COALITION OF

Wound Care Manufacturers

September 13, 2022

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services Department of Health and Human Services Attention: CMS-1707-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically to regulations.gov

Re: Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems and Quality Reporting Programs; Price Transparency of Hospital Standard Charges; Radiation Oncology Model; Request for Information on Rural Emergency Hospitals

Dear Ms. Brooks-LaSure,

On behalf of the Coalition of Wound Care Manufacturers ("Coalition"), I am pleased to submit comments in response to the CY 2023 proposed Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems. The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including skin substitutes and as such we have a vested interest in this proposed rule and offer the comments below.

The Coalition is extremely concerned with the skin substitute section of the proposed rule. We raised significant issues in the FY 2022 rule which were unfortunately not addressed adequately or accurately by the Agency. These concerns continue with the release of this proposed rule.

General Comments

The Coalition is very concerned that the Agency states that changes to the coding and payment of skin substitutes are being made to provide clarity and consistency. We attest that the changes being proposed do the exact opposite of these goals. The Agency continues to provide incremental changes without providing details on the larger picture on how skin substitutes will be paid. In fact, the changes that the Agency is making provides little clarity – and actually the opposite – it creates more confusion. Furthermore, CMS outlined its proposal to pay for skin substitutes as part of the practice expense incident to supplies in the physician offices but this type of payment approach is not consistent with how CMS pays for these products under a prospective payment system. The payment structures are supposed to be and were designed to be different and therefore the Agency needs to better articulate what is intended by consistency in payment.

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Moreover, CMS has provided consistency in HCPCS coding which provided clarity for skin substitutes for over 12 years by issuing Q codes for them. CMS already has caused confusion and a lack of clarity with the issuance of C1849 for synthetic skin substitutes in 2020 and continues to create confusion in this proposed rule by eliminating HCPCS Q codes for skin substitutes – a code that is widely known and accepted by industry, coders, providers, and payers - and using HCPCS A codes instead. CMS needs to withdraw all proposals related to CTPs until the Agency is ready to propose the types of larger changes they may be seeking with the details necessary for stakeholders to provide meaningful comment as is required under the Administrative Procedures Act. The incremental approach without details is creating administrative burdens when questions still remain as to whether CMS can legally make the changes being proposed.

Our specific comments follow.

Inequities in the Current Payment System Continue to Create Barriers to Access

Payment for Add on Codes

The primary cost for the application procedure is the skin substitute product itself. The specific cost for a procedure for an individual patient will vary depending on the size of the wound being treated. Under the OPPS, CMS packages payment for all add-on codes, including the skin substitute procedure add-on codes, into the payment for the base procedure. Rather than appropriately recognizing the variation in cost between small and large wounds, CMS pays the same amount for both. Add-on codes that are packaged into the OPPS bundled rates are not adequate to allow the provider-based departments (PBDs) to purchase the additional sq. cm. of skin substitutes necessary to apply to all wound/ulcer sizes. In fact, none of the add-on codes have been available for additional payment. This policy creates substantial barriers to treating larger wounds in the hospital outpatient department. In practice, larger wounds are not typically treated in the hospital outpatient department because of the effect of the add-on code packaging policy and therefore, the estimated cost from the OPPS claims data reflects the cost of treating smaller wounds that would be reported with the base code. To be blunt, because the add-on codes represent wounds/ulcers that require the purchase of additional product, patients with wounds/ulcers larger than 25 sq. cm up to 99 sq. cm and also those greater than 100 sq. cm, are not being offered medically necessary skin substitutes in the PBDs because the financial burden is being placed on PBDs who cannot, and should not have to, absorb this cost.

Add-on codes are distinct clinical procedures that have been valued by the AMA independently from the primary procedure and the AMA specifies should be listed separately in addition to the primary procedure. CMS's packaging policy inappropriately voids the AMA's separate valuation of these codes. CMS's policy also essentially results in hospitals not being reimbursed for the additional clinical care and supplies required, including the additional amount of skin substitutes, that may be required when performing an add-on service, which ultimately has adversely impacted patient access to these services in a PBD.

