COALITION OF

Wound Care Manufacturers

February 10, 2023

Ms. Carol Blackford
Director
Hospital and Ambulatory Policy Group
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Mr. Ryan Howe
Deputy Director
Hospital and Ambulatory Policy Group
Centers for Medicare & Medicaid Services
Department of Health and Human Services
7500 Security Boulevard
Baltimore, MD 21244

Submitted electronically to MedicarePhysicianFeeSchedule@cms.hhs.gov

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

Dear Director Blackford and Deputy Director Howe:

On behalf of the Coalition of Wound Care Manufacturers, I am providing further feedback on questions posed during the CMS Town Hall meeting held on January 18, 2023. Founded in 2000, the Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including skin substitutes. Our members have a vested interested in ensuring that whatever policy objectives CMS has and whatever policy it moves forward with are created in a sound manner and do not negatively impact patient access to these products which are known to reduce infection and amputations in patients with diabetic foot ulcers.

The Coalition is adamantly opposed to any change to the way skin substitutes have been coded and reimbursed in the physician's office for over 30 years and believe these seismic changes will lead to significant limitations on the access to care for numerous patient populations including but not limited to: minorities, patients in rural areas and patients with diabetes. The bundling of skin substitutes is not in the best interest of Medicare beneficiaries who are likely going to be subjected to unnecessary anesthesia and longer waits to get their wounds treated as operating room time is difficult to come by. Most importantly, as a result of the potential to limit access to care, there could be increases in infections, amputations and sadly loss of life.

Skin substitutes are an effective advanced treatment for patients with chronic wounds and therefore, an important treatment modality for clinicians. But with all due respect, the Agency still has not released substantive information on the proposal to bundle skin substitutes in the physician's office. The Coalition was hopeful that during the Town

5225 Pooks Hill Rd | Suite 627S
Bethesda, MD 20814
T 301.530.7846 | C 301.807.5296

Hall meeting CMS would have provided more details to the proposal. Sadly, this was not the case. Without significantly more detail, we believe it is nearly impossible to provide substantive and meaningful comments. These products are too important in the treatment of wounds to potentially have any issues with access. **Loss of limb or even life is not something to be taken lightly. CMS needs to get this right – the implications are too significant for any errors in policy changes**.

CMS should NOT move forward with any proposed rulemaking for CY 2024. The Agency should instead issue a framework document – as it did for 505 (2)(b) drugs. This will allow for substantive information to be provided by the Agency and continued dialogue with Stakeholders.

The Coalition response to the questions CMS posed during the Town Hall meeting are provided below.

Question 4 "**What should we consider as alternatives regarding any potential changes to terminology"**

The Coalition categorically opposes the change in nomenclature from "skin substitutes" to "wound care management products." CMS stated that the reasons that the Agency was seeking a name change was due to the evolution of this product category over time and that skin substitutes "do not actually function like human skin that is grafted onto a wound." However, we maintain that it is a term that is well known and used and accepted by clinicians as well as public and private insurers. It has also been accepted by the AMA who had used this term in creating the Current Procedural Terminology (CPT) codes, such as 15271- 15728 which are still current. "Wound care management products" is way too broad a term and does not provide the clarity that CMS is seeking. In fact, CMS had to go through great lengths in the proposed rule to not only distinguish wound care dressings and bandages from skin substitutes (87 FR 46028) but also CMS acknowledges in the proposed rule potential issues with the use of the term "care management" and its likely conflation with AMA CPT evaluation and management (E/M) codes.

However, the question CMS posed in the Town Hall meeting: "**What should we consider as alternatives regarding any potential changes to terminology"** suggests that the Agency is not interested in keeping the current skin substitute nomenclature. As such, **the Coalition recommends the Agency should use the term in the ASTM standards document, "Cellular and/or tissue- based products for skin wounds (CTPs)".**[1] The ASTM states that "*CTPs are defined primarily by their composition and comprise of cells and/or the extracellular components of tissue. CTPs may contain cells (viable or nonviable), tissues, proteins, and other materials for which there is a rationale*

