COALITION OF

Wound
Care
Manufacturers

Oral Testimony at MAC "Listening Sessions" on LCDs/LCAs for use of CTPs in DFU/VLU

May 16, 2024

Good afternoon. My name is Karen Ravitz and I am the health policy advisor for the Coalition of Wound Care Manufacturers. Founded in 2000, the Coalition represents leading manufacturers of wound care products used by Medicare and commercially insured beneficiaries for the treatment of wounds; including cellular and or tissue-based products for skin wounds or CTPs that are the subject of this policy.

Thank you for the opportunity to provide our feedback to WPS (and to the other MACs over the days ahead) on the proposed LCD and accompanying LCA. The Coalition appreciates that the MAC adopted many of the changes recommended by the Coalition in our previously submitted comments– including but not limited to the ability for patients to obtain additional applications when medically necessary and documented. There are many areas in which we believe clarification is necessary but will provide those issues in our written comments.

For the hearing today I would like to focus on three issues:

First, while we fully support evidence-based policies, more clarity is needed to better understand the evidentiary bar. For example, while it appears that the MACs are only providing coverage for products with RCT studies, there are several products that have RCT studies which are not covered. It also appears that the only RCT studies that the MAC is accepting is for products that have applications within the policy parameters. The MAC has also indicated that coverage will be provided for CTPs having peer reviewed published evidence and yet there are products that have peer reviewed evidence that are also not covered. There is no consistency in the evidence that is being accepted by the MAC nor is there any transparency as to what metrics were utilized to review the evidence. As such, we would request the MAC be more transparent in its criteria for product coverage and publish what is considered an adequate trial design and outcome to gain coverage.

Second, we would also like to better understand the time frame and process a manufacturer will need to undertake when submitting evidence for consideration. Does the manufacturer need to submit a reconsideration request in order for the MAC to review evidence for consideration of being placed on the Group 2 list? OR, since changes can usually be made to the LCA without going through notice and comment

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– which is why the LCAs were established in the first place, a manufacturer can simply submit their evidence for consideration and the MAC will review and place the product on the Group 2 covered list if the MAC deems the evidence to be satisfactory without going through the notice and comment period? If the latter, how long will it take for the MAC to review and make a decision for inclusion? Will the decision include the rationale for either not placing or placing the product on the group 2 covered list? We raise this issue as in previous drafts we have been told inconsistent messages and would appreciate clarity being provided.

We would also like to know when WPS reviewed evidence for this policy what was the cut off date as there are recent studies that do not seem to be included in the evidentiary review for this draft policy.

Finally, we would like to ensure that all of the 15 codes and corresponding products listed in the group 2 covered products list are available for coverage and reimbursement for both DFUs and VLUs. Are you able to confirm this today?

As mentioned, the Coalition will be submitting written comments with additional issues being addressed.

Thank you for the opportunity to speak today.