230 E. South Temple
Suite 100
Salt Lake City, UT 84111
801.867.4061

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**Via Electronic Submission to www.regulations.gov**

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244-8013

**Re: Docket ID: [CMS-3421-NC]**
**Medicare Program; Transitional Coverage for Emerging Technologies**

Dear Administrator Brooks-LaSure,

BioUtah is pleased to offer comments on the Transitional Coverage for Emerging Technologies (TCET) Notice with Comment (CMS- 3421-NC), released by the Centers for Medicare & Medicaid Services (CMS) on June 22, 2023.[1]

For certain Food and Drug Administration (FDA)-designated Breakthrough Devices (Breakthrough Devices) nearing FDA market authorization, TCET would establish a voluntary new Medicare coverage course within the existing National Coverage Determination (NCD) and Coverage with Evidence Development (CED) processes. Manufacturers of eligible Breakthrough Devices that fall within a Medicare benefit category can obtain national coverage for an estimated three to five years, pending the development of evidence.

BioUtah is an independent 501(c)(6) trade association serving Utah's life sciences industry, with strengths in medical device manufacturing and services, research and testing, diagnostics, biotechnology, biopharmaceuticals and healthIT, amongst others. These industry sectors drive economic growth in the state and are dedicated to delivering life-enhancing and life-saving products.

Utah's life sciences hub is among the fastest growing in the nation. A number of medical innovations being developed by Utah medical device and diagnostic companies address some of our seniors' most challenging health conditions, such as cancer, Parkinson's disease, degenerative disc disease, chronic kidney disease, heart disease, joint replacement and more.

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

## Overview and General TCET Principles

**BioUtah believes that TCET is a positive step forward with respect to operational aspects of the national coverage process. However, we also believe that more needs to be done to create a final meaningful expedited coverage pathway with adequate capacity to consider emerging technologies, including diagnostics. Improvements are needed to ensure that Medicare's seniors, including patients in our most vulnerable communities, are able to swiftly benefit from innovative medical devices.**

BioUtah appreciates the administration's aim to "accelerate patient access to beneficial medical products while generating evidence" [2]. In its TCET Notice, the agency outlines certain "TCET General Principles" [3] including limiting the pathway to certain candidates, conducting early evidence reviews and engagement with manufacturers, avoiding duplicative or conflicting evidence development requirements, ensuring any CED requirement be time-limited under the pathway, and giving manufacturers the option at different stages to withdraw from TCET. The TCET Notice also describes how CMS intends to engage with the FDA and the Agency for Healthcare Research and Quality.

While TCET is intended to shorten the "gap" between FDA market authorization and Medicare coverage for Breakthrough Devices, the process still leaves companies with too much uncertainty about timing of coverage, the potential for agency delays during Evidence Previews and benefit category determinations, and costly data collection. Given the reliance on existing processes, it's not clear that TCET would significantly reduce the current lag time between FDA approval or clearance and Medicare coverage.

This hits startup companies particularly hard. Without timely and predictable coverage, it can be difficult for smaller companies to begin to generate revenue and attract the investment needed to commercialize their emerging technologies.

A study last year by the Stanford Byers Center for Biodesign found it takes an average of five years for medical technologies to achieve nationwide coding, coverage and payment. This delay not only impacts patients, but also increases costs, which flow through the entire healthcare system. [4]

BioUtah has long advocated for accelerated approaches to Medicare coverage of innovative medical devices as well as diagnostics. We support policy proposed in bipartisan legislation, the "Ensuring Patient Access to Critical Breakthrough Products Act," that would create a separate dedicated pathway to provide immediate provisional national Medicare coverage for Breakthrough Devices that receive FDA market authorization.

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[2] 88 Fed. Reg. at 41,637

[3] Ibid., 41,638

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

Under the bill, coverage would last four years from as early as the date of FDA market authorization - after review of a premarket notification 510(k), De Novo request, or premarket approval application for the product. During this provisional period, additional evidence would be generated and CMS would have authority to pull coverage to safeguard beneficiaries.