[1] *Standard Guide for Classification of Cellular and/or Tissue-based Products (CTPs) for Skin Wounds. ASTM International. Current edition approved Feb15, 2022. Published March 2022 Last previous edition approved in 2016 as F3163-16DOI:10.1520/F3163-22*

for benefit beyond that achievable with conventional wound coverings. CTPs may additionally include synthetic components".[2] While synthetics are not in the title, it is very clear from the definition included in the standards document that in fact they are a CTP. The CTP term will better achieve CMS's goal of more accurately describing the entire suite of products but without the possible misinterpretation as other medical products or services. The CTP nomenclature has been vetted very stringently (including by the FDA who participated in the ASTM discussions) and is a widely accepted term in the industry. It is used by clinicians, researchers, manufacturers, private payers and even by some of the Medicare contractors.

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

CMS has stated that their objectives in making changes to the current payment of skin substitutes is to ensure a consistent payment approach for them across the physician office and hospital outpatient department setting. However, CMS has merely stated what they want to do in hypotheticals but has not, in any way, stated how the Agency will go about making these changes. CMS has not described:

1. The methodology it would use to calculate the bundled payments.
2. The amount of money that would be included in the bundle for skin substitutes. In fact, CMS is required to establish proposed PE relative value units (RVU) for skin substitute application procedure codes 15271-15728 in order for skin substitutes to be paid as "incident to" supplies that are bundled into the Medicare PFS payment. Yet, CMS failed to do so in the proposed rule and did not provide any further clarity during the Town Hall meeting.
3. How the bundled amount would be updated.
4. Given the budget neutrality requirements of the practice expense, how CMS sees the impact of including skin substitutes into the practice expense and the impact it will have on providers who do not use them.
5. What will the impact of this changed reimbursement methodology be on minorities, patients with diabetes as well as on patients living in rural areas.
6. Why CMS is making this change, what other proposals were considered and why were they not chosen?
7. How will CMS create an equitable payment given the large variety of products and the large variation of prices?

As stated previously, CMS indicated that the reason for the proposal to bundle skin substitutes in the physician office was its desire to have a consistent payment approach

[2] *This guide defines terminology for description of cellular and/or tissue-based products (CTPs) for skin wounds. CTPs are TEMPs (tissue-engineered medical products) that are primarily defined by their composition and comprise viable and/or nonviable human or animal cells, viable and/or nonviable tissues, and may include extracellular matrix components. CTPs may additionally include synthetic components*

between the physician office and the hospital outpatient department. However, these payment systems are different and are meant to be different. Bundling in the physician office for this product category will be very challenging to implement and will have significant negative consequences on patient access.

Furthermore, CMS has stated its desire to be consistent with the hospital outpatient setting. The **Hospital Outpatient PPS (OPPS) packaging of** skin substitutes **has not worked well, created artificial inflation, created perverse incentives for the use of higher cost products, significantly decreased the use of low-cost products as a result of inadequate payment, has created access to care problems for patients with larger sized wounds (due to no add on code payment) and has been revised multiple times over the years.** There are issues with packaging in the OPPS which CMS has recognized and tried to address by putting forth multiple proposals for alternative payment methodologies over the past 5 years in order to have a more effective system. So why would CMS try to be consistent with a system that is not working well and has created access to care issues? If anything, the OPPS should be using the same consistent payment approach that was used prior to bundling in 2014 – and is currently being used to set the rate in the physician fee schedule – ASP+6%.

If CMS is truly interested in a consistent payment approach that will not impact patient access but will provide cost savings to the Medicare Trust Fund, the Coalition recommends that the Agency continue to use ASP +6, and publish ALL products and their pricing on the Medicare Part B Pricing Data File. Utilizing ASP pricing is easy for the Agency since the framework is already in place, and implementation would be very easy. CMS has not given ASP a chance nor have there been enforcement efforts in place.

Using ASP pricing, CMS could establish uniform pricing based on all skin substitute ASPs not only being reported but also published on the quarterly ASP files. This would allow for pricing consistency and would achieve CMS's goal of reducing out of pocket co-payments since CMS would not be paying for skin substitutes based on list or invoice pricing but rather on vetted sales price, inclusive of discounts. Using ASP is a more transparent means of pricing these products and at the same time CMS can also achieve cost savings in the process. The Coalition submits that publishing any reported ASP for skin substitutes (1) creates a level field for all manufacturers; (2) prevents overbilling of the Medicare Trust Fund; (3) decreases Medicare beneficiary financial responsibility; (4) ensures clinicians select products based on clinical efficacy and (5) assures transparency in the program.

