August 2, 2023

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

In Re: CMS-3421-NC, Medicare Program; Transitional Coverage for Emerging Technologies

Submitted electronically at www.regulations.gov

Dear Administrator Brooks-LaSure:

The American Association of Tissue Banks (AATB or Association) and the American Association of Tissue Bank's Tissue Policy Group (AATB TPG or TPG) submit these comments related to the Centers for Medicare and Medicaid Services (CMS or Agency) proposed procedural notice outlining a new Transitional Coverage of Emerging Technologies (TCET) pathway for certain devices designated as "breakthrough" by the U.S. Food and Drug Administration (FDA). In general, we applaud CMS for issuing this proposal and encourage the agency to take further action to support market access for innovative devices.

The American Association of Tissue Banks (AATB) is a professional, non-profit, scientific, and educational organization. AATB is the only national tissue banking organization in the United States, and its membership totals more than 120 accredited tissue banks and over 6,000 individual members. These banks recover tissue from more than 58,000 donors and distribute in excess of 3.3 million allografts for more than 2.5 million tissue transplants performed annually in the U.S. The overwhelming majority of the human tissue distributed for these transplants comes from AATB-accredited tissue banks.

The AATB TPG includes Chief Executive Officers and senior regulatory personnel from U.S. tissue banks that process donated human tissue. The purpose of the TPG is to drive policy in furtherance of the adoption of laws, regulations, and standards that foster the safety, quality, and availability of donated tissue. The TPG's membership is responsible for the vast majority of tissue available for transplantation within the U.S.

Market Access. CMS' proposed 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. At this time, the AATB TPG is not aware of any human cell or tissue products in development that would be regulated as Class III devices, and that would meet these requirements; however, we believe at least one product currently on the market would have qualified if the TCET pathway existed previously.

We believe expedited coverage under the proposed pathway for breakthrough devices, including tissue-based devices, would enable Medicare beneficiaries to benefit from greater access to advanced therapies that have the potential to address unmet serious and debilitating health care needs. We encourage CMS to enact the proposed TCET pathway for breakthrough devices, and we further encourage the agency to extend the application of the TCET pathway to other products that receive similar designations from the FDA, such as the Regenerative Medicine Advanced Therapy (RMAT) designation.

The RMAT designation was enacted as part of the 21st Century Cures Act, and products qualify if they are "a regenerative medicine therapy, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, except for those regulated solely under Section 361 of the Public Health Service Act and part 1271 of Title 21, Code of Federal Regulations." RMAT-designated products must also be "intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition;" and demonstrate in preliminary clinical evidence that "the drug has the potential to address unmet medical needs for such disease or condition." These requirements are similar to the Breakthrough Devices program criteria, especially the Breakthrough Device requirement that "no approved or cleared alternatives exist; it offers significant advantages over existing approved or cleared alternatives, including the potential, compared to existing approved alternatives, to reduce or eliminate the need for hospitalization, improve patient quality of life, facilitate patients' ability to manage their own care (such as through self-directed personal assistance), or establish long-term clinical efficiencies."

Given the similarities between these two categories of products – primarily, that both categories either address unmet medical needs or represent a significant improvement over existing products – we encourage CMS to extend the application of the TCET pathway to RMAT-designated products. Extending the application of the TCET pathway and providing sponsors of RMAT-designated products with the opportunity to engage with CMS before reaching the market would ensure such manufacturer is appropriately considering and gathering evidence on whether the product is reasonable and necessary for the diagnosis or treatment of an illness or injury for individuals in the Medicare population.

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We hope that you will find this information useful in your deliberations. The AATB and the TPG stand ready and willing to assist CMS with its deliberations in any way that you deem appropriate.

Respectfully,

Marc Pearce
President & CEO
American Association of Tissue Banks

Doug Wilson
Chair
Tissue Policy Group

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To learn more visit: www.aatb.org