



American Association of Tissue Banks® AATB TPG, LLC

September 13, 2022

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

In Re: Docket No. CMS-1772-P, Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Organ Acquisition; etc.

Submitted electronically at www.regulations.gov

Dear Madams and Sirs:

The American Association of Tissue Banks (AATB or Association) and the American Association of Tissue Bank's Tissue Policy Group, LLC (AATB TPG or TPG) submit these comments related to proposed changes to the terminology for "skin substitutes" by the Centers for Medicare and Medicaid Services (CMS) within the Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems and Quality Reporting Programs (i.e., the OPPS/ASC proposed rule). Please see our comments to the Medicare Physician Fee Schedule for a more comprehensive view of key policy concerns related to "skin substitutes."

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 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.

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”¹ or “to serve as a barrier.”² 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 describing the use of skin grafting in clinical practice for the first time.³ George Pollock used his own skin in addition to the patient’s own skin to cover a burn in 1871.⁴ The first report of successful use of allograft skin to treat a burn was by Girdner in 1881.⁵ In 1903, Wentscher reported that allograft skin retained cellular viability after 3-14 days.⁶ James Barrett Brown, M.D. (1899-1971), with his work in the early 1930s, revolutionized the concepts of skin grafting.^{7,8} 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.⁹ 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.¹⁰ 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^{11,12,13,14} and chronic wounds.¹⁵

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.¹⁶ In 1913, two additional studies

¹ 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*.

² 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*.

³ Reverdin JL. Greffeepidermique, experiencefaitedans le service de M le docteurGuyon, a l’hopitalnecker. Bull Imp SocChir Paris. 1869;10:511-5

⁴ Pollock GD. Cases of skin grafting and skin transplantation. Trans ClinSocLond. 1871;4:37-54

⁵ Girdner JH. Skin-grafting with grafts taken from the dead subject. Med Record NY. 1881;20:119-20

⁶ Wentscher J. A further contribution about the survivability of human epidermal cells. Dtsch Z Chir. 1903;70:21-44.

⁷ Blair VB, Brown JB, Hamm WG. Early Cre of burs. JAMA 1932;98:1355-1359.

⁸ Blair VP, Brown JB. The use and uses of split thickness skin grafts of intermediate thickness. Surg Gynecol Obstet. 1928;98:82-97.

⁹ Ibid.

¹⁰ 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

¹¹ 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

¹² 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.

¹³ 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.

¹⁴ 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.

¹⁵ 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.

¹⁶ Davis JW. Skin transplantation with a review of 550 cases at the Johns Hopkins Hospital. *Johns HopkinsMed J Hosp Rep* 1910;15:307-96.

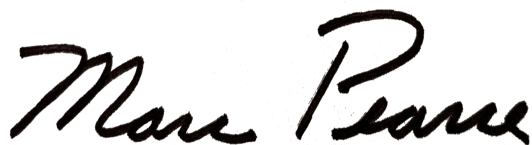
were published related to the use of amnion for skin grafting.^{17,18} In 1940, DeRotth used chorion and amnion to treat eye wounds.¹⁹

CMS proposal with the OPPS/ASC proposed rule. CMS proposes to replace the term “skin substitutes” with the term “wound care management” or “wound care management products.” As part of the OPPS/ASC proposed rule, CMS noted that “[t]he CY 2023 PFS proposed rule contains a proposal to treat all skin substitute products consistently across healthcare settings as incident-to supplies. If this proposed policy is finalized, manufacturers would not report ASPs for skin substitute products starting in CY 2023, so CMS would no longer be able to use ASP+6% pricing to determine whether a product should be assigned to the high cost or low-cost group. However, manufacturers would continue to report WAC and AWP pricing information, which will allow CMS to continue to use its alternative process to assign these products.”

Concerns with the terminology of “wound care management products.” While we appreciate the overall goal of replacing the older terminology of “skin substitutes” for these products, we are discouraged that CMS has attempted to include purely synthetic products within this classification. Products that are 100% synthetic should be considered “incident to supplies,” given their cost structure and their overall efficacy. Thus, it is appropriate that these products be denoted through A codes. Further, excluding these products is consistent with industry standards, including [ASTM F3163-16](#), which “defines terminology for description of cellular and/or tissue-based products (CTPs) for skin wounds.” The ASTM standard includes allografts, xenografts, and hybrid synthetics. In light of all of these concerns, ***we recommend that (1) you utilize the terminology “cellular and/or tissue-based products for skin wounds” or “CTPs for skin wounds” and (2) exclude all 100% synthetic products from this category.***

We hope that you will find this information useful in your deliberations. We look forward to participating in any additional public discussions on this topic, including an open-door forum/listening session mentioned in the proposed rule. The AATB and the TPG stand ready and willing to assist the FDA with its deliberations in any way that you deem appropriate.

Respectfully,



Marc Pearce, MBA
President & CEO
American Association of Tissue Banks



Joe Yaccarino
Chair
Tissue Policy Group

¹⁷ Stern M. The grafting of preserved amniotic membrane to burned and ulcerated surfaces, substituting skin grats. J Am Med Assoc 1913;83:478–80.

¹⁸ Sabella N. Use of the fetal membranes in skin grafting. Medical Records NY 1913;83:478–80.

¹⁹ De Rotth A. Plastic repair of conjunctival defects with fetal membranes. Arch Ophthalmol 1940;23:522–5.