



August 28, 2023

Chiquita Brooks-LaSure  
Administrator  
Centers for Medicare & Medicaid Services  
7500 Security Blvd  
Baltimore MD 21244

**Re: Medicare Program; Transitional Coverage for Emerging Technologies (CMS-3421-NC)**

Dear Administrator Brooks-LaSure,

The Advanced Medical Technology Association (AdvaMed) is pleased to offer comments on the Centers for Medicare & Medicaid Services' (CMS) Transitional Coverage for Emerging Technologies (TCET) notice.<sup>1</sup> AdvaMed has long supported both policy and process improvements that would result in a predictable pathway to national Medicare coverage for new medical devices and diagnostics.

AdvaMed's member companies produce the life-saving and life-enhancing medical devices, diagnostic products and health information systems that are transforming health care through earlier disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest to the smallest medical technology innovators and companies, producing health care technology both in the United States and around the world.

Given the diversity of our membership, we have several associations within AdvaMed that serve specific medical device, digital, and diagnostic sectors. AdvaMedDx functions as an association within AdvaMed and its member companies produce advanced in vitro diagnostic tests that facilitate evidence-based medicine, improve quality of patient care, enable early disease detection, and often reduce overall health care costs. Another division, AdvaMed Accel, represents small and mid-sized companies. Many of these early-stage, start-up, and pre-revenue companies create breakthrough devices that would be directly affected by the TCET notice and would benefit from greater predictability regarding coverage of breakthrough technologies. AdvaMed Accel intends to submit separate comments specifically addressing the importance of the TCET program to the small company ecosystem. Our third division, AdvaMed Digital Health Tech, includes the leading innovators in digital health. These companies represent leaders in medical devices, digital therapeutics, healthcare information technology, and emerging technologies for patients and consumers. These companies are directly impacted by the predictability of coverage for new technologies.

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<sup>1</sup> Federal Register, Vol. 88, No. 122, pp.41633-41644, June 27, 2023



Medicare has broad authority to provide coverage for items and services that are determined to be reasonable and necessary for Medicare beneficiaries. Most Medicare coverage is determined at a local level using the reasonable and necessary standard. In some cases, Medicare will develop a National Coverage Determination (NCD), which specifies coverage of an item or service, and outlines specific coverage parameters. Medicare NCDs are widely influential because they directly apply to the 65 million Medicare beneficiaries enrolled in fee-for-service Medicare and Medicare Advantage (MA) plans but also because Medicaid programs and commercial insurers often view NCDs as a baseline for establishing their own coverage policies.

In 2016, Congress enacted the 21st Century Cures Act<sup>2</sup> which, among other things, advanced medical device innovation by creating a new Food and Drug Administration (FDA) program to expedite the development of diagnostics and devices that represent “Breakthrough” technologies and to promote their use in health care delivery. At that time, Congress did not include provisions that would have created a streamlined approach to Medicare coverage, coding, and payment for those innovations.

However, CMS did expand the methodologies for providing additional payment for new technologies, including Breakthrough technologies, in the hospital inpatient and outpatient prospective payment systems. For example, in its Fiscal Year (FY) 2020 Hospital Inpatient Prospective Payment System (IPPS) final rule, CMS provided for an alternative new technology add-on payment (NTAP) pathway for Breakthrough technologies, deeming such technologies to meet criteria for newness and substantial clinical improvement and thus to automatically qualify for NTAP if the cost criterion was also met. In the Calendar Year (CY) 2020 Hospital Outpatient Prospective Payment System (OPPS) final rule, CMS provided for an alternative transitional pass-through payment (TPT) for Breakthrough technologies, deeming such technologies to meet the substantial clinical improvement and thus to automatically qualify for TPT payment if the newness and cost criteria are also met.

Unfortunately, CMS did not provide an expedited coverage pathway for innovative technologies. AdvaMed, and other stakeholders, believe this is an equally critical need that needs to be addressed. Additionally, a recent study published in *JAMA Health Forum* measured time from FDA authorization to Medicare coverage for technologies requiring a new reimbursement pathway and found that of the 64 novel technologies with no current reimbursement pathway, only 44 percent successfully achieved explicit or implicit coverage following FDA authorization, with a median time to coverage of 5.7 years.<sup>3</sup> This is not acceptable.

AdvaMed and CMS do share a common goal – the establishment of a clear and expeditious coverage process, based on scientifically sound clinical evidence with appropriate safeguards, for emerging technologies that will benefit Medicare-eligible patients, including the 51 percent of Medicare-eligible patients enrolled in MA organizations—which include high numbers of Black,

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<sup>2</sup> P.L. 114-255, December 13, 2016.