To remedy this issue, on August 22, 2022, the Alliance of Wound Care Stakeholders ("Alliance") requested that the Advisory Panel on Hospital Outpatient Payment (the "Panel") urge CMS to issue an exception for the payment of CTP application add-on codes and assign the existing CPT add-on codes (15272 and 15276; 15274 and 15278) to an appropriate APC group allowing for payment.

This recommendation would provide an easy remedy for CMS to implement and there has been precedent set in CMS providing these types of exceptions, (i.e. chemotherapy).

The Panel approved the Alliance's recommendation that CMS assign the existing CPT add-on codes (15272 and 15276; 15274 and 15278) to an appropriate APC group allowing for payment and issue an exception for the payment of skin substitute add-on codes. During the discussion, it was evident that the Panel agreed that these CPT codes should be assigned to appropriate APCs allowing for payment and should not be treated any differently than blood products that also were approved to have add-on code payment.

The Coalition urges CMS to adopt the Panel's recommendation.

Assignment of APC for the Same Size Wound/Ulcer Regardless of Anatomical Location

The Coalition recommends that the APC for the same size wound/ulcer should be the same whether the wound/ulcer is located on the leg or foot, since the same resources and amount of product are being utilized. CMS has assigned APC 5054 when a 125 sq. cm wound/ulcer is located on the foot and APC 5055 when that same size wound/ulcer is located on the leg. This inequity does not make sense as the treatment of the wound/ulcer require the same amount of product to be purchased regardless of where the wound/ulcer is located.

During the August 22, 2022 Advisory Panel on Hospital Outpatient Payment (HOP) meeting, the Alliance of Wound Care Stakeholders provided another recommendation to the Panel: to assign the same APC groups for the same size wound regardless of anatomical location on the body. The Panel also approved this recommendation.

Facilities should not have inequities in payment when the same resources are being utilized for the same size wound. Anatomic location for a wound/ulcer should not be a barrier to access nor should there be a cost differentiation in treating the same size wound that happens to be located on a different body part. During the Alliance testimony, it was stated that CMS did not adopt this recommendation as they were mistakenly under the impression that the codes in question only applied to children. While the code descriptor does include specific language for children, the code applies to both children and adults. Either way, the same resources are being utilized and anatomic location should not matter – they should be paid the same and be assigned to APC 5055.

The Coalition urges CMS to adopt the Panel's recommendation to assign the same APC groups for the same size wound regardless of anatomical location on the body.

Elimination of HCPCS Q Codes to Designate CTPs

CMS has made a determination to reverse over 12 years of issuing "Q" codes for skin substitutes by now issuing "A" codes to the entire product sector and require those products already in the marketplace with known "Q" codes to either reapply for an "A" code or have one issued to them depending on the make-up and designation of the product. CMS must recognize that it cannot make a broad brush sweeping change to call all skin substitutes "supplies" and issue them "A" codes in the name of "clarity." We believe there is nothing clear about this change and it creates more confusion.

The Coalition is opposed to the elimination of HCPCS Q codes and the assignment of all skin substitutes to HCPCS "A" codes. A codes are assigned to supplies. Skin substitutes are not supplies and therefore it is inappropriate to designate them as supplies and issue A codes to this class of products. CMS is simply ignoring the fact that a majority of skin substitutes are in fact biologicals in their attempt to achieve consistency across an entire class of products. However, there are over 150 skin substitutes in the marketplace today and the overwhelming majority are biologicals. Therefore, if the Agency really wants to have consistency, it makes sense that the **majority of products be the driver of policy decisions and not the minority,** especially given that most of these products do meet the definition of a biological.