The cost savings that are attached to utilizing ASP are significant and one that has even been recognized by the OIG who recently stated in their report on ASP "**with clearer ASP reporting and publishing guidelines, the Agency would recognize cost**

savings".[3],[4] MEDPAC has also recognized the importance of ASP pricing on cost savings. Specifically, MEDPAC stated that "using **ASP will help protect the Medicare Trust Fund by not overpaying for products that are not listed on the national ASP file)".[5]** This is an important and salient point for the Agency to consider as it not only strives for consistency but also tries to protect the Medicare Trust Fund.

The proposed changes to the way skin substitutes will be paid for in the physician fee schedule will create inappropriate incentives to delay treatment of patients with multiple ulcers (e.g., treat one ulcer per visit), to use lower quality products, and to use an insufficient amount of product to treat these ulcers completely. As a result of the payment changes, physicians will no longer be able to afford these advanced therapies and will likely not provide them in their offices any longer or at least in a limited capacity which will undermine healthcare outcomes for Medicare beneficiaries generally and particularly for underserved populations such as African Americans, Latinos, and Native Americans, who are at higher risk for these ulcers because they disproportionately suffer from diabetes and obesity.[6],[7] CMS's proposed approach to reimbursement of skin substitutes will also stifle the incentive to innovate and bring to market the kind of new medical products that require millions of dollars of research and development and a lengthy FDA approval process.

If CMS is truly interested in a consistent payment approach that will not impact patient access but will provide cost savings to the Medicare Trust Fund, the Coalition recommends that the Agency use ASP +6, publish ALL products and their pricing on the Medicare Part B Pricing Data File over the next two to three years, and under its enforcement authority ensure ASP is being reported correctly - before any substantive changes are made.

---

[3] *Manufacturers May Need Additional Guidance To Ensure Consistent Average Sales Price Calculations (OEI-BL-21-00330)*

[4] *CMS Should Bolster Its Oversight of Manufacturer-Submitted Average Sales Price Data To Ensure Accurate Part B Drug Payments (OEI-03-21-00390)*

[5] *https://www.medpac.gov/document/http-www-medpac-gov-docs-default-source-reports jun19_medpac_reporttocongress_sec-pdf/ at 64.*

[6] *Tan TW, Shih CD, Concha-Moore KC, et al. Disparities in outcomes of patients admitted with diabetic foot infections. PLoS One [Internet]. 14(2), e0211481 (2019). Available from: https://journals.plos.org/plosone/article?id=10.1371/journal.pone.0211481.*

[6] *Tan TW, Shih CD, Concha-Moore KC, et al. Correction: Disparities in outcomes of patients admitted with diabetic foot infections (PLoS ONE (2019) 14:2 (e0211481) DOI: 10.1371/journal.pone.0211481). PLoS One. 14(4) (2019).*

[7] *Suckow BD, Newhall KA, Bekelis K, et al. Hemoglobin A1c Testing and Amputation Rates in Black, Hispanic, and White Medicare Patients. Ann. Vasc. Surg. 36, 208–217 (2016).*

Question 2 - **How could we 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?**

First – the Coalition does not agree with the Agency that skin substitutes should be considered supplies**.** Skin substitutes **are a heterogeneous group of biologic, synthetic, or biosynthetic materials that can provide temporary or permanent coverage of open skin wounds**. Skin substitutes ideally possess the composition and function of skin or have the potential for autologous regenerative healing when applied to a wound. **These matrixes are affixed to the wound and become incorporated into the wound bed. They are not disposable like other products that are considered "incident to supplies" such as wound dressings or BAND-AIDs®.** Therefore, proposing to consider these products as "incident-to" supplies in the physician office is clinically and definitionally incorrect. These products are in a category unto themselves and payment should be made accordingly.

