ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

Alliance of Wound Care Stakeholders Oral Testimony for CTP/LCD Town Hall Meeting Dec. 10, 2024

My name is Marcia Nusgart and I am the CEO of the Alliance of Wound Care Stakeholders. Thank you for the opportunity to speak at this Multi-MAC Town Hall Meeting regarding the Medicare policy for the Skin Substitute Grafts/CTPs for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers. The Alliance is a non-profit multidisciplinary trade association of physician specialty societies, clinical and non-clinical associations, patient organizations, wound care provider groups, wound care clinics and business entities whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas.

The Alliance has been supportive of this LCD moving forward to becoming final. We are appreciative of the MACs listening to stakeholders and making substantive changes to create this policy reflective of evidence-based quality wound care practice. Specifically, these examples include:

- Increase in covered application limit from 4 to 8
- Episode of care treatment duration from 12-16 weeks
- Reviewing new evidence and adding 3 products to the "covered product" list

However, we have many substantive concerns and questions that we have sent to you that we believe need to be addressed before the February 12th implementation of the policy. Our member clinicians have questions regarding scenarios for multiple wounds as well as number of applications. For instance, if patients with a very large venous leg ulcer have made significant progress towards wound healing but may need more time to completely close after meeting the 16 week mark and/or 8 applications, how can they obtain the continued treatment and what is necessary in order for them to receive this care?

Our comments and thus our questions also centered on the evidence that the MACs used in making the coverage decisions. We questioned what threshold below a RCT would the MACs be willing to accept for products to be covered in the LCD in the future and if there are other endpoints such as time to closure when evaluating the evidence? We voiced concern about the GRADE methodology not appearing to be applied equally and consistently. When the final LCD was issued, the MACs used a different methodology to review the evidence. How can the MACs assure stakeholders that the new methodology being used is applied equally and consistently given the lack of consistent and equal review in the proposed LCD? Will the MACs create a new chart based on the new methodology for the coverage or non-coverage rationale?

Finally, what is of utmost importance to our members is clarification of the reconsideration timelines and processes for manufacturers to submit new evidence for coverage. The MACs have not published if there is one or multiple deadlines that manufacturers have to submit evidence or the exact dates for their submission . There is no direction on whether the evidence should be submitted to one or all of the MAC medical directors. Our recommendation for a more efficient process to get products covered is for is the MACs to place the newly covered products in the coding and billing article so that an LCD reconsideration is not needed.

As stated, while we appreciate the opportunity to present, we value hearing the Q/A since there are so many issues that need to be clarified. Thus, we believe there is a need for more education, more webinars and a MedLearn Connects to be created to address these important issues. We would be happy to serve as a resource to you as the MACs move forward in implementation of this LCD.

Again, thank you for the opportunity to present.