



September 6, 2023

The Honorable Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
U.S. Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

In Re: CMS-1784-P, Medicare and Medicaid Programs; CY 2024 Payment Policies under the Physician Fee Schedule and Other Changes

Submitted electronically at www.regulations.gov

Dear Administrator Brooks-LaSure:

The American Association of Tissue Banks (AATB or Association) and the American Association of Tissue Bank's Tissue Policy Group (AATB TPG or TPG) submit these comments related to payment for "skin substitutes" under the Centers for Medicare and Medicaid Services (CMS or Agency) CY2024 Physician Fee Schedule (PFS) Proposed Rule (i.e., PFS Proposed Rule).

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 6,000 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 U.S. 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.

Concerns with and Response to CMS CY2024 PFS Proposed Rule.¹ In general, we appreciate that CMS did not finalize the proposed changes related to skin substitutes from the CY2023 PFS Proposed Rule, but we continue to strongly object to the premise that skin substitutes (or CTPs for skin wounds) should be considered incident to supplies captured within the Practice Expense Relative Value Unit (PE RVU) methodology. These products 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 in supporting the healing of

¹ Note: the AATB and TPG have included an addendum describing the history of use

wounds such as diabetic foot ulcers versus standard of care;^{2 3 4 5} the standard of care includes treating wounds with actual supplies currently categorized under A codes [e.g. collagen alginates (A6010)].

Incorporating skin substitutes 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 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, and the conversion factor is again facing a steep decline for 2024 as well.

Furthermore, annual PFS payment updates are not meaningfully tied to inflation. While payments under the Medicare Outpatient Prospective Payment System (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 skin substitutes 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 skin substitutes 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.

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

Other Comments. We note that CMS addressed whether skin substitutes would be subject to the new refundable drug requirement by stating that these products “would not be counted for purposes of identifying refundable drugs for calendar quarters during 2023 and 2024.” We support this approach, which provides stability and reduces burden for tissue processors during this uncertain period.

Finally, in addition to our responses above, the AATB and TPG continue to 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

² Guo 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.ijssu.2017.02.008. Epub 2017 Feb 14 .

³ Cazzell 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

⁴ Reyzelman 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.

⁵ Zelen 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.

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, as CMS has previously proposed, could quickly overwhelm the TRG and result in significant delays to obtain such letters. Furthermore, applying such a requirement retroactively to existing products without an appropriate “on-ramp” may result in an abrupt loss of access to these products. Last year, the AATB and TPG [reviewed](#) a large number of recent tissue bank submissions to the TRG and found that TRG response times averaged 140.7 days, with a range of 26 to 344 days.

The AATB and TPG, therefore, recommend that CMS take these considerations into account when contemplating policies that would require receipt of a TRG letter and provide manufacturers with ample time to adhere to any new requirements, including at least eighteen months to apply for and obtain a TRG letter, and additional time, as needed, to meet other regulatory requirements that may apply. In our view, for example, CMS’ proposal in the CY 2023 PFS Proposed Rule to require receipt of a TRG letter and apply for a new HCPCS Level II code within 12-months would have been infeasible and would have resulted in severe disruptions in beneficiary access to many well-established products, and instead, an 18-month timeline would have been necessary to achieve compliance with minimal disruption.

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We hope that you will find this information useful in your deliberations. 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

ADDENDUM: History of Use

History of use. Certain wound-related “361 HCT/Ps,” which include certain amnion, split-thickness skin, and decellularized dermis products, per the Food and Drug Administration, have “utility to serve as a protective covering”⁶ or “to serve as a barrier.”⁷ Recognizing the need to assist individuals with severe burns, skin grafting was one of the first allografts. The use of allograft skin dates back to Reverdin in 1869

⁶ See Example 11-3 related to skin products with the FDA’s final guidance titled *Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use*.

⁷ See Example 10-2 related to amniotic products within the FDA’s final guidance titled *Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use*.

describing the use of skin grafting in clinical practice for the first time.⁸ George Pollock used his skin in addition to the patient's skin to cover a burn in 1871.⁹ The first report of successful use of allograft skin to treat a burn was by Girdner in 1881.¹⁰ In 1903, Wentscher reported that allograft skin retained cellular viability after 3-14 days.¹¹ James Barrett Brown, M.D. (1899-1971), with his work in the early 1930s, revolutionized the concepts of skin grafting.^{12,13} His work highlighted the nature of allografts – that split-thickness skin from the mother was completely absorbed within three weeks of being transferred to her severely burned son.¹⁴ Organizations, such as the Ancient Arabic Order of the Nobles of the Mystic Shrine – or Shriners – helped further the use of skin grafts to assist burn care for children for 50 years.¹⁵ As skin grafting became more common to save the life of burn patients, banking of skin paralleled the development of blood banks in the 1930s and gave way to the development of The Navy Tissue Bank in 1949. Thus, it is unsurprising that the human split-thickness skin and decellularized dermis are still used today for various applications, including diabetic foot ulcers^{16,17,18,19} and chronic wounds.²⁰

Similarly, the human amniotic membrane has been utilized to treat wounds for over a century. In 1910, Davis utilized the lining of the amniotic sac as a skin graft.²¹ In 1913, two additional studies were published

⁸ Reverdin JL. Greffeepidermique, experiencefaitedans le service de M le docteurGuyon, a l'hopitalnecker. Bull Imp SocChir Paris. 1869;10:511–5

⁹ Pollock GD. Cases of skin grafting and skin transplantation. Trans Clin Soc Lond. 1871;4:37–54

¹⁰ Girdner JH. Skin-grafting with grafts taken from the dead subject. Med Record NY. 1881;20:119–20

¹¹ Wentscher J. A further contribution about the survivability of human epidermal cells. Dtsch Z Chir. 1903;70:21–44.

¹² Blair VB, Brown JB, Hamm WG. Early Cre of burs. JAMA 1932;98:1355-1359.

¹³ Blair VP, Brown JB. The use and uses of split thickness skin grafts of intermediate thickness. Surg Gynecol Obstet. 1928;98:82-97.

¹⁴ Ibid.

¹⁵ Čapek KD, Culnan DM, Desai MH, Herndon DN. Fifty Years of Burn Care at Shriners Hospitals for Children, Galveston. Ann Plast Surg. 2018;80(3 Suppl 2):S90–S94. doi:10.1097/SAP.0000000000001376

¹⁶ Guo 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

¹⁷ Cazzell 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.

¹⁸ Reyzelman 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.

¹⁹ Zelen 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.

²⁰ Walters J, Cazzell S, Pham H, Vayser D, Reyzelman A. Healing Rates in a Multicenter Assessment of a Sterile, Room Temperature, Acellular Dermal Matrix Versus Conventional Care Wound Management and an Active Comparator in the Treatment of Full-Thickness Diabetic Foot Ulcers. *Eplasty*. 2016;16:e10. Published 2016 Feb 4.

²¹ Davis JW. Skin transplantation with a review of 550 cases at the Johns Hopkins Hospital. Johns Hopkins Med J Hosp Rep 1910;15:307–96.

related to the use of amnion for skin grafting.^{22,23} In 1940, DeRotth used chorion and amnion to treat eye wounds.²⁴

²² Stern M. The grafting of preserved amniotic membrane to burned and ulcerated surfaces, substituting skin grafts. *J Am Med Assoc* 1913;83:478–80.

²³ Sabella N. Use of the fetal membranes in skin grafting. *Medical Records NY* 1913;83:478–80.

²⁴ De Rotth A. Plastic repair of conjunctival defects with fetal membranes. *Arch Ophthalmol* 1940;23:522–5.