



September 6, 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-1770-P, Medicare and Medicaid Programs; CY 2023 Payment Policies under the Physician Fee Schedule and Other Changes

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 reimbursement and process for assigning specific codes for "skin substitutes" by the Centers for Medicare and Medicaid Services (CMS) within the CY2023 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 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 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

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 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.

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.

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

Summary of key proposals within the CMS PFS proposed rule. With the PFS proposed rule, CMS detailed a series of proposed changes related to “skin substitutes,” including the following:

- CMS proposes to change the terminology it uses for the suite of products referred to as “skin substitutes” to instead use the term “wound care management” or “wound care management products.”
- CMS proposes that skin substitute products that are commonly furnished in the physician office setting be considered as “incident to supplies” in accordance with section 1861(s)(2)(A) of the Act, effective January 1, 2024.
- CMS proposes a deadline of 12 months after the effective date of the CY 2023 PFS final rule for applicants to submit HCPCS Level II applications for HCT/Ps.
- CMS proposes to establish “A” codes for all skin substitute products meeting the criteria for a HCPCS Level II code and proposes to contractor price these codes effective January 1, 2024.
- Effective January 1, 2024, CMS proposes that the assignment of A codes to all wound care management products that are not drugs or biologics would continue with respect to products for which a HCPCS Level II code is requested for the first time, as well as for wound care management products to which CMS previously assigned a Q code.
- CMS proposes to no longer evaluate HCPCS Level II coding applications for such products on a quarterly basis beginning January 1, 2024, and to instead evaluate them through the biannual coding cycles for non-drugs and non-biological products.
- CMS proposes to allow a 12-month period from the effective date of the CY 2023 final rule (that is, January 1, 2024) to allow for re-application submissions.
- After a public meeting and appropriate review by CMS, CMS proposes to discontinue all existing Q codes for wound care management products and to establish new A codes for such products that have submitted the appropriate documentation. CMS proposes to make the effective date of the new A codes to coincide with the discontinuation date of the corresponding Q codes.
- For a product that is described by the applicant as a 361 HCT/P, CMS is proposing that the first-time application or re-application would need to provide a recommendation letter from the Tissue Reference Group (TRG) of the Food and Drug Administration (FDA) which would aid in CMS’ determination of how the product should be classified for coding purposes.
- CMS proposes to take a similar approach (i.e., require a TRG letter within the HCPCS submission) for all new 361 HCT/Ps in which Q codes are issued before January 1, 2024.

In addition, CMS proposed some similar changes in the Hospital Outpatient Prospective Payment (OPPS) and Ambulatory Surgical Center (ASC) Payment Systems and Quality Reporting Programs (i.e., the OPPS/ASC proposed rule).

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.

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.***

Concerns with the proposed payment process. While we appreciate the overall goal of CMS to reimburse CTPs for skin wounds similarly, irrespective of the site of care, ***we remain concerned that the proposed process effectively results in an inability to appropriately ascertain the actual, proposed payment rate.*** This is particularly problematic in light of published papers that note that there is limited commercial viability for CTPs for skin wounds because “reimbursement for wound care management is highly complex and dependent on a multitude of factors, which may impede patient access to products and discourage sponsors from innovative wound care product development.”²⁰ Thus, with this additional payment complexity, CMS is likely impeding innovation, diminishing patient access to certain skin substitute products, and fostering other unintended consequences. We continue to believe that CTPs for skin wounds should be paid separately from the professional fee and, not as “incident to supplies” but rather as separately reimbursable products in acknowledgment of their value-add for wound care. ***In light of these key concerns, we request that, before moving to this proposed payment system, CMS publish a chart that provides relevant reimbursement data for all affected codes, including (1) current payment under the PFS; (2) proposed payment under the PFS; and (3) current payment under OPPS/ASC.*** We recognize that the development of this data may take additional time for the CMS to develop and publish. In light of that necessary time, ***we believe that CMS should further delay the implementation of any new payment policy by at least one year.***

