



January 18, 2023

Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted electronically at MedicarePhysicianFeeSchedule@cms.hhs.gov

RE: Feedback in Response to the CMS Skin Substitutes Town Hall

Dear Madams and Sirs:

The American Association of Tissue Banks (AATB) and the American Association of Tissue Bank's Tissue Policy Group (AATB TPG or TPG) are pleased to submit these comments in response to the Centers for Medicare & Medicaid Services (CMS) Skin Substitutes Town Hall on January 18, 2023.

Pioneered in the late 1800s, skin grafting was one of the first allografts, or tissues grafted from one patient to another. Since then, skin grafts, or "skin substitutes," have become a common way to treat patients with a variety of conditions, including burns, diabetic foot ulcers, and chronic wounds. Skin substitutes are used in nearly every hospital in the United States; in fact, it is estimated that over 160,000 skin grafts are performed per year across the country on patients with severe burns alone.¹

Access to skin substitutes is particularly important given the disproportionate need across racial and ethnic groups, as Latinos, African Americans, and Native Americans have the highest incidence of foot ulcers in the United States.² Ensuring access to skin substitutes, therefore, would support health equity and improved health outcomes for historically disadvantaged populations.

The AATB and TPG are concerned, however, that CMS' current consideration and potential future action regarding payment for skin substitutes could significantly restrict access to these products, particularly for Medicare beneficiaries seeking care in physician office settings. We therefore appreciate the opportunity to provide additional feedback to CMS potential future skin substitute policies, including through our verbal statement delivered at the Town Hall and this written statement that provides further elaboration.

In the announcement of the Town Hall, CMS sought feedback on the following four questions:

1. What should CMS consider as part of CMS efforts to ensure consistent, fair, and appropriate payment for services and products across different settings of care?

¹ Serebrakian, Arman T., et. al. Meta-analysis and Systemic Review of Skin Graft Donor-site Dressings with Future Guidelines. PRS Global Open. 2018 Sept. 24, doi: 10.1097/GOX.0000000000001928

² Oliver, Tony. I; Mutluoglu, Mesut. Diabetic Foot Ulcer. StatPearls [Internet]. 2022 Aug. 8. <https://www.ncbi.nlm.nih.gov/books/NBK537328/>

2. How could CMS ensure that valuation under the PFS adequately accounts for variability in relative resource costs of different skin substitute products as supplies within the Practice Expense Relative Value Unit (PE RVU) methodology?
3. Are there similarly resourced groups of products/services that could inform how payment might be stratified without risking access to services?
4. What should CMS consider as alternatives regarding any potential changes to terminology?

Our comments below address questions 4, 1, and 2, in that order.

What should CMS consider as alternatives regarding any potential changes to terminology?

The AATB and TPG appreciate CMS' stated goals behind replacing the "skin substitutes" terminology, but do not believe that "wound care management" or "wound care management products" accurately describes these products. Instead, the AATB and TPG recommend using the term "cellular and/or tissue-based products (CTPs) for skin wounds" or "CTPs for skin wounds." Consistent with this recommendation, we will use that term throughout this letter.

Notably, the AATB and TPG do not believe that purely synthetic products should be included within this classification. Treating purely synthetic products as distinct from CTPs is consistent with industry standards, including ASTM F3163-16, which includes allografts, xenografts, and hybrid synthetics as CTPs for skin wounds. For consistency and to reflect industry consensus, CMS should align with these standards.

What should CMS consider as part of CMS efforts to ensure consistent, fair, and appropriate payment for services and products across different settings of care?