<sup>3</sup> Sexton, Z. A., Perl, J. R., Saul, H. R., Trotsyuk, A. A., Pietzsch, J. B., Ruggles, S. W., Nikolov, M. C., Schulman, K. A., and; Makower, J. (2023). Time from authorization by the US Food and Drug Administration to Medicare coverage for Novel Technologies. *JAMA Health Forum*, 4(8). <https://doi.org/10.1001/jamahealthforum.2023.2260>



Latino, and dual-eligible enrollees.<sup>4,5,6</sup> We applaud CMS' efforts to recognize the importance of new innovations and the role they play in improving the lives of patients with debilitating illness. The TCET notice is a positive incremental step forward and represents CMS' continuing commitment to ensuring Medicare beneficiaries have access to new and innovative technologies that improve health and outcomes. ***AdvaMed strongly supports the TCET program proposal for FDA-designated Breakthrough technologies and urges CMS to finalize the TCET notice as quickly as possible, incorporating the recommendations made below, to ensure the TCET program will be fully leveraged to bring Medicare beneficiary access to Breakthrough technologies.***

### ***Overarching Recommendations***

AdvaMed supports CMS' TCET general principles outlined in the notice, many of which reflect recommendations made by AdvaMed last year.<sup>7</sup> ***Our comments make recommendations to better leverage the TCET program for Breakthrough technologies, including diagnostic laboratory tests, and make refinements to timelines and process to help impart more transparency and predictability. We want to emphasize how important it is to have clear understanding of timelines, both for the manufacturer and CMS at every step in this process.*** Again, AdvaMed appreciates CMS's efforts to improve access to new medical technologies in this notice and we offer detailed comments below related to:

- I. CMS Resources and Prioritizing Requests
- II. Appropriate Candidates
- III. Procedures for the TCET Pathway
- IV. Coverage under the TCET Pathway
- V. Transition to Post-Coverage

AdvaMed recommends that CMS move quickly to finalize the TCET notice incorporating the clarifications and refinements below, recognizing that additional refinements may be needed in the future. We encourage CMS to commit to routine evaluation and on-going refinement. Beyond TCET, we see additional opportunities to continue to work with CMS, using its existing authority, to continue to expand and accelerate access to innovative technologies after they are proven safe and effective by the FDA, and we look forward to continuing our work with the Agency.

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<sup>4</sup> David J. Meyers, Vincent Mor, Momotazur Rahman, and Amal N. Trivedi (June 7, 2021) Growth In Medicare Advantage Greatest Among Black And Hispanic Enrollees, *Health Affairs* Vol. 40:6 (945-950). <https://www.healthaffairs.org/doi/pdf/10.1377/hlthaff.2021.00118>.

<sup>5</sup> Sungchul Park PhD, Rachel M. Werner PhD, MD, Norma B. Coe PhD (March 27, 2022). Racial and ethnic disparities in access to and enrollment in high-quality Medicare Advantage plans. *Health Services Research (Wiley Online Library)*. <https://doi.org/10.1111/1475-6773.13977>.

<sup>6</sup> Chris Tachibana, PhD (May 5, 2022). Why Are There Disparities in Enrollment in Medicare Advantage? Fewer High-Quality Plans Are Offered to Racial and Ethnic Minority Groups, Penn LDI Leonard Davis Institute of Health Economics. <https://ldi.upenn.edu/our-work/research-updates/why-are-there-disparities-in-enrollment-in-medicare-advantage/>.

<sup>7</sup> AdvaMed Pre-rulemaking Letter to CMS on TCET. AdvaMed. (2022, August 1). <https://www.advamed.org/wp-content/uploads/2022/08/advamed-tcet-prerulemaking-letter-chiquita-brooks-lasure.pdf> (Accessed August 12, 2023)



## I. CMS Resources and Prioritizing Requests

### Impact of CMS Resource Constraints on TCET Program Utilization

Throughout the TCET notice, CMS cites resource constraints as justification for TCET program design decisions, namely restricting the pathway to five products annually. CMS acknowledges more than five technologies will try to access the TCET program each year, but CMS is limiting the number of TCET applications it will accept to no more than five. CMS has not provided any reasonable policy rationale to support limiting the number of TCET applications per year. This is an arbitrary limit that seems to be driven by limited CMS resources.

During CMS' August 1, 2023, TCET Stakeholder Call, the Agency committed to reassessing the number of technologies within TCET and explore ways to accommodate an increased number as resources allow.<sup>8</sup> While we recognize and appreciate CMS' willingness to refine TCET after implementation, resource constraints should not dictate policy making or beneficiary access to innovative technologies.

The TCET program should accommodate all Breakthrough-designated devices and diagnostic laboratory tests that opt to be nominated for the pathway. By placing an arbitrary limitation on the number and type of technologies granted access to the TCET program, CMS will be forced to make value judgments between technologies based on which it believes will confer the greatest benefit on the highest number of beneficiaries. This prioritization scheme compounds the inequities inherent in limiting access to the TCET program; inevitably, some beneficiaries will be deprived of access to innovative technologies capable of saving or improving their lives. Additionally, with the arbitrary limit of five technologies annually, manufacturers may have a perverse incentive to engage with CMS earlier than necessary prior to FDA authorization, in an effort to ensure they are not edged out of the opportunity to pursue TCET, which may cause added vetting by CMS and exhausting valuable resources. In order to fully leverage the TCET program, if a product meets TCET eligibility criteria, it should have the option to pursue coverage under TCET, with no restrictions on the number eligible annually.

