American Association of Tissue Banks®

AATB Statement for Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers Multi-MAC Town Hall meeting

Marc Pearce, AATB President and CEO

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Good afternoon. My name is Marc Pearce, and I'm the President and CEO of the American Association of Tissue Banks. AATB is a professional, non-profit, scientific, and educational organization, and its membership totals more than 120 accredited tissue banks and over 7,000 individual members.

AATB's membership includes entities with products on both the covered and noncovered lists, so we are here today representing the entire tissue industry. Among other changes, we appreciate that the LCDs have been revised to allow for 8 applications over a 16-week treatment period.

AATB is concerned, however, that a longer period was not provided for companies with products on the noncovered list to gather evidence, especially considering how many products will no longer be covered. As you know, manufacturers of what the FDA regulates as "361 HCT/Ps," a category that includes many skin substitutes, are not required to conduct clinical trials or provide the level of evidence required under the final LCDs in order to market their products. AATB does not disagree with CMS and the MACs' interest in limiting coverage to those products that are reasonable and necessary, but as the evidentiary requirements under the LCDs are new, we believe companies should have additional time – at least one year – to compile and submit the evidence needed to demonstrate a product's effectiveness. Without an extension, there is a real risk that businesses could fail and that patients will lose out on the opportunity to benefit from innovative products.

AATB's second concern is that MACs will restrict coverage of skin substitutes for non-DFU or VLU wounds to the same limited set of products allowed for DFUs and VLUs. Such an approach would not be evidence-based and would harm patients who could benefit from other available products. Instead, we request that the MACs continue down a path of coverage for reasonable and necessary treatments, determined by documentation and the clinical judgement of the treating provider based on use of these products for other indications.

Finally, AATB is concerned that the reconsideration process to add products from the noncovered list to the covered list could be time-consuming and burdensome for both the manufacturers and MACs. To begin, the process of submitting and reviewing information across the seven jurisdictions could result in a duplication of effort for both sides as well as potential discrepancies across jurisdictions if MACs issue revised LCDs on different timelines. Furthermore, we question how MACs will accommodate requests by multiple different manufacturers, including when requests come in on a staggered basis. Will the LCD be re-opened for each request? What will happen if a request for reconsideration is submitted during the middle of the LCD comment period, or after a comment period has closed but before a final revised LCD is issued? We encourage CMS and the MACs to develop and publicly communicate a streamlined process for responding to reconsideration requests to add additional products. Such a process should allow for relatively quick action and coverage on requests that meet the new evidentiary standard.

AATB suggests that one possible solution could be designating a “lead” MAC to make decisions with respect to adding new products to the covered list; this “lead” role could be rotated among MACs over time, as needed. However, we are also interested in hearing from MACs on how to reduce this regulatory burden on tissue banks as they seek coverage via an LCD redetermination.

Thank you for considering these comments and holding this town hall meeting.