

August 1, 2022

Via Electronic Mail

Ms. Chiquita Brooks-LaSure,
Administrator
Mr. Jon Blum,
Principal Deputy Administrator & COO
Department of Health & Human Services
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244

Dear Administrator Brooks-LaSure and Principal Deputy Administrator Blum:

The Advanced Medical Technology Association (AdvaMed) is pleased to provide the Centers for Medicare & Medicaid Services (CMS) with the following recommendations as the Agency contemplates a proposed rule on Transitional Coverage for Emerging Technologies, or TCET. We appreciated our recent engagement with you to discuss the need for Medicare coverage reforms and we look forward to continuing the dialogue.

AdvaMed's member companies produce lifesaving and life-enhancing medical devices, diagnostic products, and health information systems that are transforming health care through early disease detection, less invasive procedures, and more effective treatments. AdvaMed members range from the largest companies to the smallest medical technology innovators. We also have two divisions – AdvaMedDx, which represents manufacturers of *in vitro* diagnostic tests, and AdvaMed Accel, which represents smaller to mid-sized companies, including early-stage companies and start-ups, that are developing emerging technologies.

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. We believe that CMS, in order to advance its health equity and other goals, can and must play a critical role in advancing access to emerging innovations that would improve health outcomes for the array of Medicare beneficiaries it serves. We also believe that we 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 42 percent of Medicare-eligible patients enrolled in

Medicare Advantage organizations—which include high numbers of Black, Latino, and dual-eligible enrollees.^{1,2,3}

Accordingly, we urge CMS to establish a new program to provide transitional national coverage for emerging technologies that offers a distinct alternative pathway, including a commitment from CMS to engage early with companies to identify evidence gaps and, if necessary, evidence development plans that will allow for timely transitional coverage.

We commented during the TCET Listening Session on March 31, 2022, that the current NCD process can take six to nine months, or longer, after CMS initiates an NCD, and CMS typically issues only a handful of NCDs each year. Consequently, the existing NCD process may not be a good fit for many emerging technologies, leaving Medicare beneficiaries without access to truly innovative preventive, diagnostic, prognostic, or therapeutic technologies. We look forward to working with CMS on the development of a TCET program that recognizes the need to ensure that Medicare beneficiaries have appropriate and timely access to these technologies, as discussed in more detail below.

A Conceptual Framework

Conceptually, the framework for this pathway should include:

- **Opt-in.** A voluntary, opt-in approach, for eligible products that allows for early engagement between manufacturers and CMS to identify evidence needs in a timely manner;
- **Evidence Generation.** Alignment around a plan for evidence generation in the Medicare population, with agreement regarding methodologies and types of data CMS will require;
- **Beneficiary Protections.** Appropriate safeguards to protect Medicare beneficiaries;
- **Transparency.** Opportunity for public comment;
- **System Readiness.** Adequate time frame to ensure system readiness (e.g., coding, payment, contractor instructions, and any other operational needs); and
- **Follow-on Devices.** Thoughtful approach to providing transitional coverage to follow-on products.

¹ 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>.

² 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>.

³ 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/>.



As we describe in greater detail below, such a framework, through which companies can voluntarily seek national transitional coverage for their emerging medical technologies, would reduce the gap between Food and Drug Administration (FDA) authorization and Medicare coverage for those technologies. Under the program, an evaluation of the existing clinical evidence for a new technology and its impact on Medicare beneficiaries would be essential. This evaluation would allow CMS and a manufacturer, together, to identify any gaps in evidence and to reach agreement on a plan for further evidence generation, if necessary.

Ideally, this engagement, evaluation and development of an evidence plan should take place early – prior to FDA authorization, before the results of the pivotal clinical trials are completely available, and perhaps even before the start of a pivotal trial, to ensure evidence development for the target patient population or that the evidence generated is generalizable to the Medicare population.⁴

Recommendations for Transitional Coverage for Emerging Technologies Program

Again, a new CMS TCET program should be voluntary, and allow a manufacturer of an eligible emerging technology to opt-in, have its existing evidence and/or evidence generation plan evaluated for sufficiency for coverage, and collaborate with CMS on development of additional evidence generation, if necessary, to address any gaps in the clinical evidence.