AdvaMed is committed to helping CMS receive those resources and recently commissioned a white paper to assess the Medicare coverage process.<sup>9</sup> The report focuses on coverage for devices and existing issues related to procedural delays, the lack of transparency in Medicare's NCD process, the use of Coverage with Evidence Development (CED), harmonizing with the FDA, and ensuring patient safety. The report offers six recommendations that aim to improve the NCD process, either through changes to the Medicare statute or regulation or both, and also provides four additional recommendations to enhance agency staffing resources. The report found that the number of NCD requests completing the NCD process decreased annually

<sup>8</sup> See *Comments from Dr. Steve Farmer*. Transcript of TCET Stakeholder Call, August 1, 2023. <https://www.cms.gov/files/document/transcripttransitionalcoverageforemergingtechnologies08012023.pdf>

<sup>9</sup> Gaumer, Z., Bassano, A., Mannon, M., Payne, C., and Macdonald, A. (2023, July 20). Medicare coverage processes: An analysis of procedural and resource concerns. AdvaMed. <https://www.advamed.org/wp-content/uploads/2023/07/AdvaMed-HMA-NC-Report-07202023.pdf> (Accessed August 12, 2023)



between 2003 and 2022, as the length of time required to complete the NCD review process increased.<sup>10</sup>

### **Prioritization of TCET Nominations**

CMS plans to prioritize devices it determines to have potential benefit for the greatest number of Medicare beneficiaries. With the recommendation to finalize TCET with no annual limit on the number of nominations, prioritization of requests shouldn't be necessary. However, if prioritization is required, AdvaMed recommends CMS establish more clearly defined and transparent criteria such as: technologies that have a significant impact to improve lives; work to address an unmet patient need; and/or work to address health disparities.

Improving the operational aspects of the NCD process, including CED and the TCET program, is important because this process plays a critical role in maintaining a robust Medicare program. The consistency of the NCD process across fee-for-service Medicare and MA is particularly important as MA plans have grown rapidly in recent years. With the release of TCET, CMS has demonstrated a commitment to ensuring beneficiaries have access to innovative medical technologies. We respectfully request CMS fully commit to the vision of improved beneficiary access to novel technologies by removing arbitrary barriers to the TCET program.

#### ***Recommendations:***

- **AdvaMed recommends no annual limit on the number of applications accepted into the TCET program.**
- **CMS should work with Congress to provide more resources for CMS to ensure it can effectively carry out its mission in a timely manner, including the TCET program.**
- **With no annual limit on TCET nominations, prioritization of requests should not be required. If needed, AdvaMed recommends that CMS establish more clearly defined and transparent criteria.**

## **II. Appropriate Candidates**

### **Inclusion of *In Vitro* Diagnostic Products (IVDs)<sup>11</sup>**

The TCET notice states:

*In section 201(h)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321(h)(1), the definition of devices includes diagnostic tests. Diagnostic lab tests are a highly specific area of coverage policy development, and CMS has historically delegated review*

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

<sup>11</sup> The notice refers to diagnostic laboratory tests, but does not define the term. For purposes of clarity, we recommend using the term *in vitro* diagnostic product (IVD), a term defined per FDA regulation and well-understood by regulated industry. "In vitro diagnostic products are those reagents, instruments, and systems intended for use in the diagnosis of disease or other conditions, including a determination of the state of health, in order to cure, mitigate, treat, or prevent disease or its sequelae. Such products are intended for use in the collection, preparation, and examination of specimens taken from the human body. These products are devices as defined in section 201(h) of the Federal Food, Drug, and Cosmetic Act (the act), and may also be biological products subject to section 351 of the Public Health Service Act." 21 CFR Sec. 809.3



*of many of these tests to specialized MACs. We believe that majority of coverage determination for diagnostic tests granted Breakthrough Designation should continue to be determined by the MAC through existing pathways.*

At the outset, we believe CMS should clarify the applicability of this exclusion given the conflicting language used in the Notice. In this regard, the first and third sentence of the exclusion refer to “diagnostic tests,” while the second sentence uses the term, “diagnostic lab test.” For purposes of our comments, we assume the proposed exclusion only applies to IVDs and not to other diagnostic tools, such as imaging devices.

IVDs are an important sector of emerging medical technologies, and just like other medical devices, face barriers and delays to achieving Medicare coverage. On the heels of a multi-year public health emergency, the nation experienced firsthand the value and importance that IVDs have on Americans’ lives. As of March 2023, of the 786 technologies with breakthrough designation, approximately 20 percent are IVDs.<sup>12</sup> Of the 65 Breakthrough technologies that have been authorized by FDA, approximately 20 percent are IVDs.<sup>13</sup> For example, earlier this year a test for traumatic brain injury was approved with Breakthrough designation and provides clinicians with the ability to assess concussions and triage patients. Additionally, in 2022, FDA authorized through the Breakthrough program two tests that measure analytes in human specimen to assess the underlying pathology in conjunction with clinical assessment to increase diagnostic certainty for Alzheimer’s Disease. Currently, there is no coverage policy for Alzheimer’s Disease clinical laboratory tests (i.e., NCD or LCD). However, the language within the notice regarding the eligibility of IVDs clearly excludes these innovative—and potentially lifesaving—tests from the TCET program. Preventing IVDs from participating in the TCET program runs counter to CMS’ main TCET objective to ensure Medicare Beneficiaries have access to emerging technologies.

IVDs are no more specific than other medical devices, and IVDs are not the only area where, historically, review has occurred under the local jurisdictions of Medicare Administrative Contractors (MACs). CMS’ TCET proposal should include IVDs reviewed and authorized by FDA. While MACs assist CMS in determining whether an IVD is appropriate for Medicare coverage, laboratory-developed tests—which do not undergo FDA premarket review—would be ineligible for the TCET program.

