ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY™
★CELEBRATING 20 YEARS★

July 31, 2023-Revised

Ms. Nicole Marcos
Designated Federal Official (DFO)
Centers for Medicare & Medicaid Services
7500 Security Boulevard
Baltimore, MD 21244–1850

RE: File Code CMS–1801–N

Dear Ms. Marcos:

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 requests that the Hospital Outpatient Payment Panel vote to recommend to CMS the following specific cellular and/or tissue-based products (CTPs) for skin wounds (outdated and not clinically appropriate term is skin substitutes) related changes:

1. CMS should
   - assign the existing CPT® add-on codes (15272, 15276, 15274, and 15278) and HCPCS codes(C5272, C5276, C5274, and C5278) to appropriate APC groups allowing for separate payment and
   - issue an exception to separately pay for these add-on codes.
2. CMS should assign the CPT and HCPCS codes for the same size wound, regardless of anatomical location on the body, to the same APC groups.
3. CMS should assign all new CTPs with either "Q" or "A" HCPCS codes, to the low-cost APC groups until a manufacturer provides cost information to CMS.
4. CMS should realign both the high-cost and low-cost application procedure codes to higher paying APC groups that reflect the current average sales prices of all CTPs. Manufacturers are required to submit ASP pricing and this pricing should be used to map to an appropriate APC for all CTPs whether they are issued a HCPCS "A" code or "Q" code.
5. CMS should not assign CTPs that are not in sheet form (e.g., gel, powder, ointment, foam, liquid, or injected) to any APC group because these products are not allowed to use the current application codes of 15271-15278 or C5271-C5278, which drives the APC group assignment. CTPs that are not

5225 Pooks Hill Rd | Suite 627S | Bethesda, MD 20814 | T 301.530.7846 | C 301.802.1410
marcia@woundcarestakeholders.org

in sheet form track to services and procedures such as clinic visits and debridement of chronic wounds and therefore should not map to any APC.

We appreciate that the Panel approved the first two recommendations for the past two years and we request that they again approve them as CMS unfortunately has yet to adopt and implement them. These recommendations stem from two patient access issues which are related to the prohibitive costs that hospital outpatient departments (HOPDs) incur if they provide medically necessary CTPs to patients with larger wounds/ulcers.

The Alliance has concerns with the reasons CMS has cited for not adopting these in the CY2023 Medicare Hospital Outpatient PPS Final Rule response. Therefore, we are not only providing the rationale for your consideration but also our concerns with CMS's Response to Comments to provide further clarification on these two topics.

1. CMS Should Assign The Existing CPT® Add-on Codes (15272, 15276, 15274, and 15278) and HCPCS codes (C5272, C5276, C5274, and C5278) To Appropriate APC Groups Allowing For Separate Payment And Issue An Exception To Separately Pay For These Add-on Codes.

Rationale for Recommendation

The first barrier to access relates to the packaging of the add-on codes. When the payment for CTPs were packaged into the payment for the application, the add-on codes were also packaged. Because the add-on codes represent wounds and ulcers that require the purchase of additional product or a larger product, patients with wounds/ulcers larger than 25 sq. cm. up to 99 sq. cm. and also wounds/ulcers greater than 100 sq. cm. are not being offered medically necessary CTPs in the HOPDs. The reason for this is that the packaged OPPS rates for the base codes are not adequate to allow the HOPDs to purchase the sizes of CTPs necessary to apply to wound/ulcer sizes that are aligned with the add-on code descriptions.

To remedy this issue, the Alliance **urges the Panel to recommend that CMS issue an exception to separately pay for the CTP application add-on codes**. The allowance of payment for the add-on codes is an easy remedy for CMS to implement and there has been precedent set by CMS providing this exception to other procedures which require the purchase of additional product (e.g., chemotherapy).

