ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

August 14, 2020

Elise Barringer,
Designated Federal Official (DFO)
Centers for Medicare & Medicaid Services,
7500 Security Boulevard,
Mail Stop: C4–04– 25,
Baltimore, MD 21244–1850.

RE: File Code CMS–1755–N

Dear Ms. Barringer:

The Alliance of Wound Care Stakeholders is a nonprofit multidisciplinary trade association representing physician specialty societies, clinical and patient associations whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. Our members possess expert knowledge in complex chronic wounds, and in wound care research. These clinicians treat patients with wounds in all settings – including the hospital outpatient arena. A list of our members can be found on our website: (www.woundcarestakeholders.org).

The Alliance respectfully requests that the Panel recommend to CMS these wound care related items:

- That CMS follow its own regulatory guidance in the packaging of and assigning skin substitute products into the appropriate high or low cost tier. We further recommend that CMS should hold off in implementing the C1849 new code until CMS can provide to the Panel the impact this code will have on the APC - (this is not a coding issue but rather an issue of APC integrity). Information that the Panel should specifically request is: 1. How CMS will use the information gathered from a generic code - which contains multiple products - in the establishment of the APC payment rates which has been based on product, price and claim specific information since 2013. 2. The regulations state that each skin substitute is required to submit product specific pricing information. How will this information be gathered for individual products within this generic code? 3. Similarly, how will the claims data for each product within this generic code be identified and tagged for that individual product when establishing the APC? 4. Will CMS use the pricing and claims data for all of the products in this category and lump this information together to establish pricing and 5. How did CMS arrive at the conclusion that the products within the C code should be assigned to the high cost tier rather than the low cost tier?
- Remove placement of the C1849 synthetic skin substitute products from the high cost tier

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Synthetic Skin Substitues Should Follow the Same Packaging Guidelines As All Other CTPs to Ensure Accurate APC Payment Rates and APC device offset rates Are Established

While we know that it is outside of the Panels charter to recommend to CMS to eliminate the C1849 skin substitute code and require them to have all the synthetic skin substitute products receive a unique HCPCS Q code, it is within the Panels charter to ensure that the integrity of the APC will not be compromised and that CMS is adhering to their already established regulatory process,

By recommending that the CMS follow the same regulatory processes that are already in place for all other categories of skin substitutes/CTPs, the Panel will prevent CMS from over-paying for some brands of synthetic/resorbable skin substitutes/CTPs. Just like the other categories of skin substitutes/CTPs, some brands of synthetic resorbable skin substitutes/CTPs should be appropriately assigned to the low-cost package and some should be appropriately assigned to the high-cost package.

If CMS moves forward with allowing the generic synthetic skin substitute code to be utilized in the provision of wound care, it will be impossible for claims data and specific pricing data to be obtained. This will impact not only the APC rates but the offset data as well. As per the Hospital Outpatient regulations, CMS pays for individual skin substitutes that do not have pass-through status by packaging them into the APC for the associated service. CMS divides skin substitutes into a high cost group and a low cost group in terms of packaging. CMS assigns individual skin substitutes with a geometric mean unit cost (MUC) or a products per day cost (PDC) that exceeds either the MUC threshold or the PDC threshold to the high cost group. The placement of a product into the high or low cost bucket, is based on claims data and individual product pricing submitted to CMS. According to the regulations,

> *consistent with our policy since CY 2016, we propose to continue to determine the high cost/low cost status for **each skin substitute product** based on either **a product's geometric mean** unit cost (MUC) exceeding the geometric MUC threshold or the **product's per day cost** (PDC).*

Further CMS states,

> *we propose to continue to assign skin substitutes with pass-through payment status to the high cost category. We propose to assign skin substitutes with pricing information but without claims data to calculate a geometric MUC or PDC to either the high cost or low cost category based on the product's ASP+6 percent payment rate as compared to the MUC threshold. If ASP is not available, we propose to use WAC+3 percent to assign a product to either the high cost or low cost category. Finally, if neither ASP nor WAC is available, we propose to use 95 percent of AWP to assign a skin substitute to either the high cost or low cost category. We propose to continue to use WAC+3 percent instead of WAC+6 percent to conform to our proposed policy described in section V.B.2.b. of this proposed rule to establish a payment rate of WAC+3 percent for separately payable drugs and biologicals that do not have ASP data available. New skin substitutes without pricing information would be assigned to the low cost category until pricing information is available to compare to the CY 2021 MUC and PDC thresholds.*
>
> According to the regulations above, CMS Is collecting individual product pricing information and determines the placement into the high or low cost tier based on an "individual" product. The APC payment rate and the APC device offset rate are dependent on claims data for each of the skin

substitutes (more appropriate term: cellular and/or tissue-based products [CTPs] for skin wounds). In addition, the correct assignment to the high cost and low cost APC package is dependent on claims submission for each product and on quarterly submission of Average Sales Price for each product.