Moreover, the MolDx Program, which makes coverage determinations specifically for molecular diagnostic tests and establishes coverage for six MAC jurisdictions, will continue to be active

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<sup>12</sup> Using FDA’s Breakthrough website to determine the percentage of Breakthrough Device designations identified as IVDs, clinical panels for immunology, molecular genetics, clinical chemistry, pathology, microbiology, and clinical toxicology were added together and divided by the total number of Center for Devices and Radiological Health (CDRH) has granted (786). <https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program#s8> (Accessed August 10, 2023)

<sup>13</sup> To determine the percentage of Breakthrough Device market authorizations identified as IVDs, the list provided on the website of market authorizations was scanned for IVDs, added together, and divided by the number of total CDRH devices with Breakthrough Device market authorization (65). <https://www.fda.gov/medical-devices/how-study-and-market-your-device/breakthrough-devices-program#s8> (Accessed August 10, 2023) Market authorization includes FDA approval via the premarket approval application (PMA), and FDA clearance through the 510(k) clearance or *de novo* submission pathways.



and available for use by molecular diagnostic test manufacturers who achieve FDA authorization via the Breakthrough pathway. However, this MAC-level coverage pathway includes several coverage limitations, and IVDs should be given the opportunity to pursue the TCET program for national coverage. For example, one of our members has developed a blood test that has received Breakthrough Device Designation. The test predicts progression to cirrhosis and liver related events in patients with nonalcoholic steatohepatitis, but because it is a protein-based test, it will not be reviewed by the MoIDX Program. While MoIDx can and should remain an option for these FDA approved tests and manufacturers, it should not be the only pathway available for novel Breakthrough technologies. The MoIDx Program is not a national program and by definition would limit access to care in regions that do not participate in the program, as a result it should not be perceived as an adequate substitute for a national coverage option through the TCET program. We therefore believe any medical device that receives Breakthrough Device market authorization by the FDA and meets the other TCET criteria, including IVDs, should be eligible for TCET. Including IVDs within the eligibility criteria is also consistent with the Medicare Coverage for Innovative Technologies (MCIT) final rule<sup>14</sup> and the Parallel Review Program.<sup>15</sup> In fact, as of June 2023 there have been 96 formal requests to participate in the Parallel Review Program, and the only two products that have achieved coverage via the Parallel Review Program were IVDs.<sup>16</sup>

#### ***Recommendation:***

- **FDA authorized IVDs with Breakthrough Designation should be equally eligible to pursue the TCET pathway.**

#### **Medicare Benefit Category**

One of the criteria for a TCET candidate is that a product must be “within a Medicare benefit category.” *AdvaMed supports a broad definition of “within a benefit category,” as this approach aligns with the purpose of the TCET program to provide an additional pathway to Medicare coverage for innovative breakthrough technologies (including diagnostic and screening tests) in order to avoid unnecessary access delays following FDA authorization.*

AdvaMed recognizes that CMS does not have authority to cover technologies that do not fit within a benefit category. However, CMS should review and update current regulatory definitions of existing Medicare benefit categories to reflect technological innovations in clinical practice and health care delivery. One area where review and consideration of changes to regulations can create opportunities for coverage within Medicare’s current benefit category

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<sup>14</sup> In the MCIT final rule (CMS-3372-F), CMS clarified that any medical device that receives such designation by the FDA (section 515B(d)(1) of the FD&C Act (21 U.S.C. 360e-3(d)(1)) and meets the other criteria outlined in this rule is eligible for the MCIT pathway. This includes any clinical lab diagnostic test, including in-vitro diagnostics, and devices that are not implanted, as long as it meets the MCIT eligibility criteria as outlined at § 405.603.

<sup>15</sup> Federal Register. Vol. 81. No. 205. pp. 73113-73115. October 24, 2016.

<sup>16</sup> See *Q&A for Parallel Review*. Center for Devices and Radiological Health. (2023, July 20). Device coverage initiatives: Connecting with payors. U.S. Food and Drug Administration. <https://www.fda.gov/about-fda/cdrh-innovation/medical-device-coverage-initiatives-connecting-payors-payor-communication-task-force#:~:text=In%202011%2C%20the%20FDA%20and,the%20subsequent%20CMS%20national%20coverage> (Accessed August 12, 2023)



structure is the area of digital health technologies, for example those using apps, algorithms, augmented or artificial intelligence, and software as a medical device. Many FDA-designated breakthrough technologies use digital technologies or have digital technology components that define their uniqueness among those technologies used in health care delivery. We believe that many of these technologies could be covered under Medicare's existing benefit categories if a clearer pathway were established through regulation for their coverage.

We are encouraged by CMS activity in this space. Medicare advances in coverage and payment include paying for autonomous AI that can diagnose diabetic retinopathy as a physician service and acknowledging an AI solution that accelerates the time to treatment for patients experiencing stroke in the hospital setting. We also recognize and appreciate that CMS has a request for information in the CY 2024 Physician Fee Schedule proposed rule on a number of different areas to improve the Agency's understanding of the opportunities and challenges related to coverage and payment of one category of digital health technologies, digital therapeutics, under Medicare. We urge CMS, using its existing authority, to continue working with industry and other stakeholders to review and consider additional changes to existing regulatory policies that lack clarity or specificity and actually create unnecessary barriers to coverage of some breakthrough technologies, including but not limited to digital therapeutics.

