from Alliance for Aging Research to CMS (Aug. 11, 2021), <https://www.agingresearch.org/wp-content/uploads/2021/08/Alliance-for-Aging-Research-Comment-on-CMS-NCA-CAG-00460N-8-11-2021-FINAL.pdf>.

<sup>3</sup> Emily P. Zeitler & Lauren G. Gilstrap, *Coverage With Evidence Development: Where Are We Now?*, 28 AM. J. MANAGED CARE (Aug. 2022), <https://www.ajmc.com/view/coverage-with-evidence-development-where-are-we-now->.

<sup>4</sup> See generally Comment from Alzheimer’s Disease Task Force to CMS (Feb. 10, 2022), available at <https://www.cms.gov/files/document/peschincomment02102022.pdf>.

<sup>5</sup> See generally Alliance for Aging Research, *FAÇADE OF EVIDENCE: HOW MEDICARE’S COVERAGE WITH EVIDENCE DEVELOPMENT PARADIGM RATONS CARE AND EXACERBATES INEQUITY* (Feb. 13, 2023), available at <https://www.agingresearch.org/wp-content/uploads/2023/02/Facade-of-Evidence-CED-2-13-2023.pdf>.

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Breakthrough Devices Program.<sup>6</sup> The goal of the breakthrough designation was to get patients expedited access to new devices fulfilling an unmet need and allowing FDA, once essential safety criteria were met and other clinical evidence presented, to approve or clear these products for patient use. The proposed TCET pathway conflicts with Congressional intent and will create a two-tiered system with non-beneficiaries securing access to these devices but requiring Medicare beneficiaries outside the “evidence development” trials created by CMS having to wait for treatments. We appreciate that CMS’s coverage and FDA’s approval standards differ.<sup>7</sup> That said, we urge CMS to reconsider how to enable faster access to potentially life-saving technologies for Medicare beneficiaries while remaining aligned with the purpose of the Breakthrough Devices Program. Quite simply, approval without the reasonable ability to access is not meaningful from the perspective of the beneficiary.

FDA only grants a breakthrough device designation to a device upon a showing that the product provides a more effective treatment or diagnosis for a life-threatening or irreversibly debilitating disease or condition and meets one of the following: (i) represents breakthrough technology; (ii) presents the only option (*i.e.*, no approved or cleared alternatives exist); (iii) offers significant advantages over existing approved or cleared alternatives; or (iv) its availability is in the best interest of patients.<sup>8</sup> Notwithstanding the determination by its sister agency that the breakthrough device offers significant advantages over existing treatments and FDA’s decision that access is in the best interest of patients, CMS contemplates that most—if not all—of the eligible Breakthrough Devices<sup>9</sup> will be subject to coverage with evidence development requirements. CMS claims that such products generally have insufficient evidence of clinical benefit in the Medicare population at the time of FDA marketing authorization to support national coverage.<sup>10</sup> CMS’s presumption that FDA-designated breakthrough devices are not “reasonable and necessary” under Section 1862(a)(1)(A) of the Social Security Act flies in the face of FDA’s determinations and undermines FDA’s mission to protect patients. And, to be clear, the legal standard for breakthrough devices is *more* than “safe and effective.” There is a five-step test, noted above, that includes many of the factors that CMS should incorporate in its reasonable and necessary evaluation for coverage.

CMS previously finalized the MCIT final rule (since withdrawn) that would have covered FDA-designated breakthrough devices for Medicare beneficiaries immediately upon FDA approval or

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<sup>6</sup> See 21<sup>st</sup> Century Cures Act, Pub. L. 114-255 § 3051 (codified at 21 U.S.C. § 360e-3) (as amended by Sec. 901 of the FDA Reauthorization Act of 2017, Pub. L. 115-2).

<sup>7</sup> See Statement of Rep. Guthrie, Hearing on Innovation in Medicare (July 18, 2023), *available at* <https://energycommerce.house.gov/posts/health-subcommittee-chair-guthrie-opening-statement-on-innovation-in-medicare> (stating that the TCET proposal “significantly narrows the number and type of products that can use the Breakthrough Devices program for streamlined Medicare coverage” and “is also undermining our innovative ecosystem through actions taken to limit Medicare access to FDA approved breakthrough medical devices and technologies. Instead of rewarding this innovation by providing a streamlined path to Medicare coverage for these novel products, like the ... Medicare Coverage of Innovative Technologies rule would have done, the [proposal] is reducing access to cures for patient policies through its proposed Transitional Coverage of Innovative Technologies rule.”).