Additionally, the Alliance **recommends that APC groups 5053, 5054 and 5055 be retained but additional APC groups should be created to appropriately address the costs to purchase the appropriate amount of product for wounds/ulcers 26-50 sq. cm., 51-75 sq. cm., 76-99 sq. cm., and each additional 100 sq. cm.** Again, currently, the CPT codes are assigned to APCs based on the wound size - smaller wounds (under 25 sq. cm) or larger size wounds (over 100 sq. cm). The current system makes CTPs for patients with wounds /ulcers that are in between 25 sq. cm. and 100 sq. cm. as well as those over 100 sq. cm. cost-prohibitive for HOPDs since they are not reimbursed for the extra product that would be needed to treat the patient's medically necessary wounds/ulcers.

In order to appropriately pay HOPDs now for the various sizes of products required for the wounds and most importantly, so that patients with larger wounds can gain medically necessary access to CTPs, each base

code for the application of the products must track to separate APC groups and each add-on code must also track to separate APC groups. The OPPS payment rates for the add-on code APC groups should include payment for the additional product that must be purchased. **If CMS is not agreeable to this recommendation, as they have not been for the past 2 years, we recommend that the additional product necessary be billed separately (in addition to the APC payment for the application) to allow the HOPD to afford the purchase of the extra product required to treat the larger wounds/ulcers.**

Concerns Related to CMS's Response to Comments

Unfortunately, CMS provided faulty logic, in the 2023 OPPS Final Rule, for not accepting this recommendation of the Panel.

CMS's policy to unconditionally package add-on code procedures has had the following ramifications: it completely undermined the AMA CPT coding framework; it has not ensured that HOPDs are reimbursed for all medically necessary services performed; and it ultimately has impacted Medicare beneficiary access to important medically necessary and indicated CTPs in HOPDs. CMS's policy also essentially results in HOPDs not receiving reimbursement for the additional clinical care and supplies required, including the additional amount of CTPs that are required when performing the add-on service, which ultimately has adversely impacted patient access to these services in a HOPD.

The lack of access to care in the HOPD has been demonstrated in a the newly published study in the Journal of Medical Economics, "Chronic wound prevalence and the associated cost of treatment in Medicare beneficiaries: changes between 2014 and 2019." (This study is included as an attachment to these comments.) The key findings of the study which validates the shift from patients being treated in the HOPD to the physician's office are:

- **Shifts in site-specific spending**: HOPD fees saw the largest reduction ($10.5 billion to $2.5 billion) although home health agency expenditures decreased from $1.6 billion to $1.1 billion. Physician offices saw an increase from $3.0 billion to $4.1 billion and durable medical equipment increased from $0.3 billion to $0.7 billion.
- **Decreasing overall cost**: Despite the increase in prevalence, healthcare expenditures associated with chronic wound care *decreased* over the study period. The researchers used three different methods to estimate expenditures. Regardless of the method used, there was a reduction in expenditure, with the most conservative method showing a decrease from $29.7 billion to $22.5 billion. This is particularly surprising since overall Medicare costs increased over the same time frame.
- **Shifts in wound types and cost:** The largest changes were increases in arterial ulcers (0.4% to 0.8%) and skin disorders (2.6% to 5.3%), although the authors suggest that the movement from ICD-9 to ICD-10 over the study time period may factor into the changing prevalence of certain types of wounds. As in 2014, surgical wound complications were the most expensive in 2019, with pressure ulcers the second most expensive. For most wound types there were decreases in expenditures, but the "generic" chronic ulcers and venous leg ulcers registered small-to-moderate increases.

The Alliance believes that **packaging all add-on codes is indiscriminate, does not promote payment accuracy or advance patient care and creates barriers to access. However, the allowance of payment**

for the add-on codes – as recommended by this Panel - is an easy remedy for CMS to implement and there has been precedent set by CMS providing these types of exceptions (i.e. chemotherapy).

Yet, CMS has stated that since the OPPS is a prospective payment system and that CTP products are packaged into the payment for their application**, "**paying separately for add-on codes defeats the goals of such a payment system" and "a prospective payment system is not intended to discourage providers from rendering medically necessary care to patients."

