August 28, 2023

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare and Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

The State Medical Technology Alliance (SMTA) is pleased to offer the following comments on the Centers for Medicare & Medicaid Services' (CMS) Transitional Coverage for Emerging Technologies (TCET) notice. The SMTA is comprised of state and regional life sciences associations from across the country representing the biotechnology and medical technology industries, universities, research institutions, and venture capital firms, all of which are dedicated to developing and delivering life-enhancing and life-saving products. The medical technology innovators that are members of SMTA associations range from the large multinational to emerging, small companies.

The SMTA has long supported a swift and streamlined approach to Medicare coverage of innovative medical devices and diagnostics that improve health outcomes for patients with debilitating or life-threatening illnesses, and we commend CMS for revisiting this critical issue. While the TCET notice is a positive step forward, we believe significantly more can be done to ensure patients have timely access to new technologies, soon after they are approved by the Food and Drug Administration (FDA). We also recognize the breadth and scope of the TCET program is constrained by existing, available resources for CMS. Therefore, in addition to providing recommendations to improve the existing proposal, we are committed to working the Agency, the Administration, and the Congress to pass legislation and explore ways CMS can use its existing authority to build on the TCET program and enable more robust beneficiary access to safe and innovative medical technologies.

Considering this understanding and commitment, we make the following recommendations regarding the TCET program:

**Recommendation**: Include diagnostic laboratory tests as appropriate candidates for the TCET program

**Explanation**: The TCET notice states CMS believes most coverage determinations for diagnostic laboratory tests granted Breakthrough Device designation should

continue to be determined by the Medicare Administrative Contractors (MACs) through existing pathways. However, diagnostic laboratory tests are not the only area where review has historically occurred under the MACs. In addition, specialized MACs are not a suitable substitute for the national coverage offered under the TCET program. For example, the MolDx Program only makes coverage determinations for molecular diagnostics and establishes coverage for six MAC jurisdictions. Reliance on this program or other MAC-level review greatly limits coverage opportunities for new and novel in vitro diagnostics. Like the Medicare Coverage of Innovative Technologies (MCIT) final rule, we believe *any* medical device receiving Breakthrough designation by the FDA, and that meets all other TCET criteria, should be eligible for the pathway.

**Recommendation:** Remove the annual cap on nominations to ensure the TCET program can be fully leveraged to improve patient access

**Explanation**: CMS anticipates that while it will receive eight nominations per year for the TCET pathway, resource constraints will limit the Agency to only accepting five annually. As noted above, we understand that the TCET program is limited by resources available to CMS; similarly, the SMTA is committed to working with others to increasing resource access to build on a final TCET policy. However, resource constraints should not dictate policymaking or beneficiary access to innovative technologies. We therefore believe any product meeting the TCET program eligibility criteria should have the option to pursue the pathway, free of any annual numerical restriction.

**Recommendation:** Include an appropriate lookback period for recently authorized Breakthrough products

**Explanation:** The TCET notice does not contain defined or required timelines for when the TCET program will be finalized, which creates added uncertainty for manufacturers that are nearing or may have been recently granted FDA authorization through the Breakthrough program. These technologies should be given an opportunity to pursue nomination, 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. To address this concern, the final TCET notice should include a lookback provision to allow TCET eligibility for breakthrough technologies, including those nearing authorization (i.e., less than 12 months).

**Recommendation:** Ensure clear timelines for review of benefit category, coding, and payment

**Explanation**: The TCET notice lacks clarity on certain processes, such as determination of Medicare benefit category, coding, and payment. Defining these steps with clear timelines for CMS review will help achieve the goal of the TCET

program being an accelerated pathway for appropriate patient access to novel and innovative products.

**Recommendation**: Improve transparency in the TCET program nomination process

**Explanation**: CMS' current method for managing the National Coverage Determination (NCD) process – requests, prioritizing topics, and providing information to the public regarding the waiting list – lacks transparency. The lack of specified timeline for CMS to respond to requests, or follow-up for more information, significantly hinders stakeholders' ability to understand process and timing.

Similar issues exist within the TCET notice. The proposal does not include public tracking of requests until an NCD is initiated; meaning any details around number of nominations or acceptances are not public. To ensure the TCET program operates as intended, CMS must provide greater transparency into these processes as part of the final policy.

The SMTA applauds CMS's commitment to ensuring Medicare beneficiaries have access to new and innovative technologies and look forward to a final policy that incorporates the above recommendations as the next step in improving the lives of patients with debilitating and life-threating conditions.

Sincerely,

Arizona Bioscience Association, Inc. (AZBio)
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Bio Nebraska
BioUtah
California Life Sciences
Colorado BioScience Association
Florida Medical Manufacturers Consortium
Georgia Bio
Healthcare Institute of New Jersey (HINJ)
Illinois Biotechnology Innovation Organization (iBio)
Indiana Health Industry Forum
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