<sup>8</sup> U.S. Food & Drug Admin., *Breakthrough Devices Program: Guidance for Industry and Food and Drug Administration Staff*, at 8-14 (Dec. 2018), <https://www.fda.gov/media/108135/download>.

<sup>9</sup> CMS defines “eligible Breakthrough Devices” as medical devices that are: (i) FDA-designated Breakthrough Devices; (ii) determined to be within a Medicare benefit category; (iii) not already the subject of an existing Medicare NCD; and (iv) not otherwise excluded from coverage through law or regulation). 88 Fed. Reg. at 41639.

<sup>10</sup> *Id.* at 41637.

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clearance for up to four years.<sup>11</sup> In that rulemaking, CMS presumed that FDA-designated breakthrough devices satisfied the Act’s “reasonable and necessary” standard and declined to impose additional clinical studies.<sup>12</sup> CMS explained that the MCIT pathway would “accelerate the coverage of new, innovative breakthrough devices to Medicare beneficiaries.”<sup>13</sup> CMS even lauded that the MCIT pathway “was completely supported by the public comments,” including ours.<sup>14</sup> But the Agency now takes an opposite position in the Notice. CMS parades the TCET pathway as a vehicle to expedite access to technologies for Medicare beneficiaries but without respect for FDA’s qualified decision-making and only for manufacturers who agree to CMS’s evidence development requirements. We urge CMS to reverse its view and return to the position the Agency took in the original MCIT rulemaking to accelerate access to meaningful and potentially life-saving technologies for beneficiaries.

**B. Duplicating or Conflicting with FDA Post-Market Requirements**

Where CMS finds that CEDs are appropriate for an eligible Breakthrough Device, CMS broadly promises that it will work to ensure that it does not impose duplicative or conflicting evidence development requirements with FDA post-market requirements.<sup>15</sup> We agree with CMS’s proposal in principle. However, we are concerned that CMS does not provide transparency into how CMS purports to achieve this goal, thereby raising questions about the hurdles beneficiaries may encounter before accessing eligible Breakthrough Devices.

We respectfully request CMS provide additional details on this matter. We anticipate that CMS may need to coordinate with the relevant FDA review team throughout the application’s review cycle and during its evaluation of the evidence development plan (EDP)(i.e., CED requirements).

**III. CMS Masks Participation in the TCET Pathway as “Voluntary”**

Although CMS proposes to invite manufacturers of eligible Breakthrough Devices to “voluntarily” participate in the TCET pathway,<sup>16</sup> we are concerned that there is no real choice at all, and that patients appear to be excluded from the process. CMS downplays the reality that manufacturers who do not follow through with the TCET pathway and subject themselves to CED requirements are virtually excluded from Medicare coverage altogether without regard to the implications for beneficiaries resulting from lack of access. There is nothing “voluntary” about the pathway for beneficiaries, who are left in the balance as CMS and manufacturers engage in the proposed process for beneficiaries to have access to these FDA-approved devices.

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<sup>11</sup> 86 Fed. Reg. 2987, 2991 (Jan. 14, 2021).

<sup>12</sup> *Id.* at 2992.

<sup>13</sup> *Id.* at 2988.

<sup>14</sup> *Id.* at 2992; see Comment from Alliance for Aging Research to CMS (Nov. 2, 2020), available at <https://www.regulations.gov/comment/CMS-2020-0098-0291>. The Alliance supported CMS’s proposal to align Medicare coverage for breakthrough medical devices with FDA market approval for a period of up to four years, but did not support CMS’s proposal to codify a definition for “reasonable and necessary.”

<sup>15</sup> 88 Fed. Reg. at 41639.

<sup>16</sup> *Id.* at 41638.