We submit that CMS's logic is flawed since procedures that require the purchase of a product should receive special considerations. The CMS response may be true for procedures, such as debridement, but cannot be logically applied to procedures that have advanced therapy products packaged into them. **CMS continues to erroneously believe that HOPDs are reimbursed adequately when they treat a patient with a wound/ulcer larger than 25 sq cm. This is simply wrong.**

As we have stated multiple times,when the AMA work group revised the procedure codes for the application of CTPs, it carefully selected the base codes and add-on codes based on the typical wound/ulcer sizes. Unfortunately, when CMS originally packaged the CTP products into the procedure codes, the Agency **did not include adequate product costs** into the application procedure base codes. In fact, the Alliance of Wound Care Stakeholders has presented CMS with data over the years to show that product costs are and continue to be higher than the allowable amounts in the packaged rates. However, CMS did not correct the inadequate product costs included in the application base codes, which was further compounded when CMS also packaged the add-on codes. The incorrect product allowable in the base codes and the packaged add-on codes have prevented access to CTPs to patients with wounds/ulcers between 26 and 99 sq. cm. and larger than 100 sq. cm. That is why most patients with those size wounds/ulcers do not have the opportunity to receive CTPs in HOPDs. Therefore, **this system is in fact discouraging HOPDs from rendering medically necessary care as a result of inadequate reimbursement for larger sized wounds.**

In addition, CMS stated in its response to the recommendations: *"A substantial portion of the cost of a skin substitute graft application procedure is the graft skin substitute product itself, and the cost of the skin substitute graft products is reflected in the cost of the overall procedure.*" CMS is correct that the substantial portion of the cost of the CTP application procedure **is the cost of the product itself**. However, **the cost of the product is NOT adequately reflected in the computed cost for the primary procedures, and there is NO cost afforded to the add-on codes.** This is a significant issue and one that the Panel also has recognized and has repeatedly requested CMS to address.

Furthermore, CMS erroneously stated that "*facilites are making a profit on the products being used to treat smaller sized wounds and those financial gains even out the losses for product used on the larger sized wounds."* **This is simply wrong**. Since CMS requires providers to purchase the right size product to match the wound/ulcer size, the **HOPD does not experience much, if any, financial gain when they apply CTPs to wounds/ulcers less than 25 sq. cm. because the allowable amount did not originally and still does not cover the costs for small size CTPs**. This data has been provided to CMS by the Alliance multiple times in comment letters as well as in meetings with the Agency. Therefore, it is illogical to assume that the financial gain (which is none-to-little) for small size wounds/ulcers will offset the huge financial loss that the HOPDs would experience if they purchase product for wounds/ulcers between 26 and 99 sq. cm. and larger than 100 sq. cm with no additional payment.

Because precident has been set in other areas in which exceptions have been made allowing payment for the add-on codes in OPPS, **the Alliance respectfully requests the Panel once again to support the Alliance recommendation that CMS assign the existing CPT add-on codes (15272, 5276, 15274, 15278) and HCPCS codes (C5272, C5276, C5274, and C5278) to appropriate APC groups, and to issue an exception for separate payment of the CTP application add-on codes.**

2. CMS Should Assign The CPT And HCPCS Codes For The Same Size Wound, Regardless Of Anatomical Location On The Body, To The Same APC Groups.

Rationale for Recommendation

The second access issue relates to the anatomic location of the wound/ulcer and the APC group that CMS has assigned to the application procedure code. The APC group assignment should be the same for the same size wound/ulcer whether the ulcer is located on the leg or foot, since the same resources and amount of product must be purchased. However, that is not how CMS has assigned the APCs. This example illustrates why this is problematic:

Both Patient A and Patient B have leg wounds/ulcers. Patient A has a 75 sq. cm. wound/ulcer and Patient B has a wound/ulcer measuring 125 sq. cm. The CPT code base code 15271 is appropriately assigned to APC 5054, for the patient with the 75 sq. cm wound/ulcer and the CPT based code 15273 is appropriately assigned to APC 5055 for the patient with the 125 sq. cm. wound/ulcer because the HOPD must purchase more product for the patient with the 125 sq. cm. wound/ulcer.

