Title: Comments provided by AATB during the CGS Listening Session held September 13, 2023:

The American Association of Tissue Banks is a professional, non-profit, scientific, and educational organization, with more than 123 accredited member tissue banks and over 7,000 individual members. The use of skin substitutes is an important issue for patients with chronic wounds, so we are thankful for this opportunity to provide feedback and hope to be a resource to CGS.

AATB has several concerns with CGS' final LCD and LCA. We therefore encourage CGS to:

- Update the LCA to provide payment for appropriately-regulated allografts in the Group 3 set of HCPCS codes;
- Provide at least 18 months for manufacturers to obtain proof of regulatory status and only use such evidence to confirm regulatory compliance;
- Revise the application limit to be consistent with patients' clinical needs, type of wound, and medical judgement of the treating physician; and
  Postpone the proposed implementation date until at least January 1, 2024.

First, AATB is concerned that numerous products are inappropriately excluded from coverage.

As we have previously noted, the Food and Drug Administration (FDA) has issued final guidance describing how tissue processors of two primary product types – amniotic membrane and various skin products – can legally distribute such tissues in compliance with FDA's regulatory scheme for human cells, tissues, and cellular and tissue-based products (or "HCT/Ps").

However, many cellular and tissue products (or "CTPs") are excluded from separate coverage and payment under the LCD and LCA, even when they are compliant with FDA's regulatory scheme, based on a determination that the CTPs are considered wound coverings or wound dressings, rather than skin substitutes.

AATB disagrees with this distinction and contends that many of the CTPs excluded from coverage are – in fact – skin substitutes. These allografts are often provided in the form of a sheet that is anchored to the wound with sutures, adhesive strips, or other similar mechanisms. This sheet provides "scaffolding" for the wound site by providing a temporary extracellular matrix framework for new skin cells to attach and grow into during the healing process, even if their primary purpose is to serve as a barrier or covering. Numerous randomized control trials support the use of CTPs – including those that serve as barriers and wound coverings or provide an extracellular matrix framework – in the treatment of diabetic foot ulcers and venous leg ulcers. The LCD's exclusion of allografts designated as wound coverings or wound dressings will therefore result in the discontinuation of coverage for numerous CTPs that play a significant role in the management of DFUs and VFUs.

Considering the importance of these products, we encourage you to cover all allografts that meet applicable regulatory requirements, including those considered a wound covering or barrier by the FDA, and defer to the professional judgement of the patient's physician to determine which allograft is most appropriate.

As noted previously, AATB believes all allografts in compliance with relevant FDA regulations should be covered by Medicare. If CGS continues to require proof of FDA regulatory compliance for 361 HCT/Ps (such as a letter from the FDA Tissue Reference Group), AATB believes that sufficient time should be

given for tissue processors to acquire those letters and that the CTPs should be covered while tissue processors work to obtain them. Specifically, we believe that an 18-month transition period is needed to account for the time it takes for companies to prepare TRG submissions and receive responses from the FDA. This timeline is based on our internal analysis that, in some cases, it takes more than 300 days to receive a final TRG letter; an increased workload for the TRG would further exacerbate delays.

We are further aware that language used in TRG letters is not standardized and is based on both the content of the applicant's submission and the TRG's interpretation of the submission contents at the time of review. We urge you to use the TRG letter only to verify that a CTP is appropriately regulated, not that a CTP may or may not be distributed or used for specific intended uses.

AATB understands that the 4-application limit was based on published evidence for a number of products that were used to heal small chronic wounds (i.e. less than 4 sq cm). However, there are many chronic wounds that will require more than four applications to heal. Rather than apply a hard limit, we suggest that the number of applications be supported by clinical notes in the patient's chart based on the patient's condition, the type of wound (VLU vs DFU), and the medical judgement of the treating physician.

The LCD limit of 4 applications within 12 weeks, with no meaningful flexibility, may result in providers stopping treatment to the detriment of beneficiaries who need it most: those with large and/or complex wounds, over long durations, and/or patients who are immunocompromised or have severe co-morbidities. In fact, restricting the number of applications could result in higher costs and necessitate more complex treatments for patients with such wounds.

Finally, we note that patient access to CTPs is particularly important given the disproportionate impact of DFUs and VFUs on racial and ethnic minority populations. Latinos, African Americans, and Native Americans in particular have the highest incidence of DFUs in the nation. Limiting access to these important wound care products may lead to greater disparities and worse outcomes for patients.

To provide sufficient time to address our concerns and protect beneficiary access to skin substitutes, we urge CGS to postpone the implementation date of the final LCD and LCA until at least January 1, 2024.

Thank you for considering these comments.