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A simple illustration reveals that the TCET pathway presents an illusion of choice for manufacturers and a losing proposition for patients. Assume a manufacturer has an eligible Breakthrough Device and is seeking FDA market authorization (*i.e.*, approval or clearance). The manufacturer, from CMS's vantage point, is improperly presumed to not have sufficient clinical data to support coverage at the time of FDA market authorization.<sup>17</sup> The manufacturer understands that it could potentially obtain coverage for its product under the TCET pathway provided that it agrees to additional evidence development requirements. At the same time, the manufacturer is confoundingly told by CMS that it does not have to engage in the TCET pathway at all or, if it does, can withdraw from consideration up until CMS opens an NCD. CMS presents a classic Hobson's choice: If the manufacturer does not agree to engage in the TCET process, then CMS all but assures it will deny Medicare coverage for the breakthrough device and forecloses beneficiary access to the device.

Even if the TCET pathway offers manufacturers a true choice to opt-out, CMS in the notice omits the consequences that doing so would have on millions of beneficiaries. Most devices, including breakthrough devices, are today routinely covered by the Medicare Administrative Contractors on a claim-by-claim basis without an NCD or CED ever being issued. Nevertheless, CMS presents an approach that would establish an NCD with CED within six months of FDA authorization of an eligible Breakthrough Device.<sup>18</sup> During that interim six-month period, CMS effectively halts beneficiary access to the innovative technology and compromises outcomes for beneficiaries who have a life-threatening or irreversibly debilitating condition. For Medicare patients that would benefit from an FDA-approved or cleared breakthrough device at the time of FDA market authorization, any waiting period without coverage can have a detrimental impact on their care or survival. CMS therefore presents another illusion of choice for manufacturers: Manufacturers who are driven to bring their innovative, new technologies to beneficiaries as soon as possible must undertake the TCET pathway – despite the coverage restrictions imposed – or patients will not have the option to access an item with clinical benefit. We object to these delays and urge CMS to develop a pathway that provides robust access to beneficiaries of breakthrough devices upon FDA approval or clearance.

**IV. CMS Establishes Arbitrary Constraints that Hinder Meaningful Participation in the TCET Pathway**

CMS also proposes to impose—needlessly and without explanation—arbitrary limitations on patients and the manufacturer's ability to meaningfully participate in the TCET pathway and, ultimately, to make their products available to beneficiaries in an expeditious manner. We are concerned that CMS' arbitrary time constraints around interactions with the Agency will fundamentally impair the utility of the TCET pathway.

CMS fixes short and strict schedules that will likely preclude patients from obtaining coverage for their eligible Breakthrough Device. CMS specifies it will limit the initial intake meeting with TCET pathway candidates (manufacturers, not patients) at 30 minutes and the Evidence Preview ("EP")

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<sup>17</sup> *Id.* at 41636.

<sup>18</sup> *Id.* at 41639.

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meetings with appropriate TCET candidates at 60 minutes.<sup>19</sup> CMS does not offer any rationale, nor scientific data, nor empirical evidence to support these durations. By constraining the initial intake meeting to a half hour, CMS curtails all stakeholders' opportunity to explain its complex, breakthrough device to CMS and to obtain answers about the TCET pathway. Additionally, the patient's voice in the early stages is completely ignored by the proposal. Before the meeting ever begins, CMS already undermines the crucial, first step for patients or a manufacturer to present its case for eligibility to the TCET pathway, to present the relevance and importance of its device for Medicare populations, and to understand how to achieve coverage for beneficiaries under this wholly new process.<sup>20</sup> Similarly, in capping the EP meeting to an hour, CMS stifles stakeholders' capacity to: (i) discuss with CMS, AHRQ, and FDA the agencies' assessment of the strengths and weaknesses of publicly available evidence for the item or service, including any gaps for coverage purposes; and (ii) propose corrections to any errors and raise any concerns with the Evidence Preview.<sup>21</sup> CMS effectively paralyzes the opportunity for all key parties to come to a mutual understanding about the state of evidence, which informs the subsequent Evidence Development Plan ("EDP") (*i.e.*, CED requirements) and impacts which beneficiaries can access the eligible Breakthrough Device, when, and how.

We seek the Agency's clarification on the basis for these time constraints. If the Agency upholds these strict parameters, we respectfully request the Agency establish a process that allows all stakeholders, including patients, to request a meeting with their respective CMS, AHRQ, and/or FDA reviewers at any point during the prescribed TCET process and the Agency commit to responding to those requests in a timely manner.