However, if the application of CTPs were applied to Patient A and Patient B with the same size wound/ulcer, on their foot instead of their leg, the CPT base code for Patient A should be 15275 and the application code for Patient B should be 15277. In the current APC group assignments, both CPT base codes are assigned to the same APC group 5054. However, the HOPD would purchase and apply 50 sq. cm. more product and should appropriately report the application code 15277 for Patient B. The application base code15277 should be assigned to APC group 5055. The HOPD purchased the same amount of product – whether the wound/ulcer was located on the patient's leg or on their foot, and as such, 15277 and 15273 should both be assigned to APC group 5055 to provide patients with the same size wounds/ulcers regardless of the anatomic location with access to medically necessary CTPs.

Concerns Related to CMS's Response to Comments

Unfortunately, CMS's response not only inappropriately addressed the Panel's recommendation, but CMS read the code description incorrectly, and thus, CMS's Response to Comment is faulty. The CPT/HCPCS codes 15271/C5271, 15273/C5273, 15275/C5275 and 15277/C5277 for the application of CTPs apply to both adults and children. CMS is incorrect when it indicates that some of the codes only apply to the application of CTPs to children's wounds/ulcers.

Although it is clear that CMS continues to be confused about the code descriptions for 15277 and C5727, for the past two years the Agency has used the same incorrect information to justify not moving forward with the Panel's recommendation to assign APCs for the same size wound regardless of anatomical location on the body. The Agency has stated that *"these codes were only for the application of CTPs to children."* Yet, the

CPT code descriptors very clearly state they apply to any 100 sq cm wound surface area OR 1% of body area of infants and children.

In fact, **all the CTP application code descriptions for wounds/ulcers equal to or greater than 100 sq cm are identical and specifically state:**

> *"100 sq cm wound surface area, or 1% of body area of infants and children; and "each additional 100 sq cm wound surface area, or part thereof, or each additional 1% of body area of infants and children, or part thereof."*

The Panel in 2021 and the Panel on August 22, 2022 once again agreed that CMS should assign APCs for the same size wound regardless of the anatomical location on the body so that 15273 and 15277 should be assigned to APC 5055 and 15271 and 15275 should continue to be assigned to APC 5054.

The Alliance once again **requests that the Panel recommend that CMS should assign APCs for the same size wound regardless of the anatomical location on the body so that 15273 and 15277 be assigned to APC 5055, and 15271 and 15275 continue to be assigned to APC 5054.** These codes apply to adults as well as children and should be assigned to APC 5055 as the same resources are used regardless of anatomic location of the wound.

3. CMS Should Assign All new CTPs, With Either "Q" or "A" HCPCS Codes, to the Low-Cost APC Package Until the Manufacturer Provides Cost Information to CMS.

Beginning in 2013 when CTPs were packaged in the HOPDs, CMS mapped CTPs assigned HCPCS "Q" codes into an appropriate APC group based on pricing data that had to be submitted by the manufacturer. CMS identified the pricing information that it required the manufacturer to submit to determine the placement of the product in the high or low cost group. If the cost was not provided to CMS, the product would automatically be placed in the low cost group. CMS currently places some CTPs assigned "Q" codes into the high or low cost package based on the Median Unit Cost (MUC) or the Per Day Cost (PDC) and then the product is mapped to an appropriate APC group.

Recently, CMS began to issue HCPCS "A" codes to CTPs with FDA 510(k) clearance and has automatically placed them into the high cost package without receiving any pricing data to validate their placement in the higher APC grouping.