However, the assignment of one HCPCS code, C1849, to all synthetic and resorbable skin substitutes is not going to provide the unique and individual product/cost information needed to appropriately assign each unique brand of synthetic and resorbable skin substitutes to the correct APC package. By not assigning unique codes to each of the unique synthetic and resorbable skin substitutes and by automatically assigning the products to the high cost package, the OPPS program has a high probability of being overcharged for products that should be in the low cost package.

This claims data is used along with quarterly ASP submissions to establish the appropriate APC placement. Based on the current CMS methodology for skin substitutes, there is no way to calculate device offsets or proper rate settings unless separate codes are established by product names. New products to market are assigned to the low bucket until there are sufficient claims data to determine a rate for these products.

As such, the Alliance requests - in the name of transparency - that the Panel recommend to CMS to: 1. Follow their own regulatory guidance, 2. Delay the implementation of the C code so that more information can be provide to the Panel to ensure the integrity of the APC. Specific information that should be provided by CMS includes, 1. an explanation as to how the rate setting for these synthetic skin substitutes will be established 2. Based on the provisions in the regulations what data was submitted to CMS justifying the placement of the entire group of product into the high tier, and 3. Provide a list of the products that are included in this C code. While we know it is outside of the Panel charter to recommend the elimination of the C1849 code, we believe that this is a technical issue which changes the nature and structure of the APC and therefore the issuance of this code is not consistent with the requirements for payment for other skin subsitutes and will negatively impact rate setting and device offset costs.

Removal of C1849 from High Cost Tier

We have concerns with the synthetic skin substitutes being placed in the high cost tier for pricing purposes. As a result of packaged payment, skin substitutes have been bundled since 2013. Payment is determined based on whether a particular individual product is in the high or low cost tier. The placement in one of these tiers is based on cost of the individual product and claims data for that product. Yet, CMS has proposed in this CY 2021 rule that all synthetic skin substitutes – regardless of their pricing or any claims being submitted - should be placed in the high cost tier. We are not in agreement with this.

In the hospital outpatient setting, one code is utilized which includes both the application of the CTP and the product itself. A Q code is still necessary in order to determine which product was used and therefore what level of reimbursement the facility will receive. The threshold to determine whether a product will fall into the high or low cost group is established annually **based on claims data** and published in the Hospital Outpatient Prospective Payment System regulations. It is difficult to determine claims data for a particular individual product when there is no specific identifying code for that product. The C code is for any synthetic skin substitute and not for a particular individual

product. C codes in the outpatient setting usually represent a passthrough. No synthetic product has applied for a passthrough according to the proposed rule for HOPPS.

To our knowledge, there are no synthetic products that have received a Q code or have been billed in the hospital outpatient setting for wound care although there are several synthetic skin substitutes in the marketplace. Therefore, we question which synthetic skin substitutes have been placed in the high cost tier, how many products are included in this category, what claims data has been utilized to calculate that these products were appropriately designated high cost tier products? Moreover, any synthetic product that is currently in the marketplace or will be coming into the marketplace will automatically be placed in this category without the requisite data being supplied to CMS.

As such, we not only are recommending that the C1849 code be eliminated, we also are recommending that any product in the C1849 code be removed from the high cost tier until adequate product specific data has been obtained. Without appropriate data collection it is uncertain whether individual synthetic products should be in the high cost category or low cost category. Per CMS regulations, we recommend that individual synthetic skin substitute products should be assigned to the low cost OPPS package until the manufacture(s) have submitted their average sales price (ASP) information to CMS. If the manufacturer's ASP information shows that the product should be in the high cost package, CMS should make that reassignment. From that point on, a synthetic product should follow the current OPPS payment methodology based on its product claims data.

We appreciate the opportunity to offer our comments. We are happy to provide any additional information.

Sincerely,

Marcia Nusgart R.Ph.

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Executive Director