**V. CMS Inadvertently Discriminates Against Older Americans and Select Manufacturers**

CMS generally discriminates against Medicare beneficiaries by capping the TCET pathway to no more than five candidates per year.<sup>22</sup> CMS explains that it must limit the TCET pathway at this time due to alleged "resource constraints."<sup>23</sup> But CMS does not reconcile this arbitrary ceiling with the number of new devices which are potential candidates for the pathway. In reality, CMS is nowhere close to the total number of FDA breakthrough designations granted each year. FDA issued 64 breakthrough designations in the first quarter of 2023 alone, 166 in 2022, 151 in 2020, and 110 in 2019.<sup>24</sup> It is all but certain that the limits on TCET candidates will create access issues to Medicare beneficiaries, who now will be limited to a lottery of five breakthrough devices per year, when others have access to the full range of approved devices to meet their medical needs.

Importantly, the legal standard of "reasonable and necessary" does not include an exception to coverage because the Agency is limited by resource constraints to properly evaluate coverage. Indeed, one can speculate that CMS is compelled to limit the duration of the meeting because of Agency convenience—not beneficiary need—as CMS attempts to duplicate the role of FDA by re-

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<sup>22</sup> 88 Fed. Reg. at 41644.

<sup>23</sup> *Id.*

<sup>24</sup> U.S. Food & Drug Admin., *Breakthrough Devices Program* (updated July 12, 2023), <https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program#metrics>.

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visiting the medical evidence. But for the sake of beneficiary access CMS must concede that FDA, in designating a product as a breakthrough device, would have already determined that the evidence demonstrates the device provides a more effective treatment or diagnosis for a life-threatening or irreversibly debilitating disease or condition. In doing so, the approved or cleared product either represents breakthrough technology, presents the only option for treatment (*i.e.*, no approved or cleared alternatives exist), offers significant advantages over existing approved or cleared alternatives, or its availability is in the best interest of patients. Rather than expending program resources on restricting access – and with insufficient staff to meet the need for timely and thorough review that would be generated by the TCET – we encourage the agency to consider that CMS simply has no clinical basis to second-guess FDA’s determination or to suggest that FDA’s determination is not reliable for the Medicare population.<sup>25</sup> Congress intended to authorize FDA to carry out the Breakthrough Devices Program and provided FDA with the resources and personnel with expertise to make these determinations, including review of the extensive clinical information that must be provided without CMS’ influence.

We are separately dubious with CMS’ framing of the TCET pathway as an effort to assist the greatest number of beneficiaries. While we agree that CMS should facilitate access to innovative technologies, we are mindful that CMS’ use of CED is inextricably tied to limiting Medicare expenditures.<sup>26</sup>

**VI. CMS Oversteps its Jurisdiction and Interferes with the Practice of Medicine**

Notwithstanding the flaws and consequences of the TCET pathway, CMS’ deployment of the NCD process raises a separate threshold issue. It appears that CMS’ justifications for using the NCD process—at least here, in the TCET pathway—contravenes the Act.

CMS explains that it views the NCD process as a mechanism to erect “appropriate safeguards” for Medicare beneficiaries such as coverage criteria. CMS continues that, “[u]nless these coverage criteria are established within coverage determinations, devices could be provided by unqualified individuals, offered at inappropriate facilities, and utilized by patients who may be unlikely to benefit.”<sup>27</sup>

But this explanation flies counter to the statutory mandate. Section 1801 of the Act provides, in relevant part:

*Nothing in this subchapter shall be construed to authorize any Federal officer or employee to exercise any supervision or control over the practice of medicine or the manner in which medical services are provided, or the selection, tenure, or compensation of any officer or employee of any institution, agency, or person*

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<sup>25</sup> By submitting manufacturers to its demands for including individuals who reflect the ages, demographics, and comorbidities of Medicare populations, CMS overlooks other clinical or scientific justifications to exclude such patients from clinical investigations.

<sup>26</sup> See Comment from Alzheimer’s Disease Task Force to CMS, *supra* note 4, at 28; FAÇADE OF EVIDENCE, *supra* note 5, at 11.

<sup>27</sup> 88 Fed. Reg. at 41638.