In addition, despite CMS’ stated goal to pay similar rates for CTPs for skin wounds at various sites of care, the proposed payment policy with the PFS is different from the current payment policy within the hospital outpatient and ambulatory surgical center settings. Specifically, the OPPS/ASC payment process includes certain protections for CTPs for skin wounds including:

- having a low- and high-cost category, which provides more appropriate reimbursement in light of the wide range of costs associated with purchasing such products;
- instituting a “hold harmless” such that a skin substitute that falls from the high-cost to low-cost category receives one year of payment at the high-cost rate; and
- perhaps most importantly, not having a budget neutrality factor. Within the OPPS/ASC payment process, there is an ability for the average cost within the low- and high-cost category to fluctuate, depending on overall market pricing as well as additional skin

²⁰ Verma, KV et al. Food and Drug Administration perspective: Advancing product development for non-healing wounds. *Wound Repair Regen.* 2022 May; 30(3): 299-302. Doi: 10.1111/wrr.13008.

substitutes seeking reimbursement. However, under the PFS, “incident to” supplies contribute to practice expense (PE) relative value units (RVUs), which are subject to PE budget neutrality adjustments. The PFS is also subject to an overall budget neutrality requirement that typically applies to the PFS conversion factor and may reduce payment if CMS’ changes to RVUs would otherwise increase expected payment. Thus, if not addressed properly, the application of the budget neutrality factor may provide inappropriate downward pressure on total skin substitute reimbursement, as well as on overall physician payment rates.

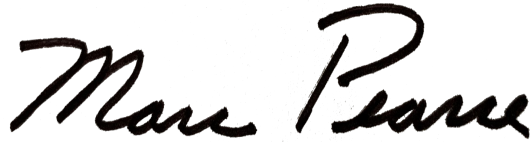
Finally, by classifying CTPs for skin wounds as “incident to” supplies, CMS acknowledged that it would result in a reduction in the frequency of meetings for HCPCS code review (from four times a year as it is now to twice a year), but it is also unclear if the proposal would result in new CTPs for skin wounds being unable to receive pass-through payments and whether CMS has envisioned a similar process for the newly assigned products (e.g., New Technology Ambulatory Payment Classification).

Concerns with the TRG letter process. While we are aware that, since 2020, CMS has required “361 HCT/Ps” to submit a letter from the FDA’s TRG to confirm its status, we are concerned with your proposal to require all other “361 HCT/Ps” utilized for skin wounds to submit such letters by January 1, 2024, given our recent experience with the TRG in receiving such letters. The FDA TRG process is not streamlined, and it may take an inordinate amount of time (e.g., over 300 days) to receive a final TRG letter. In light of this, we recommend that ***CMS delay, by at least one year, the submission of the TRG letter for certain “361 HCT/Ps” for skin wounds (from January 1, 2024, to January 1, 2025).*** In addition, ***we suggest that you consider working with the FDA to determine a list of factors that would automatically require such a letter*** (e.g., amnion that is not in sheets, amnion with the use of “wound healing,” etc.) ***and otherwise allowing all of the current “skin substitute” codes to be retained.*** 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.

Concerns with the coding. As previously discussed, we firmly believe that CTPs for skin wounds should continue to be separately reimbursable and not inappropriately paid as “incident to supplies.” While we acknowledge that the current Q code process may not be perfect, given that those codes are generally intended to be temporary codes for miscellaneous services, we remain concerned with converting current CTPs for skin wounds to A codes, given that A codes are for supplies. 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)]. In light of these concerns, ***we recommend that all the current Q codes for CTPs for skin wounds continue as Q codes and not convert to A codes.***

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,

A handwritten signature in black ink that reads "Marc Pearce". The letters are cursive and fluid.A handwritten signature in black ink that reads "Joe Yaccarino". The signature is stylized with a long horizontal line extending to the right.

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

Joe Yaccarino
Chair
Tissue Policy Group