Alliance Oral Testimony
WPS Open Public Meeting collecting feedback on proposed LCD
"Skin Substitute Grafts/Cellular & Tissue-Based Products for the Treatment of DFU and VLU"
May 22, 2024

*** Similar comments were delivered at the open public meetings of each of the other MACs ***

My name is Marcia Nusgart and I am the CEO of the Alliance of Wound Care Stakeholders. Thank you for the opportunity to provide the Alliance's concerns related to the release of the Skin Substitute LCD and the accompanying LCA. The Alliance is a non-profit multidisciplinary trade association of physician medical specialty societies and clinical associations 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. This oral statement was written with the advice of Alliance clinical specialty societies and organizations that not only possess expert knowledge in complex chronic wounds, but also in wound care research.

The Alliance has several concerns with the current draft and areas we identified which need further clarification that we will address in our written comments. However, today I would like to address three issues.

First: The proposed policy continues to permit only 4 applications of CTPs in a 12-week period. As opposed to previous drafts WPS is permitting additional applications and an extension of the 12-week period of time when medically necessary and documented in the patient file. The Alliance **fully supports the proposed LCD language permitting additional applications or an extension of the 12-week period** based on medical necessity with documentation provided in the patients' medical record. It is important that a patient be able to receive more applications when medical necessary especially when their wounds are progressing. So, the Alliance appreciates and supports this clinically necessary and appropriate change from previous drafts.

Second: The Alliance certainly supports coverage based on evidence. We have always been on the record supporting evidence-based medicine. However, we are concerned that WPS eliminated coverage for a significant majority of products in the market currently - many of which have evidence to support their use. As such, we believe that WPS needs to be **clearer as to the evidentiary bar**. For example, there are studies that support products that were eliminated from coverage. There are studies and evidence available that were **not** identified or included in your list of evidence reviewed.

A key question is this: What is the process for a manufacturer to submit evidence that does not appear to have been reviewed? More information on the evidentiary bar and any recourse that a manufacturer has with respect to evidence review should be provided.

Third and finally, we would also like to urge WPS that once this policy becomes finalized, there be **ample time to implement this policy** - given the limitation on the number of products that are currently on the proposed list of covered products. Patients will be in midst of treatment plans on products that may not be covered any longer. Their treatment plans are 12 weeks and any changes to those treatment plans can negatively impact care. Furthermore, facilities who do not use products on the proposed list of covered products will need to go through a formulary review process of the products that are covered to determine what they should add to their formulary. We're told this process can take upwards of 8 months. As such, we encourage WPS to ensure there is enough time to implement the provisions of the LCD once finalized so not to negatively impact patient care.