For example, the FDA has approved a technology that would function as an artificial pancreas for persons with diabetes and defined this technology as having three components: a continuous glucose monitor (CGM), an insulin pump, and an algorithm. The algorithm allows the CGM and insulin pump to talk to each other and automatically adjust the patient's glucose levels. Medicare now covers and pays for each of the first two components as durable medical equipment (DME), but regulations do not provide clarity or specification for how the algorithm could be covered and paid for separately.

We believe that the algorithm could be covered and paid for separately as a supply necessary for the functioning of the technologies that qualify for coverage under the Medicare DME benefit category—in the same way Medicare now covers non-durable test strips used with durable blood glucose monitors and oxygen used in durable oxygen canisters. This example and many others are offered as pathways to coverage for digital technologies in a 2020 AdvaMed-CapView study, "Modernizing Medicare Coverage of Digital Health Technologies." The study examines each of Medicare's major benefit categories to illustrate how coverage and payment for digital technologies can be accommodated through review and changes to existing Medicare regulations, rather than through changes to Medicare statute.<sup>17</sup>

#### ***Recommendation:***

- **CMS should use its existing regulatory authority to ensure AI, virtual, app-based, and other digital technologies will be eligible for the TCET program.**

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<sup>17</sup> For a deeper discussion on this topic focusing on the growth of digital technologies and their implications for the Medicare Program, see AdvaMed-CapView September 2020 report entitled, "Modernizing Medicare Coverage of Digital Health Technologies," <https://www.advamed.org/sites/default/files/resource/advamed-modernizing-medicare-coverage-of-digital-health-technologies-september-2020.pdf>





### **Appropriate Lookback Period for Recently Authorized Breakthrough Products and those Nearing Authorization**

We applaud the Agency for working to develop the TCET notice. However, there are no defined or required timelines for when TCET will be finalized. This creates uncertainty for manufacturers that are nearing or may have been recently granted FDA authorization through the Breakthrough program. For example, one of our members has a product with Breakthrough designation for skin cancer detection. The company announced in June 2022 the successful completion of its FDA pivotal study and announced early this year that it is under review by FDA. The company expects to soon receive FDA authorization, likely before TCET is finalized. Additionally, another member received a Breakthrough Device Designation from the FDA for treating lung tumors on November 16, 2021 – only four days after CMS rescinded the MCIT program on Nov 12, 2021. Technologies like these should be given an opportunity to pursue nomination into the TCET program, but the TCET notice as currently drafted does not address program access for technologies other than those approximately 12 months away from FDA market authorization. AdvaMed recommends that the final TCET notice include a lookback provision to allow TCET eligibility for breakthrough technologies that are FDA market authorized up to three years prior to the effective date of the TCET final notice.

Additionally, when TCET becomes active there will be some products that are well within the 12-month window (e.g., two to three months from FDA authorization) and would like to pursue TCET. While nothing in the notice states they would be barred from pursuing TCET, it is likely that they may not be prioritized given the proposed annual cap on nominations, and the limited timeframe for performing TCET program reviews and approvals. This is further evidence for removing any limit on nominations. AdvaMed recommends that CMS explicitly state that technologies nearing FDA market authorization (i.e., within the 12-month window prior to authorization) are allowed to apply to the TCET program.

#### ***Recommendations:***

- **CMS should provide a lookback provision in the final TCET notice to allow TCET eligibility for Breakthrough technologies that are FDA market authorized up to three years prior to the effective date.**
- **CMS should clarify Breakthrough technologies nearing authorization (i.e., within the 12-month window) upon TCET effective date can also pursue nomination.**

### **New Indication for a Product with an Existing NCD**

Another criterion for TCET eligible candidates is that devices cannot already be the subject of an existing NCD. However, we encourage CMS to expand the TCET eligibility criteria to include technologies with an existing NCD that receive breakthrough designation from the FDA for a novel indication that is non-covered under an existing NCD or that is not related to the existing NCD. It is equally important that new indications with Breakthrough Device market authorization by FDA be eligible for TCET. For example, there is an existing device that has Breakthrough designation for both lower back pain and fibromyalgia, which are very different indications with different evidence and research needs. If the device is covered under an NCD



for indication, it should not negate the opportunity for the device to also be considered under another NCD for the other indication.

***Recommendation:***

- **CMS should expand TCET eligibility to products with an existing NCD that receive breakthrough designation from the FDA for a novel indication.**

### III. Procedures for the TCET Pathway

#### **Transparency into Nomination Process**

Within the TCET notice, there is no public tracking of TCET requests until an NCD is initiated. This means the nomination process, including the number of requestors and the number accepted into the pathway in a given year, is not public. *We believe CMS must provide greater transparency regarding the nomination process and urge that this be included in the final TCET notice.*

Besides what is posted in the Medicare Coverage Database, there is not much transparency from CMS regarding how the Agency manages NCD requests, prioritizes requests or keeps track of requests that are in the queue for future review (the “waiting lists”). CMS at one point did publish an NCD waitlist dashboard on its website but has not updated it since September 2020. This dashboard was a positive step towards greater transparency. We urge CMS to update this dashboard requests and include TCET statistics.