More importantly, the Coalition does not believe that CMS has legal authority to reclassify all skin substitutes from biologics to supplies as multiple statutory requirements would be violated including but not limited to 1861(s)(2)(A) of the Social Security Act as well as Section 351 of the Public Health Service Act (PHSA). Additionally, it would be a departure from longstanding Agency practices. CMS has long stated in regulatory language that skin substitutes are biologicals and that they do not want to conflate wound dressings which are A codes from skin substitutes which are issued Q codes. [i] [ii]

This significant departure of CMS's own language as well as the violation of multiple statutes requires that before the Agency can move forward with making this significant departure in changing the HCPCS coding of skin substitutes, it must justify and provide significantly more detail as to its legal rationale in order to allow for stakeholders to provide meaningful comment. The Agency thus far has not met this threshold and therefore has violated the Administrative Procedures Act.

The Coalition recommends the following:

- **CMS not move forward in eliminating Q codes**
- **Skin substitutes designated as HCT/Ps should not be required to reapply for A codes**
- **CMS issue Q codes to all skin substitutes inappropriately issued an A code over the past two years**

All of the Coalition recommendations will meet CMS's goals without creating major disruption, significant administrative burden and potential patient access issues.

TRG Requirement

As a general matter, the Coalition agrees with the Agency's proposed requirement for 361 HCT/P products to obtain a determination from the FDA Tissue Reference Group or a Request for Designation from the FDA to ensure that the products are appropriately marketed and regulated. A TRG letter can certainly meet that need. However,

- **The TRG only meets twice a month and is currently experiencing significant backlogs for issuing determinations. Determinations are currently taking up to a year**
- **CMS can request TRG letters without also eliminating Q codes and requiring all skin substitutes to transition into A codes.**

The Coalition is concerned about the ability of FDA to accommodate the timeline to provide applicants with the required TRG letter of recommendation. To ensure that FDA can work within this timeframe, the Coalition recommends CMS assess FDA's progress in advance of next year's rulemaking and report that data in the CY 2024 proposed rule. At that time, CMS should consider

whether the timelines proposed need to be adjusted to best accommodate the resources at FDA to ensure no discontinuation or gap in products available to Medicare beneficiaries. In the meantime, the Agency can require that a TRG letter is obtained by the manufacturer within two years of this proposed rule being finalized. This should ensure that adequate time is given to manufacturers with the assurance that the Agency will be monitoring the FDA and provide an adjusted timeframe to the FDA should it not be able to issue the letters in a timely fashion. The Coalition would like to emphasize that CMS could still require the TRG recommendation letter within a certain period of time without transitioning to A codes (i.e., keeping the product specific Q codes). This would reduce the administrative work required to submit a new HCPCS II application for an A code.

Finally, as CMS is aware, two MACs, First Coast Service Options and Novitas, recently released draft local coverage determinations (LCDs) (DL36377 and DL35041) and LCAs *DA 57680 and DA52117* . The LCDs do not explicitly mandate 361HCT/P products to obtain a TRG letter, but the draft articles strongly implies that proposed covered products (Group 2 codes) could be removed from coverage and placed in the non-covered Group 3 list if a TRG letter is not provided to the MAC and a product that is currently on the non-covered list will remain there until a TRG letter is submitted.[iii] The MAC will be enforcing this "recommendation" as early as September 24, 2023. This deadline is not only unworkable, it interferes with CMS' proposed policy. These LCDs are effectively requiring a TRG letter on a far more expedited basis than CMS would be requiring in regulation if it finalizes the above policy. The Coalition is extremely concerned about this timeline and recommends that CMS instruct the MACs to remove this recommended/mandated requirement from these draft LCDs/LCAs to allow CMS national policy makers to decide when and if to mandate this type of compliance. We are concerned that multiple requirements will cause unnecessary confusion among providers and potential disruption in patient care.

