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 would care related items:

- Eliminate the new code C1849 – synthetic skin substitutes resorbable and require any synthetic skin substitute to apply for an appropriate HCPCS Q code to be considered a "skin substitute"
- Remove placement of the C1849 synthetic skin substitute products from the high cost tier
- Change the current "skin substitute" terminology to "cellular and or tissue based products for skin wounds"

1. The Alliance recommends that CMS eliminate the new code C1849 (skin substitute, synthetic resorbable per sq cm.) CMS has proposed to include synthetic products in its description of skin substitutes in addition to biological products. We are in agreement that synthetic skin substitutes should be placed in the description. In addition to ASTM, the standard setting association, including synthetics in its F3163-16 standard guide for Classification of Cellular and/or Tissue-Based Products for Skin Wounds (CTPs), the Alliance also included synthetics in our classification system during our 2012 meeting with CMS on CTPs.

   However, since CMS has now determined that synthetics should be placed in the "skin substitute" description, they should also have the same coding requirements as all other "skin substitutes". "Skin substitutes" that are issued a Q code by the CMS HCPCS Workgroup are brand and product specific and based on a "per sq.cm" size unless the product is an injectable. All other skin substitutes in the marketplace have applied for and were awarded Q codes by the HCPCS work group. Establishing a

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general category for synthetic skin substitutes and issuing a C code should not be permitted especially given the protocol that CMS has established for other products in this sector. It is our understanding that several synthetic products have applied for Q codes. Instead of issuing Q codes for these products, the HCPCS Workgroup had given these products A codes such as surgical supply, miscellaneous. If CMS believes that these products are in fact "skin substitutes", the Agency should reevaluate the applications already submitted and appropriately issue Q codes for those products. For any other product coming into the marketplace,the company can apply for a Q code and be evaluated in the same manner as all other skin substitute products.

As such, the Alliance requests that the Panel recommend to CMS to eliminate the C1849 code for synthetic skin substitutes and require any company that believes that their product is a "skin substitute" to request a Q code and go through the HCPCS coding process.

2. 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.

3. We request that CMS use the more clinically accurate term "Cellular and/or Tissue Based Products for Skin Wounds" instead of "skin substitutes". The Alliance believes that the term "skin substitutes"

is not a technically accurate term and does not describe the technology that is either currently or will be in the marketplace for products that contain living cells or that constitute tissue-based products intended for use in the management, treatment, or healing of skin wounds – such as the synthetic products.

Historically, these products have been referred to as "skin substitutes" in reference to their initial use as substitutes for skin grafts in clinical procedures. However, over time, the usage of these products shifted toward chronic ulcers where skin grafts are infrequently used and not standard of care. Moreover, newer products in this category may look nothing like skin and, indeed, have not been designed to function as skin replacements. Thus, there is a need to define terminology in the context of skin wounds as opposed to skin grafting procedures.

As CMS has stated in the 2014 rule (and recited in this current proposed rule) " skin substitute products do not actually function like human skin that is grafted onto a wound; they are not a substitute for a skin graft." We are in agreement with this statement.

As such, the Alliance recommends that CMS adopt the term "Cellular and/or tissue based products for wounds**"** ("CTPs") which does accurately describe and is broad and inclusive of both current and future technology. We would respectfully point out that other organizations, contractors and the wound care clinical community are adopting this verbiage. For instance, as stated above American Society of Testing and Materials (ASTM) has created a draft guidance standard specifically using the CTP nomenclature. In addition, Medicare contractor such as Cigna Government Services uses the term "Cellular and/or Tissue Based Products for Wounds" as the title for its LCD.

The Alliance believes that the term "skin substitute" is misleading and inaccurate to describe the products that are the subject of this LCD for the following reasons:

- This term is not used by either the FDA in its classification of these biologic products nor by CMS in its coding descriptors.

- The CMS HCPCS Work Group abandoned the term "skin substitute" effective in 2010 when a manufacturer requested that CMS delete this term since it was an incorrect descriptor. The manufacturer stated at the 2010 CMS HCPCS Public Meeting that this language was incorrect since allografts are mislabeled as "skin substitutes." Allografts differ in structure, tissue origin, and in some cases differ from biologic products in terms of how they are approved by the FDA (human skin for transplantation not devices). CMS thus changed the descriptors and eliminated the term "skin substitutes" from all of the Q-HCPCS codes for these items.

- In addition, the Agency for Healthcare Research and Quality (AHRQ), in its 2011 draft technology assessment on skin substitutes stated that these products were not "skin substitutes."

In summary, the Alliance believes that the term "skin substitute" is misleading and inaccurate to describe the products and requests that the Panel recommend to CMS to change the term to cellular and/or tissue based products for skin wounds or CTPs.

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

Sincerely,

Marcia Nusgart R.Ph.
Executive Director