Lack of transparency is an ongoing issue surrounding CMS’ methods for managing NCD requests. We often hear from our members that they have no visibility into the process or timeline for action on their requests. Recently, a letter from House Energy and Commerce members was sent to HHS and CMS leaders urging more transparency in how CMS make NCD determinations.<sup>18</sup>

A key tenet of TCET is the ability to accelerate national coverage for Breakthrough technologies, and thus tracking and available data of timelines in the pre-market phase is crucial to ensuring TCET is effective.

***Recommendation:***

- **CMS should provide public tracking on its website of TCET requests prior to an NCD being initiated, including for each nomination received: the date of nomination, the date of acceptance or rejection, and the date the NCD process was initiated.**

#### **Nominations for the TCET Program**

TCET is a voluntary program. **AdvaMed supports an opt-in approach under which a manufacturer would voluntarily notify CMS to pursue nomination to TCET as early as 12 months prior to an anticipated FDA decision.** An opt-in approach will allow manufacturers to

<sup>18</sup> See [https://d1dth6e84htgma.cloudfront.net/NCD\\_Letterto\\_HHS\\_and\\_CMS\\_July14\\_d05e5c2a74.pdf](https://d1dth6e84htgma.cloudfront.net/NCD_Letterto_HHS_and_CMS_July14_d05e5c2a74.pdf). Letter to Secretary Becerra and CMS Administrator Brooks-LaSure on NCD transparency. July 14, 2023. (Accessed August 13, 2023).



pursue their own business judgment and opportunity to opt-in at any point in time within the 12-month window, although a delay in notifying CMS of a manufacturer's intention to pursue TCET may delay the goal of a finalized NCD within six months after FDA market authorization.

**Recommendations:**

- **AdvaMed supports the opt-in approach of TCET, including the timeframe to submit nominations approximately 12 months prior.**
- **AdvaMed believes manufacturers should be allowed to submit nominations at any point within the 12-month window.**

**Ensure Clear Timeline for Review of Benefit Category, Coding, and Payment**

We support starting the pre-market process early to allow for time to complete all the steps. Achievement of a timely process is dependent upon clear, defined timelines, with a commitment from CMS to meet those established timelines. CMS notes in the background section of the TCET notice that one of the issues with MCIT was lack of process. The TCET notice reads:

*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.<sup>19</sup>*

AdvaMed has long advocated for, and strongly supports, true engagement and dialogue between device companies and CMS. We are encouraged by some of the clear process and timelines present in TCET, and we believe TCET can be improved by providing clearer processes for review and determination of benefit category, coding, and payment. In 2020, CMS established the Technology, Coding and Pricing Group (TCPG) to better coordinate and manage policies related to new technology innovations in care. TCPG, as well as the Hospital and Ambulatory Policy Group (HAPG), will be instrumental in facilitating access to innovative medical products through TCET alongside the Coverage and Analysis Group (CAG). We urge CMS to ensure dialogue between and amongst TCPG, HAPG, and CAG to ensure all processes are in place for coverage, coding, and payment to proceed under the TCET program. To facilitate the pre-market process within the TCET program, CMS should also set forth clear timelines to ensure coding and payment for the device is implemented in a manner that does not delay access to the new technology.

Clear processes and timelines should be better articulated to allow manufacturers to pursue appropriate coding, appropriate placement in payment system categories or establishment of new

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<sup>19</sup> See <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program> , Guidance Document, FDA Breakthrough Devices Program, FDA-2017-D-5966. December, 2018.



payment categories, and adequate reimbursement to support new breakthrough technologies. Without coding and clearly designated payment categories established at the beginning of the TCET process, manufacturers will be challenged to generate the evidence CMS may expect if CED is deployed.

Again, we encourage CMS to finalize TCET quickly, recognizing that additional refinements may be needed in the future, and we encourage CMS to commit to routine evaluation and ongoing refinement. While it may take time to resolve all of these coordination issues, CMS can manage these issues through subregulatory guidance and ongoing refinement. To that end, AdvaMed recommends that *all* steps be clearly defined, including timeframes for key activities, in public facing guidance documents.

***Recommendations:***

- **CMS should ensure there are appropriate and clear processes in place to facilitate engagement within appropriate groups at CMS including CAG, HAPG, and TCPG.**
- **CMS should clearly articulate the process for benefit category, coding, and payment review under TCET, with distinct timelines.**
- **CMS should create a process for assigning a specific code, if needed, to products accepted into the TCET program, so that codes are available for use at the start of the TCET coverage period, if needed.**

**Evidence Preview, Meeting, and Sharing Evidence Preview with MACs**

AdvaMed recognizes that CMS intends to utilize a third-party contractor for the updated evidence review. We strongly recommend that the process include an open dialogue engagement with the manufacturer to aid the contractor in their review. This is especially important for new technologies where literature search queries are more involved. We believe manufacturers should have the ability to provide recommended search criteria and submit a dossier to aid the contractor. Additionally, the Evidence Preview provided back to the manufacturer should provide detailed information on how the review was performed. And while we support CMS' proposal to hold a meeting to discuss the Evidence Preview and allow the manufacturer to propose corrections and raise any important concerns, we believe ongoing engagement with the contractor to fill in potential gaps in the evidence will be beneficial to ensuring that this process can be completed in 12 weeks. One way to facilitate dialogue would be to establish a point of contact at the manufacturer to coordinate answering questions from the contractor and a point of contact at the contractor in case new evidence becomes available that the manufacturer wants to provide. Outside of more engagement and allowance to provide information, we are concerned there may be delays in completing this process in a timely fashion. Moreover, to encourage transparency, we believe that CMS should post the list of contractors used to its website.