The Alliance is concerned with this action by the Agency for the following reason: **CMS is not following its own guidance on this issue. The mapping of CTP products to the appropriate APC group should be based on the assignment of the product to either the high or low cost package - which is determined by pricing data provided by the manufacturer.**

By automatically placing the CTPs assigned "A" codes into the high-cost APC group without receiving pricing information from the manufacturer, CMS is potentially paying high-cost rates for CTPs that are actually low-cost. As such, the Alliance requests that this Panel recommend to CMS that the Agency follows its own methodology for placing CTPs into the high or low cost package to appropriately map each CTP to the correct APC group.

Specifically, CTPs **that are issued HCPCS "A" codes should not automatically be assigned to the high cost package and potentially map to an incorrect APC group without providing appropriate pricing data.** The methodological placement of a CTP with a HCPCS "A" code into the high or low cost package should be based on the MUC or PDC just like CTPs that are issued HCPCS "Q" codes. Not only would this be equitable, but CMS would be following its own guidance. **The notion that A codes are "different" is factually not correct.** There are current 510(k) products that have HCPCS "Q" codes and newer ones that now have HCPCS "A" codes.

4. CMS Should Realign Both The High-Cost And Low-Cost Application Procedure Codes To Higher Paying APC Groups That Reflect The Current Average Sales Prices Of All CTPs.

CMS should realign both the high-cost and low-cost application procedure codes to higher paying APC groups that reflect the current average sales prices of all CTPs. To accomplish this, CMS should use the ASP of all CTPs (products assigned "Q" and "A" HCPCS codes.) which will assist in appropriately mapping to the correct APC. Because inaccurate product costs were built into the packaged payment for the application of CTPs, the HOPDs have been unable to purchase most low-cost CTPs, even for small sized wounds/ulcers. This improper payment has existed now for 10 years. Now that all CTP manufacturers are required to submit the ASPs for their products, CMS should have adequate pricing information to build actual CTP prices into the application procedure base codes and add-on codes. Once that is accomplished, CMS should realign the CTP application procedure base codes and add-on codes to APC groups that reflect the HOPDs' true costs.

Since mapping procedure codes to the appropriate APC groups is within this Panel's charter, the Alliance requests that this Panel recommend that CMS realign the application of CTP base codes and add-on codes to appropriate APC groups that reflect current prices of high-cost and low-cost CTPs. CMS can easily accomplish this by using the existing ASP data to calculate the actual costs for all the CTPs with "Q" codes and "A" codes assigned to the high-cost and low-cost groups. By using the actual reported ASP information, CMS should reassign the packaged application base codes and add-on codes to APC groups that reflect current prices, not the inadequate prices that were used by CMS ten years ago.

5. CMS Should Not Assign CTPs That Are Not In Sheet Form (e.g., Gel, Powder, Ointment, Foam, Liquid, or Injectable) To Any APC Group.

CMS should not assign CTPs that are not in sheet form (e.g., gel, powder, ointment, foam, liquid, or injectable) to any APC group because these products are not allowed to use the current application codes of 15271-15278 or C5271-C5278, which drive the APC group assignment. CTPs that are not in sheet form track to services and procedures such as clinic visits and debridement of chronic wounds. CTPs that are not in sheet form (i.e. gel, powder, ointment, foam, liquid, or injectable) do not align with the American Medical Association's application of CTP coding directions. Furthermore, Medicare does not currently cover or pay for any CTP that is not in sheet form. As such, these products should not be assigned to any APC group.

The Alliance requests that this Panel recommend to CMS to stop assigning CTPs that are not in sheet form to any high-cost or low-cost APC group as it is not appropriate to do so.

Conclusion

The Alliance appreciates consideration of the Panel requesting CMS to move forward with these recommendations. Adopting these recommendations will assure that HOPDs can provide the necessary access to CTPs for Medicare beneficiaries and ensure that payment is adequate for providers to treat their patients.

Sincerely,

Marcia Nusgart, R.Ph.
CEO, Alliance of Wound Care Stakeholders