The Coalition recommends that CMS require **all 361 HCT/P skin substitutes that are currently covered via Q codes obtain a TRG letter within two years of the CY 2023 Hospital Outpatient PPS being finalized. We further recommend that CMS assess the FDA's progress in issuing the TRG letters to ensure the timeline is adequate. Finally, the Coalition recommends that CMS instruct the** two MACs, First Coast Service Options and Novitas, **to remove the recommended/mandated TRG requirement from these LCDs to allow CMS national policy makers to decide when and if to mandate 361 HCT/P compliance so as not to disrupt patient care and access to this valuable and successful advanced treatment option.**

Retirement of HCPCS C1849

The Coalition supports the retirement of HCPCS C1849. The creation of this code has caused significant issues within the wound care space. We believe that too many products were lumped into this code without any specificity, thus making it difficult for the Agency to identify what products were actually being used. Similarly, all products lumped into this code were assigned into the high cost bucket without seemingly being required to provide pricing information to the Agency – which is contrary to the requirement for all other skin substitutes. We recommend that all skin substitute products should be assigned product specific Q codes. The Coalition supports the retirement of HCPCS C1849 and encourages the Agency to finalize this proposal.

Wound Care Management Products

The Coalition categorically opposes the change in nomenclature from "skin substitutes" to "wound care management products" as do a majority of clinical associations, specialty societies and even the AMA RUC. CMS stated that the reasons that a proposed name change was included in this rule

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 vetted through the AMA, is in language that has been used for years and remains pertinent in the Current Procedural Terminology (CPT) codes, such as 15271- 15728, and is a term that is well known, used and accepted by clinicians as well as public and private insurers. "Wound care management products" is way too broad a term, encompasses more products than what would be considered skin substitutes (e.g., disposable negative pressure wound therapy, selective debridement, surgical debridement agents, surgical dressings, low-frequency non- contact non-thermal ultrasound, support surfaces, topical oxygen therapy products, as well as Unna Boots, multilayer dressings, total contact casts, casting and strapping products), and is confusing. The term wound care management products does not provide the clarity that CMS is seeking. In fact, CMS had to go through great lengths in this 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.

The Coalition recommends that CMS either keep the current skin substitute nomenclature or use the nomenclature that the ASTM has created and is already widely used "Cellular and/or tissue- based products for skin wounds (CTPs)".[iv] 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 for benefit beyond that achievable with conventional wound coverings. CTPs may additionally include synthetic components".* [v] 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.

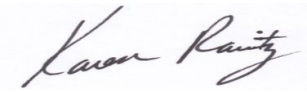
Conclusion

The Coalition appreciates the opportunity to provide our comments on this proposed rule. To summarize, our recommendations are as follows:

- CMS not adopt the term "wound care management products." We recommend that CMS either keep the term "skin substitutes" or adopt the more clinically correct term, "cellular and/or tissue based products for skin wounds" or CPTs.
- CMS should retire HCPCS C1849.
- CMS should not move forward in eliminating Q codes.
- All 361 HCT/P skin substitutes currently covered via Q codes obtain a TRG letter within two years of the CY 2023 Hospital Outpatient PPS being finalized.
- Skin substitutes designated as HCT/Ps should not be required to reapply for A codes.
- CMS issue Q codes to all skin substitutes inappropriately issued an A code over the past two years.
- CMS includes in its final rule the two Advisory Panel on Hospital Outpatient Payment (HOP) recommendations at its August 22, 2022 meeting:
    - Assign the existing CPT add-on codes (15272 and 15276; 15274 and 15278) to an appropriate APC group (the Alliance believes that this would allow for adequate work and product acquisition payment) and issue an exception for the payment of CTP application add-on codes.
    - Assign the same APC groups for the same size wound/ulcer regardless of anatomical location on the body.

The Coalition requests that CMS consider and adopt our recommendations. If you have any additional questions or would like further information, please do not hesitate to contact me.

Sincerely,



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[i] *See 78 FR 74932 "...HCPCS Q-codes are typically assigned to drugs and biologicals and are used to describe skin substitutes…*

[ii] *86 FR 63563 "The CY 2014 OPPS/ASC final rule with comment also described skin substitutes as "...a class of products that we treat as biologicals..."*

[iii] *See corresponding article DA 57680 and DA52117 "It is recommended that the manufacturer of the particular skin substitute graft or CTP product obtain the appropriate information for FDA regulatory has been received by the MAC, the product will be considered for coverage and placed into the appropriate Code Group"*

[iv] *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*

[v] *Ibid*