For those manufacturers who withdraw from the TCET pathway following the completion of an Evidence Preview, CMS is soliciting public feedback on its proposal to share the Evidence Preview with the MACs to aid them in their decision making. AdvaMed disagrees with this proposal and asks that it not be included in the final notice. The Evidence Preview is an important early phase within the TCET pathway and would be outdated by the time the device has obtained



FDA approval. Therefore, manufacturers should retain the authority to share their updated and complete evidence with the MACs at their own discretion and on their own timeline.

***Recommendations:***

- **AdvaMed recommends establishing points of contact to facilitate dialogue between the manufacturer and the contractor responsible for conducting the Evidence Preview.**
- **To increase transparency, AdvaMed recommends that CMS publish on its website a list of contractors used for this process.**
- **AdvaMed urges CMS not finalize the proposal to share the Evidence Preview with the MACs, and instead allow the manufacturer to share their evidence with the MACs at their own discretion.**

**Evidence Development Plan (EDP) Development**

If the evaluation of clinical evidence results in finding that evidence gaps exist or that more evidence is needed to assure CMS that the technology improves outcomes for Medicare beneficiaries, manufacturers will develop a plan, in collaboration with CMS, for generating such evidence as is necessary during the transitional coverage period. We agree with CMS that the design of the EDP should be conducted to reflect a least burdensome approach to evidence generation to promote access. CMS, manufacturers, and their clinical partners should establish a reasonable, mutually agreed, data collection period appropriate for the disease and stage of disease that the technology is designed to treat. An important consideration for any EDP is to strike the right balance between the collection of the most meaningful datapoints that will be needed to demonstrate a benefit to the healthcare system without making the list so long that it becomes too burdensome on the users. AdvaMed is supportive of CMS' willingness to incorporate robust fit-for-purpose evidence development into TCET, and we look forward to the Agency's forthcoming guidance. Also, we understand that registries might be needed in some cases, routinely collected real-world data, could replace the need for extensive clinical data outside the scope of CMS's key questions.

Additionally, CMS proposes for manufacturers to develop 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. AdvaMed seeks CMS' clarification on the timeline for "continued access," and also recommends CMS allow less burdensome alternatives for data collection (e.g., literature review, claims data analysis), especially considering the more readily available source of claims data and clinical studies at this stage. There should be a cutoff for continued data analysis that does not extend beyond what would be considered reasonable for a statistically significant number of patients (e.g., 200). Continued access to data that extends indefinitely would stretch CMS' and its contractors' resources and budget that could otherwise be used to support newer technologies entering into the TCET pathway. In addition, the coverage benefits should be maintained until a final NCD is established.



***Recommendations:***

- **AdvaMed supports CMS’ plan to use more agile approaches such a fit-for-purpose studies, that require the minimum amount of information necessary to adequately address the relevant clinical question or issue in the most efficient manner.**
- **AdvaMed seeks clarification on the timeline for use of “continued access” to better ensure clarity for manufacturers participating in TCET.**
- **AdvaMed recommends CMS allow less burdensome alternatives (e.g., literature review, claims data analysis) for data collection for the continued access study.**

**IV. Coverage under the TCET Pathway**

**Request for Specific Stakeholder Input on the Evidence Base and Conditions of Coverage**

We commend CMS for exploring options to increase ways it receives feedback from the relevant specialty societies and patient advocacy organizations. While CMS prefers to have information from these groups during the initial public comment period upon opening the NCD, CMS recognizes this not always possible as these technologies have recently received authorization. Therefore, CMS is encouraging these organizations to publicly post on their website any additional feedback or relevant practice guidelines within 90 days of CMS opening the NCD, and to contact CMS when this information has been posted. CMS states that all information it considers in developing the proposed TCET NCD will then become part of the NCD record and will be part of the NCD’s bibliography.

AdvaMed supports efforts to expand ways to receive input from these organizations and recommends CMS post a notification on its website and to notify the manufacturer when it receives additional information from an organization. Further, the manufacturer should also have the ability to provide a timely response to CMS on this additional information prior to its inclusion in the NCD bibliography.

***Recommendation:***

- **AdvaMed supports expanding ways to receive stakeholder input, but recommends CMS notify the manufacturer upon receipt of the additional information, post this information on CMS’ website, and allow the manufacturer to provide a response to CMS in a timely manner.**

**Coverage of Similar Devices**

The FDA Breakthrough Devices Program is designed to be product-specific, which differs from CMS’ traditional categorical approach to coverage, under which CMS typically covers and pays for similar products, or procedures in which similar technologies are used, in the same way. In other words, similar technologies manufactured by different companies may be covered in a procedure under a single NCD. The TCET notice outlines a general process for similar devices. However, AdvaMed seeks clarification on whether CMS intends for similar devices to have Breakthrough status as the language within the notice is unclear in this respect.



AdvaMed supports similar devices being subject to the same coverage conditions, including a requirement to propose an EDP. This would provide similar technologies with the opportunity to leverage the TCET program and provide Medicare beneficiaries with faster access to these technologies. In the event that CMS does not remove the annual limit of 5 technologies, coverage of similar devices should not count against any annual limit. Each of these Breakthrough technologies should be eligible for TCET under an applicable existing CED or NCD.