Furthermore, CMS has always reimbursed skin substitutes under the ASP methodology because as the Agency has stated they "were generally considered to be biological products." Although the Coalition recognizes that the Social Security Act does not define the term "skin substitute", Section 351 of the Public Health Service Act ("PHSA") does, and Congress clearly intended to use that definition. There is no legal basis for CMS to categorize these products as supplies or to deviate from the definitions provided in the PHSA or even from language used by CMS to describe these products**.** We therefore request that before CMS moves forward with this change, the Agency articulates the legal basis for its proposed action.

That said – in addressing the Agency's question, while the Coalition would like to provide appropriate criteria for the Agency's consideration, we do not believe that there is consistent equitable criteria that is appropriate for a unified payment rate for these products. The Coalition still recommends using ASP +6% before any other substantive changes are made as we believe this methodology will not only afford the Agency the consistency it is seeking, it is an easy remedy and will also achieve the cost savings necessary to help preserve the Medicare Trust Fund.

Question 3 - **Are there similarly resourced groups of products/services that could inform how payment might be stratified without risking access to services?**

Coalition members manufacture skin substitutes. There are a wide variety of products and sizes that are in the marketplace as well as variation in pricing. There are no similarly resourced groups of products/services that could inform payment stratification without risking access to services. As we already mentioned, there is too much variability in the types, sizes, and costs of products.

Conclusion

The proposed changes to the way skin substitutes will be coded and paid "for consistency sake," will create inappropriate incentives to delay treatment of patients with multiple ulcers (e.g., treat one ulcer per visit), to use lower quality products, and to use an insufficient amount of product to treat these ulcers completely. Advanced therapies including skin substitutes have been shown to heal diabetic foot and venous stasis ulcers and reduce the number of infections and amputations while saving money.[8],[9] The Coalition went on record in 2013 when the Agency had proposed to package payment under the OPPS that perverse incentives would be created and that the cost of skin substitutes would increase under that program. In fact, that did occur. The Agency created artificial inflation, all but eliminated the use of low-cost skin substitute use, created incentives for clinicians to utilize higher cost products and due to inadequate payment created barriers to access to care in provider based departments. So why move to create the same types of issues in a more complicated reimbursement system?

We submit that CMS's proposed approach to reimbursement of skin substitutes will stifle the incentive for manufacturers to innovate and bring to market the kind of new medical products that require millions of dollars of research and development and a lengthy FDA approval process.

We urge the Agency not to move forward with this proposal. Rather the Coalition recommends:

1. Utilize ASP+6 as it is currently.
2. Publish ALL ASPs.
3. Ensure the Agency is using its enforcement authority to ensure that ASP is being reported correctly.
4. Provide clearer guidance on the submission of ASP.
5. Prior to the issuance of any changes to the manner in which skin substitutes are reimbursed, issue a framework document.

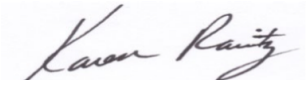
---

[8] *David G Armstrong MD, PhD, DPM, MS; William H Tettelbach MD, FACP, FIDSA, FUHM, FAPWCS, CWS; Thomas J Chang DPM; Julie L De Jong MS; Paul M Glat MD, FACS; Jeffrey H Hsu MD, FACS; Martha R Kelso RN, LNC, HBOT; Jeffrey A Niezgoda MD, FACHM, MAPWCA, CHWS; Travis L Tucker MA, MBA; Jonathan M Labovitz DPM, FACFAS, CHCQM, "Observed impact of CTPs in lower extremity diabetic ulcers-lessons from the Medicare Database (2015-2018)", Journal of Wound Care, North American Supplement Vol 30, No. 7, July 2021.*

[9] *Frykberg RG, Marston WA, Cardinal M.The incidence of lower-extremity amputation and bone resection in diabetic foot ulcer patients treated with a human fibroblast-derived dermal substitute. Adv Skin Wound Care 2015;* ***28*** *(1): 17–20.*

The Coalition appreciates the opportunity to not only provide our oral feedback during the Town Hall meeting, but also to supplement them. If the Agency wishes to have further discussion or require additional information please do not hesitate to contact me.

Sincerely,



Karen Ravitz, JD
Health Policy Advisor
Coalition of Wound Care Manufacturers
3018075296
Karen.ravitz@comcast.net