Eligibility

An emerging technology should be able to demonstrate eligibility for the program by meeting clear criteria, including one or more of the following (but not limited to):

- The device or diagnostic is a new or innovative technology, or a new or novel application of a technology (e.g., meets newness criteria as defined elsewhere by CMS based on recent FDA approval, mechanism of action to treatment of a disease or patient population, or other criteria) or no alternative FDA-approved or cleared technology exists. This could include digital, algorithmic, or artificial intelligence-based technologies, home-based technologies, or other novel technologies, such as software-based medical devices.
- An eligible technology could include a breakthrough or emerging technology that is relevant to Medicare or can demonstrate it is generalizable to the Medicare population;
- The emerging technology fits within a Medicare benefit category;
- No specific, written national coverage determination exists for the specified technology, indication or patient population;

⁴ CMS could modify depending on regulatory pathway (e.g., PMA, 510k) and the evidence being required.



- The device or diagnostic is applicable to Medicare beneficiaries;
- The device or diagnostic may be used in a variety of settings, including inpatient hospital, outpatient hospital, ambulatory surgical center, physician office or in the home (e.g., durable medical equipment, and other home-based therapies for Medicare patients);
- Other criteria as defined by CMS.

A potential model for the transitional coverage process is CMS' criteria for coverage of Investigational Device Exemption (IDE) studies. For CY 2014, through notice-and-comment rulemaking, CMS finalized changes to the IDE regulations, establishing a centralized process for reviewing and approving coverage for Medicare beneficiaries that participate in IDE studies.⁵ That process includes a voluntary opportunity for study sponsors to request coverage and to submit a packet to CMS that includes specific information. A TCET process could operate in a similar fashion. Companies could submit information to CMS about the technology, including:

- **General Information** regarding the technology's intended use, the targeted patient population, clinical workflow, therapeutic research value, and other information.
- **Information on Medicare Relevance or Appropriateness and Impact.** Companies can explain or demonstrate how their technology will improve outcomes for the Medicare population or will be generalizable to the Medicare population. Companies also could describe any gaps in evidence supporting the product in the Medicare population and potential approaches to fill those gaps, which would inform the proposed fit-for-purpose evidence generation plan.
- **Information about ongoing clinical studies.** Companies can provide information about ongoing studies to assist CMS in identifying evidence gaps.
- **Information on Disease Burden.** Companies can provide information on disease burden and describe how the technology addresses this, including Drivers of Health.
- **Disparities/Health Equity Information.** Companies may highlight any known disparities in access to treatment for the condition addressed by the emerging technology and suggest ways of addressing those inequities with the approved product during the transitional coverage period.
- **Other information** as necessary to respond to CMS' evidentiary questions.

AdvaMed looks forward to working with CMS on development of a TCET program and helping, through notice-and-comment rulemaking, to identify eligibility criteria for the program.

⁵ 78 Fed Reg 74429-37, *Medicare Program; Revisions to Payment Policies Under the Physician Fee Schedule, Clinical Laboratory Fee Schedule & Other Revisions to Part B for CY 2014* (December 10, 2013).



Evidence Generation Plan

When a manufacturer opts-in to the TCET program with an eligible emerging technology, CMS should undertake an evaluation of the existing clinical evidence for that technology. As part of the TCET program, the manufacturer would be required to provide a synthesis of the applicable published literature for the technology under consideration. To facilitate CMS' review, CMS could provide clear guidance to manufacturers, similar to the application for a new technology add-on payment, that serves as a template for manufacturers' submission of clinical information for the technology. This guidance should, among other things, reflect a least burdensome approach to evidence generation to promote access, clarify who can review the studies, and address the range of data sources that can be used (e.g., patient reported outcomes data).

If upon evaluation, CMS determines that the evidence is sufficient for Medicare coverage, CMS should provide coverage through its usual mechanisms, without the need for a transitional coverage period. If the evaluation of clinical evidence results in a finding that evidence gaps exist or that more evidence is needed to assure CMS that the technology improves outcomes for Medicare beneficiaries, manufacturers should develop a plan, in collaboration with CMS, for generating such evidence as is necessary during the transitional coverage period. Maintenance of Medicare coverage during the transitional coverage period would, in turn, be contingent upon the manufacturer continuing to satisfy the requirements of the evidence generation plan. Failure of a manufacturer to fulfill commitments under an agreed-upon evidence generation plan or any arising concerns about safety could result in tolling or termination of coverage, upon CMS' review.

The evidence generation plan could include (but not be limited to):

- Study design and appropriate pre- and post-market and other data sources that are “fit-for-purpose” (i.e., require the minimum amount of information necessary to adequately address the relevant clinical question or issue in the most efficient manner);
- Identification of study sites (if applicable to the evidence generation plan);
- Applicable patient populations;
- Endpoint(s);
- Follow-up time;
- Safety monitoring plan;
- Review of impact on applicable CMS strategic priorities including health disparities/health inequities and innovations to address health system challenges.