**As such, in addition to providing detailed comments to improve the existing proposal, BioUtah looks forward to working with CMS, stakeholders and Congress to build upon the TCET pathway and enable more robust beneficiary access to safe and innovative medical technologies.**

## Detailed Comments

### 1. To ensure the pathway is fully utilized, TCET capacity should not limited.

CMS expects to receive approximately eight TCET nominations per year and approve at most five products due to resource constraints. CMS will prioritize devices it determines to have potential benefit for the greatest number of Medicare beneficiaries. BioUtah recognizes that CMS faces resource constraints in implementing the TCET pathway and supports efforts to address these limitations. However, resource issues should not dictate policymaking intended to promote beneficiary access to innovative technologies.

**If a product meets TCET eligibility criteria, the manufacturer should have the option to pursue the pathway with no restrictions on the number that are eligible annually.**

### 2. Include Breakthrough Devices that are diagnostic laboratory tests.

The TCET pathway would apply to devices that are FDA-designated Breakthrough Devices; determined to be within a Medicare benefit category; not already the subject of an existing Medicare national coverage determination; and not otherwise excluded from coverage through law or regulation. However, this criteria for appropriate candidates excludes diagnostics.

The TCET Notice specifically 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 of many of these tests to specialized Medicare Advisory Committees (MAC). We believe that the majority of coverage determination for diagnostic tests granted breakthrough designation should continue to be determined by the MAC through existing pathways." [5]

[5] 88 Fed. Reg. at 41,639

These tests are no more specific than other areas of medicine. Further, innovative diagnostic tests are appropriate for inclusion in the TCET process because they drive more effective care decisions and help clinicians choose the right treatment, for the right patient, at the right time.

**Breakthrough Devices, including diagnostic laboratory tests, that meet all other TCET criteria should be eligible for the TCET pathway.**

3. **The TCET pathway should apply to technologies that have not received a breakthrough designation from the FDA. Products should not be disqualified on the basis of existing NCDs.**

During consideration of the repeal of the Medicare Coverage of Innovative Technologies (MCIT) rule, CMS expressed concern about limiting MCIT to only products with FDA breakthrough designations. This concern should also have merit regarding participation in TCET.

**CMS should expand the scope of eligibility to include innovative products that have the potential to significantly improve the health of Medicare patients, even if they are not Breakthrough Devices.**

**In addition, BioUtah urges CMS to eliminate the requirement that limits eligibility for TCET to devices that are "not already the subject of an existing Medicare NCD." [6] We are concerned that a device could be unfairly rejected in cases where an NCD is written broadly.**

4. **Provide a look back period for recently authorized Breakthrough Devices.**

CMS states in the TCET Notice that "[t]he appropriate timeframe for manufacturers to submit TCET pathway nominations to CMS is approximately 12 months prior to anticipated FDA decision on a submission as determined by the manufacturer." [7]

Unfortunately, the TCET Notice does not contain defined or required timelines for when the TCET program will be finalized, which creates added uncertainty for manufacturers whose products are nearing or may have been recently granted FDA authorization through the breakthrough program.

**BioUtah believes these technologies should be given an opportunity to submit a nomination.**

5. **Define clear timelines for review of the Medicare benefit category, coding and payment.**

CMS will make a preliminary decision to provisionally accept or decline a nomination within 30 business days following confirmation that the nomination

[6] Ibid.

[7] Ibid.

has been received. However, CMS indicates that determining whether a product falls into a benefit category may take longer. No specific timeline is provided. Similarly, the TCET Notice does not provide clear direction on coding and payment.

**CMS should provide more clarity with respect to these processes. Defining these stages with clear timelines for CMS review would help ensure a more predictable and streamlined pathway.**

**6. More transparency is needed into the TCET nomination process.**

At present, there is a lack of transparency surrounding CMS' methods for managing NCD requests, prioritizing topics and providing information to the public regarding the waiting list. Since TCET intends to follow the NCD statutory timeframes, we are concerned that there is no specified timeline for CMS to respond to TCET requests or to provide information regarding the waiting list. In other words, manufacturers have little visibility into the process or timeline for action on their requests.

For example, 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.

**CMS should provide greater transparency regarding the nomination process in any final TCET pathway.**

## Conclusion

In closing, CMS plays a critical role in advancing access to innovations that would benefit Medicare beneficiaries. BioUtah values the TCET pathway the agency has put forward and urges the agency to take a collaborative approach in working with industry, stakeholders and Congress to finalize a clearly articulated and expedited coverage pathway for emerging technologies.

Thank you for your consideration. For questions regarding BioUtah's comments, please contact Denise Bell at denise@bioutah.org.

Respectfully submitted,

President and CEO
BioUtah