FDA has contemplated situations where multiple devices with the same intended use may be granted breakthrough designation. Under FDA's guidance for breakthrough devices:

*Breakthrough Device designation may be granted for multiple devices with the same proposed intended use, and a Breakthrough Device designation will not be revoked solely on the basis of another designated device obtaining marketing authorization. As a consequence, multiple Breakthrough Device designations for the same intended use may be granted and have subsequent submissions pending simultaneously. However, when a Breakthrough Device has been approved or cleared or has had a De Novo request granted, no additional devices with the same intended use will be designated as a Breakthrough Device, unless the criteria for designation described above are still met in light of the first Breakthrough Device's market availability.<sup>20</sup>*

If CMS should encounter implementation issues as this new program develops and new technologies enter the market, AdvaMed stands ready to work with CMS to address these and other issues that may not have been contemplated in the development of TCET. Patient access to these innovative technologies should serve as an important guiding principle. While these are important issues to resolve over time, contemplation of how all future scenarios can be addressed should not delay issuance of the final notice.

#### **Recommendations:**

- **AdvaMed seeks clarification on whether CMS intends for similar devices to have Breakthrough status.**
- **AdvaMed supports similar devices being subject to the same coverage conditions under TCET, including a requirement to propose an EDP.**
- **AdvaMed recommends that coverage of similar devices should not count against any annual limit, in the event that CMS does not remove the annual limit of 5 technologies.**

#### **Duration of Coverage Under TCET**

AdvaMed supports the approach to tie the timing for post-market review to dates established within the EDP. CMS, together with the manufacturer, should establish a reasonable and mutually agreed upon collection period, with an emphasis on establishing timelines that allow collection of the most meaningful datapoints to demonstrate value for the Medicare population.

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<sup>20</sup> See <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/breakthrough-devices-program>, Guidance Document, FDA Breakthrough Devices Program, December, 2018



We would also encourage CMS to allow for additional time beyond the one-year after study completion to provide sufficient time to complete the analysis, draft a report, submit it for peer-reviewed publication, and be published. 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. Overall, CMS should act in a flexible manner that furthers its stated goal of “fostering innovation while ensuring people with Medicare have faster and more consistent access to emerging technologies that will improve health outcomes.”

***Recommendations:***

- **AdvaMed supports the approach to tie postmarket review dates to those established in the EDP.**
- **AdvaMed recommends CMS exercise flexibility if manufacturer requests more time to complete the data analysis.**

**V. Transition to Post-Coverage**

**Updated Evidence Review**

AdvaMed recognizes that CMS intends to utilize a third-party contractor for the updated evidence review. We wish to reiterate similar comments regarding the use of the contractor above. Again, we strongly recommend that the process include an open dialogue engagement with the manufacturer to aid the contractor in their review, and CMS should post the list of contractors used to its website. This is especially important for new technologies where literature search queries are more involved. Additionally, we encourage CMS to allow the manufacturer to extend the date of TCET coverage if additional time is needed to complete data collection.

***Recommendations:***

- **AdvaMed recommends establishing point of contacts to facilitate open dialogue between the manufacturer and the contractor responsible for conducting the Evidence Review.**
- **To increase transparency, AdvaMed recommends that CMS publish on its website a list of contractors used for this process.**
- **At the manufacturer’s request, CMS should allow a time extension if additional time is needed to complete the data collection.**

**Continued Access after Determination**

After evidence development stops according to the deadlines in the EDP, CMS will open an NCD reconsideration. If the reconsideration results in an NCD without evidence development, CMS must ensure continued access after the determination has been made. CMS’ goal should be to allow for flexibility and to avoid any gap in coverage at the end of the transitional coverage period that could affect patient access to these innovative technologies.

***Recommendation:***

- **CMS together with the manufacturer should work to ensure that there are no gaps in coverage in the transition between transitional coverage period and the updated NCD.**





As stated above, AdvaMed applauds CMS's commitment to ensuring Medicare beneficiaries have access to new and innovative technologies that improve the lives of patients with debilitating conditions.

AdvaMed urges CMS to quickly to finalize the TCET notice incorporating our proposed recommendations. As stated above, AdvaMed applauds CMS's commitment to ensuring Medicare beneficiaries have access to new and innovative technologies that improve the lives of patients with debilitating conditions. As such, we encourage CMS to commit to routine evaluation and on-going refinement. Moreover, beyond immediate consideration of TCET, we see additional opportunities to continue to work with CMS – using its existing authority – to continue to expand and accelerate access to breakthrough technologies for all patients. Medicare coverage policies and payment rates serve as effective benchmarks for Medicaid and commercial payor policies, and therefore have an impact beyond Medicare beneficiaries. For example, Medicare policies are particularly important for pediatric populations most typically covered by Medicaid, as effective coverage and payment policy helps to further patient access to medical technologies for these populations.

AdvaMed looks forward to continuing our work with the Agency. We greatly appreciate the opportunity to comment on the TCET notice. If you have questions regarding these comments or if you require additional information, please contact me at [tburke@advamed.org](mailto:tburke@advamed.org).

Sincerely,



Tara Burke, PhD  
Vice President, Payment & Healthcare Delivery Policy  
AdvaMed

CC: Tamara Syrek Jensen  
Jean Moody-Williams

