COALITION OF
Wound
Care
Manufacturers

October 5, 2020

Ms. Seema Verma
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS- 1736-P
7500 Security Boulevard
Baltimore, MD 21244-1850

Comments Submitted Electronically to **http://www.regulations.gov**

Re: CMS 1736-P - **Medicare Program: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; New Categories for Hospital Outpatient Department Prior Authorization Process; Clinical Laboratory Fee Schedule: Laboratory Date of Service Policy; Overall Hospital Quality Star Rating Methodology; and Physician- Owned Hospitals**

Dear Administrator Verma:

On behalf of the Coalition of Wound Care Manufacturers ("Coalition"), I am pleased to submit comments in response to the proposed CY 2021 Hospital Outpatient Prospective Payment System and changes to the Quality Reporting Programs. In addition to submitting these comments, the Coalition is requesting a meeting with CMS to further discuss payment methodology recommendations for Cellular and/or Tissue Based Products for Wounds (CTPs) since CMS will be continuing to consider options for changing it. The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including but not limited to Cellular and/or Tissue Based Products for Skin Wounds (CTPs – formerly known as skin substitutes).

Definition of Skin Substitute

As a general matter, CMS has stated in the 2014 rule (and restated 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. Instead, these products are applied to wounds to aid wound healing and through various mechanisms of action they stimulate the host to regenerate lost tissue". The Coalition agrees with this statement and has for years. As such, we believe that the term "skin substitute" is misleading and inaccurate to describe all of the products currently contained in this product sector – including synthetics if CMS believes they are appropriately defined as skin substitutes. Therefore, **the Coalition urges CMS to change the term from "skin substitutes" to "cellular and/or tissue based products for skin wounds" or CTPs**. The Coalition will be utilizing that nomenclature throughout our comment letter.

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The Coalition does not have a position on whether synthetic CTPs should be placed in the definition of a CTP. However, we urge CMS that if synthetics are placed into the definition of a CTP, then it applies all of the rules/protocols to synthetics as it does to all other types of CTPs that currently or will be coming into the marketplace.

Specific Comments

Synthetic CTPs

CMS has proposed several issue areas related to synthetic CTPs. The Alliance respectfully requests that CMS:

- Eliminate the new code C1849 (("Skin substitute, synthetic, resorbable skin substitute per square centimeter) as it is inappropriate and not consistent with the coding for any/all other CTPs
- Remove placement of the C1849 synthetic CTP products from the high cost tier
- Require any synthetic CTP to apply for an appropriate HCPCS Q code to be considered a CTP

As stated above, the Coalition recommends that CMS eliminate the new code C1849. Furthermore, CMS has proposed to include synthetic products in addition to biological products in its description of CTPs. The Coalition does not have a position on whether synthetic CTPs should be placed in the definition of a CTP. However, if CMS determines that synthetic CTPs should be placed in the description, as the new definition suggests, then they should also have the same requirements as all other CTPs which are or will be coming into the marketplace. The HCPCS coding system for CTP products is brand and product specific. The Q code identifies the product and is based on a "per sq. cm" size unless the product is an injectable or micronized. All other CTPs in the marketplace have appropriately applied for and were awarded Q codes by the HCPCS work group. We believe that establishing a C code for a general category of synthetic CTPs and issuing a C code should not be permitted especially given the well-established HCPCS coding protocols that CMS has issued for other products in this sector. It is our understanding that when several synthetic products have applied for Q codes, the CMS HCPCS Workgroup issued them "A" codes instead.

The Coalition believes that it is absolutely unacceptable that CMS is helping one company go around well-established protocols. It is our understanding that when Restrata, which is the only product in the 1849 code, applied for a Q code, it was issued an "A" code – which the company did not accept. If CMS believes that it issued the "A" code in error and the product is in fact a CTP – based on the newly proposed definition - CMS and its HCPCS workgroup should reevaluate the application already submitted and appropriately issue a Q code for this product. In addition, CMS and the HCPCS Workgroup should evaluate and determine coding for any other synthetic CTPs which enter into the marketplace in the same manner as all other CTP products. As such, the Coalition recommends that CMS eliminate the C1849 code for synthetic CTPs and require any manufacturer whose product they believe belong in this product category - including Restrata - go through the HCPCS coding process to obtain a Q code which is the appropriate HCPCS code category for this type of product.

Furthermore, as a result of packaged payment, CTPs 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 CTPs– regardless of their pricing or any claims being submitted - should be placed in the high cost tier. We do not agree. 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. As is outlined in the hospital outpatient regulations, 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.

Moreover, outlined in the hospital outpatient regulations, CMS sets forth the pricing information it will accept if claims data is not available. This pricing information is brand and product specific. Yet, the C code CMS has established is a generic code for any synthetic CTP and not for a particular brand or individual product. It is questionable how CMS will be able to determine what bucket synthetic products should be placed. CMS may be unaware that there are currently other synthetic products in the marketplace. Since synthetics were never approved by CMS in the past because they did not fit the CMS definition of a CTP, those products did not go through the HCPCS coding process yet are still being provided in the hospital inpatient setting. Therefore, any synthetic product currently or will be coming into the marketplace will automatically be placed in this category without the requisite data being supplied to CMS. This will skew the pricing and ultimate placement for all synthetic products being utilized. CMS will not only be paying more than it may need to pay particular products in this category, but it will also not be able to track or identify what brand specific product was actually used.

Moreover, the 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. Yet it will appear to the hospitals that synthetic products will have pass through and will provide an unfair market advantage to these products.

For the reasons identified above, we oppose the creation of the C1849 synthetic CTP code and recommend that this C1849 code be eliminated and any product in the C1849 be removed from the high cost tier until adequate data has been obtained. Without appropriate data collection, it is uncertain whether individual synthetic products should be in the high cost or low cost category. The Coalition also recommends that CMS reevaluate the Restrata HCPCS application so that it can be appropriately awarded a Q code. Once the code has been issued, Restrata can provide its pricing information to CMS in order to be placed in the high or low cost bucket until claims data is available to be submitted to CMS.

CTP Payment Methodology

CMS has now been attempting to propose a new payment methodology for CTPs for the past three years. In this proposal, CMS appears to be settling in to one of two methodologies – single pay APC or an episode of care. While some of our members support the single pay methodology, a greater number support an episode of care model. We would welcome the opportunity to meet with CMS to further discuss the payment methodology in hopes that CMS will put forward a detailed proposal in the CY 2022 proposed rule.

Establishment of New Technology APC Assignment for 0598T

The Coalition is pleased that CMS has recognized a new technology to treat wound patients with the establishment of an APC assignment for non-contact real time fluorescence wound imaging, for bacterial presence, location, and load, per session (code 0598T and code 0599T for an additional wound). As manufacturers, it is refreshing to finally see a new technology being introduced to the

marketplace to treat patients with wounds. We support the Agency's proposal to continue payment for these codes.

The Coalition appreciates the opportunity to offer our comments. We are happy to provide any additional information and look forward to engaging the Agency in further discussions on the payment methodology for CTPs.

Sincerely,

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