The AATB and TPG understand CMS' interest in aligning payment across settings of care, and we believe that there are a number of factors that CMS should take into consideration. These include:

- The demonstrated clinical value of CTPs for skin wounds relative to the standard of care. Given the evidence supporting the clinical benefits of CTPs for skin wounds, CMS should ensure that Medicare beneficiaries' maintain ongoing access to these products.
- The need to ensure payment is sufficient to cover costs, regardless of setting. To the extent possible, payment should align with costs, including when costs vary by product, the size/amount of product used, the number of applications required, and the costs of administering the products.
- The feasibility of achieving consistent and fair payment across settings when each setting is subject to its own separate rules for establishing and updating payments. In particular, we are concerned that if payment for CTPs for skin wounds are folded into the Medicare Physician Fee Schedule (PFS), payments for these products would be inappropriately constrained under the PFS relative to payments under the Outpatient Prospective Payment System (OPPS), as further detailed in our response to Question 2.
- Individual patient needs and the importance of the professional judgement of health care providers in the treatment of patients using CTPs for skin wounds. Providers should have the ability to select from a wide array of products based on patients' needs and responses to

treatments.

- The potential for increased transparency related to average sales price (ASP)-based reimbursement to achieve the goals of consistent, fair, and appropriate payment. In Q1 2023, CMS started to publish the ASP rates across a wider range of products. This enhanced transparency could drive down costs while preserving innovation and access. CMS should expand publication of ASPs and to give this process more time.
- The need for transparency, certainty, and reasonable timelines in any payment transition. If CMS were to restructure payment for CTPs for skin wounds in any setting, it would be imperative for CMS to do so in a transparent manner that clearly details the data used, including average sales prices (ASP) for individual CTPs, the methodology used to translate ASP data to pricing under a revised payment framework, and final prices that would apply. CMS should also ensure that changes are effectuated over a reasonable timeframe that provides stakeholders with clear expectations and sufficient time and opportunity to plan and implement necessary changes.

Payment for CTPs for skin wounds is complex, which means that even minor changes may have unintended consequences that can negatively impact beneficiary access. CMS must give adequate consideration to the above factors, to ensure that patients can continue to access these important products while also supporting consistent, fair, and appropriate payment.

How could CMS ensure that valuation under the PFS adequately accounts for variability in relative resource costs of different skin substitute products as supplies within the Practice Expense Relative Value Unit (PE RVU) methodology?

The AATB and TPG strongly object to the premise of this question, which assumes that CTPs for skin wounds would be considered incident to supplies captured within the PE RVU methodology. CTPs for skin wounds are not supplies, but key medical products that are critical in supporting the treatment of certain wounds. Numerous published prospective multicenter randomized control trials have proven that CTPs for skin wounds are significantly more effective supporting the healing of wounds such as diabetic foot ulcers versus standard of care;^{3,4,5,6} the standard of care includes treating wounds with actual supplies currently categorized under A codes [e.g. collagen alginates (A6010)].

We also note that incorporating CTPs for skin wounds into the PE RVU methodology would have significant ramifications for the payment that physician offices could receive for the application of these products due to the constraints on payment that apply under the PFS. First, the pool of PE RVUs is

³Guo X, Mu D, Gao F. Efficacy and safety of acellular dermal matrix in diabetic foot ulcer treatment: A systematic review and meta-analysis. *Int J Surg*. 2017 Apr;40:1-7. doi: 10.1016/j.ijsu.2017.02.008. Epub 2017 Feb 14 .

⁴Cazzell S, Vayser D, Pham H, Walters J, Reyzelman A, Samsell B, Dorsch K, Moore M. A randomized clinical trial of a human acellular dermal matrix demonstrated superior healing rates for chronic diabetic foot ulcers over conventional care and an active acellular dermal matrix comparator. *Wound Repair Regen*. 2017 May;25(3):483-497. doi: 10.1111/wrr.12551. Epub 2017 Jun 12.

⁵Reyzelman AM, Bazarov I. Human acellular dermal wound matrix for treatment of DFU: literature review and analysis. *J Wound Care*. 2015 Mar;24(3):128; 129-34. doi: 10.12968/jowc.2015.24.3.128.

⁶Zelen CM., et al. An Aseptically Processed, Acellular, Reticular, Allogenic Human Dermis Improves Healing in Diabetic Foot Ulcers: A Prospective, Randomised, Controlled, Multi-Centre Follow-Up Trial. *Int Wound J*. 2018 Apr 22. doi: 10.1111/iwj.12920.

subject to budget neutrality, which limits the ability of payments to keep pace with cost increases. Furthermore, the PFS is subject to an additional overall budget neutrality requirement, which may lead to reductions in the PFS conversion factor. Indeed, budget neutrality adjustments have led to in negative payment updates under the PFS for the last three years, since 2021.