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*providing health services; or to exercise any supervision or control over the administration or operation of any such institution, agency, or person.*<sup>28</sup>

The plain meaning of Section 1801 suggests that CMS cannot interfere with the practice of medicine, including who can provide healthcare services, what types of services they can provide, how they can provide those services, and where they can provide those services. Yet CMS in equally plain language concedes that it plans to utilize coverage criteria to regulate exactly that which are prohibited (*i.e.*, healthcare provider qualifications, healthcare settings, and recipients of healthcare services).

Courts have considered whether Section 1801 would be violated in similar contexts to those presented here. In *American Medical Association v. Weinberger*, the district court raised a potential Section 1801 question when the Secretary of Health and Human Services sought to enforce regulations that would have conditioned Medicare and Medicare reimbursement on the establishment by hospitals of “utilization review” committees, which were charged with assessing “medical necessity of a patient’s admission within 24 hours thereof.”<sup>29</sup> The court opined that, “[i]f the regulations do in fact produce decisions by doctors to admit, the Secretary by promulgating them has ‘exercis(ed) ... supervision or control over the practice of medicine.’”<sup>30</sup> Here, courts may likewise find that CMS’ attempt to supervise or control healthcare provider qualifications, healthcare settings, and recipients of healthcare services violates the statute.

We agree with CMS that Medicare beneficiaries, like all Americans, should not receive care from unqualified individuals, be offered care at inappropriate facilities, and that patients should only be offered care if they are likely to benefit. But the blunt instrument of NCD (with or without CED) does not, and cannot, address these problems. Nor under the statute may CMS use CED to regulate the practice of medicine.

**VII. CMS Leaves Open Major Questions About the TCET Pathway**

While we applaud CMS’s efforts to provide transparency through this Notice, CMS still leaves major, unfinished details about the TCET pathway. We ask the agency to revert the TCET paradigm and reinstate the proposed MCIT program. In the absence of this action, the Alliance respectfully asks that CMS provide additional information on the following matters:

- The purpose of and requirements for the “continued access study” that should be included in a sponsor’s EDP;<sup>31</sup>
- The meaning and significance of a post-market fit-for-purpose study’s potential to “demonstrate[e] external validity” with respect to an EDP submission, and whether such potential is a criterion for the protocol;<sup>32</sup>

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<sup>28</sup> 42 U.S.C. § 1395.

<sup>29</sup> *Am. Med. Ass’n v. Weinberger*, 395 F. Supp. 515, 524 (N.D. Ill. 1975).

<sup>30</sup> *Id.*

<sup>31</sup> 88 Fed. Reg. at 41641.

<sup>32</sup> *Id.*



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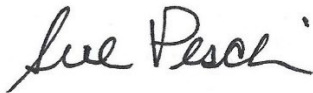
- The expectation that sponsors submit their analysis of evidence collected under CED requirements for peer-reviewed publications, and the precedent for requiring peer-reviewed publication for Medicare coverage;<sup>33</sup>
- The availability of resources (or lack thereof) at AHRQ and/or CMS to support the agencies' work to evaluate the EP and EDP and to provide feedback to manufacturers throughout the TCET pathway;<sup>34</sup>
- The nature and manner in which CMS will collaborate (or has collaborated) with AHRQ to "update specific aspects of the CED paradigm" following public input;<sup>35</sup> and
- The identity of the contractor that CMS intends to engage to conduct the EP and the standards that it will use to conduct the EP.<sup>36</sup>

**VIII. Conclusion**

We appreciate the opportunity to provide feedback on CMS's notice for the TCET pathway. However, we cannot overlook that the proposed strategy defeats Congress's goals of ensuring that breakthrough devices are made accessible to patients quickly, without CMS's intervention. For the reasons discussed above, we recommend the Agency to restore the prior MCIT final rule and presumptively cover all eligible Breakthrough Devices for a period of four years (subject to the limitations of the prior final rule).

If you have any questions, please do not hesitate to contact us. You may direct inquiries to Susan Peschin, President and CEO of Alliance for Aging Research, at [speschin@agingresearch.org](mailto:speschin@agingresearch.org).

Sincerely,



Susan Peschin  
President and CEO



Michael Ward  
Vice President of Public Policy and Government Relations

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<sup>33</sup> *Id.* at 41642.

<sup>34</sup> *Id.* at 41638.

<sup>35</sup> *Id.*

<sup>36</sup> *Id.* at 41640.