



December 30, 2022

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

In Re: CMS-1772-FC, 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 (AATB TPG or TPG) submit these comments related to objectives for refining Medicare policies for payment and coding of skin substitutes, as included in the Centers for Medicare and Medicaid Services (CMS or Agency) Hospital Outpatient Prospective Payment System (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems and Quality Reporting Programs final rule with comment, as well as in the Calendar Year (CY) 2023 Physician Fee Schedule final rule. Please see our comments on the Medicare Physician Fee Schedule (PFS) proposed rule, submitted on September 6, 2022, 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. As stated in our September 13, 2022 comment letter on the OPPS/ASC proposed rule, "skin substitutes" have a well-established history of use. In particular, certain wound-related "361 human cells, tissues, and cellular and tissue-based products," or "361 HCT/Ps," which include certain amnion, split-thickness skin, and decellularized dermis products,

per the Food and Drug Administration (FDA), 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 skin in addition to the patient’s 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

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, experiencefaite dans le service de M le docteur Guyon, a l’hopitalnecker. Bull Imp SocChir Paris. 1869;10:511-5

⁴ Pollock GD. Cases of skin grafting and skin transplantation. Trans Clin Soc Lond. 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.

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 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

Skin Substitute Terminology. CMS previously proposed replacing the term “skin substitutes” with the term “wound care management” or “wound care management products.” In both the OPPTS/ASC and PFS final rules, the Agency notes that it has decided not to finalize a change in terminology; CMS also stated that it will “further engage with stakeholders prior to adopting any new terminology in future rulemaking” (PFS final rule). Additionally, CMS announced in the PFS final rule that it plans to hold a town hall in early 2023, prior to CY 2024 rulemaking, “to further understand the concerns interested parties have about potential new terminology [CMS] could consider and any alternative terms not yet considered.” The AATB and TPG appreciate the Agency’s decision to reconsider the proposed terminology changes and look forward to further dialogue on this issue. We respectfully request to participate in the town hall to present our positions.

As noted in the AATB and TPG comment letter on the OPPTS proposed rule, we appreciate the overall goal of replacing the older terminology of “skin substitutes” for these products, but 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. Additionally, CMS does not currently recognize these products as drugs or biologics. Thus, it is appropriate that these products continue to be denoted through A codes. Further, treating these products as distinct from cellular and/or tissue-based products (CTPs) 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 these concerns, we recommended that (1) CMS 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.

Coding and reimbursement for skin substitutes. Regarding coding and reimbursement for “skin substitutes,” the AATB and TPG also appreciate that CMS recognized in the PFS final rule that “it would be beneficial to provide interested parties more opportunity to comment on the specific details of changes in coding and payment mechanisms prior to finalizing a specific date when the transition to more appropriate and consistent payment and coding for these products will be completed.” The AATB and TPG similarly appreciate that CMS plans to hold a town hall in early CY 2023 to further discuss this issue.

¹⁶ 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.

¹⁷ Stern M. The grafting of preserved amniotic membrane to burned and ulcerated surfaces, substituting skin grafts. *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.

We are concerned, however, that the both the PFS and OPPTS final rules reiterated the agency's belief that "skin substitutes are a heterogenous group and there is an increasing intersection between biological, bioengineered, and synthetic components (PFS final rule)... the current categorization of skin substitutes as either synthetic or non-synthetic is not mutually exclusive given the expansion of skin substitute products that may contain both biological and synthetic elements" (OPPTS final rule). As we described in the previous section, we believe that 100% synthetic products should be treated as distinct products.

Additionally, as noted in our September 6, 2022, letter on the PFS proposed rule, CTPs for skin wounds are NOT supplies, but key medical products that are important to the treatment of wounds. Numerous published prospective multicenter randomized control trials have proven that CTPs for wounds are significantly more effective in healing wounds such as diabetic foot ulcers versus standard of care (SOC); SOC includes treating wounds with actual supplies currently categorized under A codes [e.g. collagen alginates (A6010)]. We reiterate our recommendation that all the current Q codes for CTPs for skin wounds continue as Q codes and not convert to A codes.

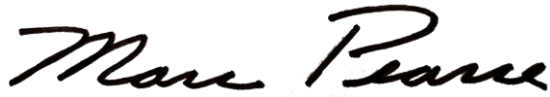
As it relates to reimbursement, particularly in the physician office setting, we are pleased CMS has added CTPs to the average sales price (ASP) file. We continue to recommend CMS publish all skin substitute products on the national quarterly Part B Drug file at the manufacturer's reported ASP +6%. This will ensure consistent reimbursement in all MAC jurisdictions, as well as save the Medicare Trust Fund inflated expenditures for this category since ASP includes all price concessions and represents the actual market cost to physicians.

Other outstanding concerns. Finally, our September 6, 2022, letter on the PFS proposed rule addresses the AATB and TPG's other concerns related to "skin substitutes." In particular, we reiterate our concerns with an across-the-board requirement, if implemented, to obtain recommendation letters from the FDA Tissue Reference Group (TRG) for certain "361 HCT/Ps" for skin wounds. Based on our internal analysis, in some cases it takes over 300 days to receive a final TRG letter. We therefore suggest that – if CMS believes TRG recommendation letters may be needed – CMS consider working with the FDA to determine a list of factors that would automatically require such a letter (e.g. amnion not in sheets, amnion with the use of "wound healing," etc.) and otherwise allowing all of the current "skin substitute" codes to remain active. As stated in the PFS comment letter, this process would help appropriately ensure that products covered by CMS are legally marketed, while not putting an undue burden on the FDA or tissue banks.

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We hope that you will find this information useful in your deliberations. The AATB and the TPG stand ready and willing to assist CMS with its deliberations in any way that you deem appropriate.

Respectfully,



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President & CEO
American Association of Tissue Banks



Joe Yaccarino
Chair
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The American Association of Tissue Banks

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To learn more visit: www.aatb.org