Furthermore, annual PFS payment updates are not meaningfully tied to inflation. While payments under the OPPS increase annually based on increases in the hospital market basket, the PFS receives zero or little inflationary updates based on current law, even before application of budget neutrality adjustments. Thus, if payments for CTPs for skin wounds are incorporated into PE RVUs, payment for these products would be significantly constrained over time. This constraint on payment growth under the PFS would lead to divergence in payments across different care settings, with payments increasing more quickly under the OPPS than under the PFS. Rather than achieving consistent payment across settings, incorporation of CTPs for skin wounds into PE RVUs could instead exacerbate payment differentials, encourage greater use in more expensive outpatient hospital settings, and limit access for patients in office settings.

Separate but related, we also note that CMS proposed moving spending for skin substitutes, which currently takes place outside of the PFS, into the PFS. However, CMS did not clearly identify how much spending would move into the PFS. Likewise, CMS did not specify whether the spending would add new PE RVUs or whether it would be incorporated within the existing pool of PE RVUs due to budget neutrality constraints; the AATB and TPG would strongly object to the latter, which would effectively cut payment for every service in the PFS. Furthermore, we believe that much greater transparency is needed regarding these considerations, such that stakeholders can provide informed feedback.

Given the above, we urge CMS to abandon consideration of incorporating CTPs for skin wounds into the PE RVU methodology.

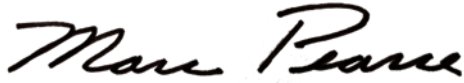
Additional Considerations

Finally, in addition to our responses above, the AATB and TPG note that – for products regulated under Section 361 of the Public Health Service Act (“361 HCT/Ps”) – CMS and its Medicare Administrative Contractors are increasingly moving towards requiring manufacturers to obtain letters from the FDA’s Tissue Reference Group (TRG) to confirm a product’s regulatory status. Currently, FDA offers TRG letters on a voluntary basis to manufacturers who wish to seek certainty regarding the appropriate regulatory paradigm for their products. Making a TRG letter a condition of Medicare coverage or payment could quickly overwhelm the TRG and result in significant delays to obtain such letters. Furthermore, applying such a requirement retroactively without an appropriate “on-ramp” may result in an abrupt loss of access to these products. If the agency moves forward with a requirement for manufacturers to obtain new HCPCS Level II codes (as proposed in the Calendar Year 2023 PFS proposed rule), the AATB and TPG recommend providing manufacturers with at least 24 months to obtain new HCPCS Level II codes. This timeline will provide manufacturers with sufficient time to request and receive a TRG letter, as well as to prepare and submit new HCPCS Level II applications and obtain new codes.

**

Thank you for taking these comments into consideration. The AATB and TPG stand ready and willing to assist CMS with its deliberations in any way that you deem appropriate.

Respectfully,



Marc Pearce
President & CEO
American Association of Tissue Banks



Doug Wilson
Chair
Tissue Policy Group

The American Association of Tissue Banks

AATB is a professional, non-profit, scientific, and educational organization. AATB is the only national tissue banking organization in the United States, and its membership totals more than 120 accredited tissue banks and over 6,500 individual members. These banks recover tissue from more than 58,000 donors and distribute in excess of 3.3 million allografts for more than 2.5 million tissue transplants performed annually in the US. The overwhelming majority of the human tissue distributed for these transplants comes from AATB-accredited tissue banks.

The AATB TPG includes Chief Executive Officers and senior regulatory personnel from U.S. tissue banks that process donated human tissue. The purpose of the TPG is to drive policy in furtherance of the adoption of laws, regulations and standards that foster the safety, quality, and availability of donated tissue. The TPG's membership is responsible for the vast majority of tissue available for transplantation within the U.S.

To learn more visit: www.aatb.org