Further, CMS should ensure flexibility for manufacturers regarding standards, methodologies, and types of data the agency will require for evidence generation plans—including through the continued facilitation of meetings to discuss evidence with the manufacturer early in the process.



Transparency - Proposed Coverage

When CMS makes an initial determination to cover an emerging technology for the transitional coverage period of not less than four years, CMS would announce proposed transitional coverage on its website with an opportunity for public comment. This announcement would include basic information about the device, the evaluation of the evidence and the evidence generation plan, such as:

- Applicable benefit category;
- Discussion of study design, broadly;
- Defined coverage for the item or service (including for beneficiaries in Medicare Advantage plans);
- Discussion of appropriate coding or payment category assignment;
- Discussion of safeguards, or plan for beneficiary protections.

AdvaMed recommends that CMS announce proposed transitional coverage upon or soon after FDA authorization, with an opportunity for public comment, because much of the necessary information will have been developed during the earlier collaboration between the company and CMS. To facilitate beneficiary access, CMS could limit the comment period (e.g., 15 days) as well as the time for review of the public comments, so that a final determination regarding the transitional coverage could be posted expeditiously, perhaps on a quarterly basis.

This process would provide transparency (while maintaining confidentiality protections for proprietary information) and guide companies and CMS in future transitional coverage decision-making. The public coverage determinations also would provide insights into CMS' deliberations for manufacturers of follow-on products, as those products likely would need to submit studies consistent with the original transitional coverage determination in order to secure transitional coverage themselves. For follow-on products, CMS would need to determine whether the original transitional coverage determinations are applicable.

System Readiness for Transitional Coverage

A new TCET program must provide adequate time to ensure system readiness, which includes appropriate coding (if necessary), assignment to relevant payment categories or otherwise establishing payment rates and issuing implementation instructions to Medicare Administrative Contractors processing the claims (e.g., quarterly update Transmittals). CMS should further consider ways to align the TCET determination with existing payment programs for innovative technology, including NTAP, New Technology APC and transitional pass-through payment, to avoid administrative burden (e.g., duplicate efforts to prove 'innovative' status) and promote efficiency



During the system readiness period, a manufacturer would also finalize and complete any necessary study agreements with participating sites, as well as its plans to perform data analysis per the agreed-upon evidence generation plan.

While we understand that adequate time is needed, this process should be completed within 90 days of the coverage determination and transitional coverage should begin no later than the second calendar quarter after FDA authorization (though this could be delayed at the manufacturer's request if the company is not ready to execute the evidence generation plan). Coverage could be timed to align with CMS quarterly updates, similar to OPSS and other file updates.

Transitional Coverage

Under the TCET program, AdvaMed urges CMS to establish transitional, national coverage for not less than four years for eligible emerging technologies. CMS could propose to end the transitional coverage period before the conclusion of the four-year period if evidence generation ceases or alternatively permanent national coverage is provided through a National Coverage Determination with evidence showing clear benefit for Medicare beneficiaries.

Additionally, CMS could end the transitional coverage period early if safety concerns become apparent. The process should provide for ongoing communication between CMS and the manufacturer throughout the transitional coverage period, highlighting clinical evidence results, including safety issues, and providing opportunities for validation, or course correction, if necessary.

Pathway to Permanent Coverage

A new TCET program should include a pathway to permanent coverage before or upon the conclusion of the transitional coverage period. The pathway should retain flexibility for manufacturers to seek:

- An extension, in order to generate additional data;
- A national coverage determination;
- A local coverage determination; or
- No written coverage determination (i.e., implicit coverage based on widespread acceptance as standard medical practice, or claim-by-claim adjudication).

If the evidence-generation results are not sufficient to support permanent coverage, CMS could also issue a noncoverage determination.

In summary, we are confident that AdvaMed and CMS share the goals of improving patient and provider access to emerging technologies for patients. We believe a process can be developed to



ensure an expeditious and predictable pathway to coverage for devices and diagnostics that will benefit the Medicare population, and we urge CMS to move quickly to issue a proposed rule this year.

We look forward to working with CMS on these issues as the Agency develops its proposed TCET rule. We greatly appreciate this opportunity to provide our input and look forward to next steps.

Sincerely,



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Senior Vice President, and
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cc: Lee A. Fleisher, MD, CMS/CCSQ
Tamara Syrek Jensen, CMS/CAG

