



August 5, 2022

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

RE: File Code CMS-1778-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 once again requests that the Hospital Outpatient Payment Panel vote to recommend to CMS two specific wound care related changes. Specifically, as was the case last year when the Panel voted unanimously, we recommend 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 CTP add-on codes.
- Assign APCs for the same size wound regardless of anatomical location on the body.

Our recommendations stem from the following two patient access issues which are related to the prohibitive cost that Provider Based Departments (PBDs) incur if they provide medically necessary skin substitutes or Cellular and/or Tissue Based Products for Skin Wounds (CTPs) to patients with larger wounds/ulcers.

Assignment of Add-On Codes to Appropriate APC

The first barrier to access relates to 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, patients with wounds larger than 25 sq. cm. up to 99 sq. cm. and also those greater than 100 sq. cm. are not being offered medically necessary CTPs in the Provider Based Departments (PBDs). The reason for this is that the add-on codes that are packaged into the OPPS bundled rates are not adequate to allow the PBDs to purchase the sizes of CTPs necessary to apply to all wound sizes. In fact, none of the add-on codes have been available for additional payment.

To remedy this issue, the Alliance urges the Panel to recommend that CMS issue an exception for the payment of 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 in CMS providing these types of exceptions (i.e. chemotherapy).

Additionally, the Alliance recommends that APC 5053, 5054 and 5055 be retained but additional APCs should be added to appropriately address the costs to purchase the appropriate amount of product for wounds 1-25 sq. cm., 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 that are in between 25 sq. cm. and 100 sq. cm. as well as those over 100 sq. cm. cost-prohibitive since facilities are not getting reimbursed for the extra product that is being utilized to treat the patient's medically necessary wounds.

In order to appropriately pay PBDs 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. There must be payment for the add-on codes that include payment for the product that must be purchased.

CMS indicated in its response to comments last year that paying separately for add on codes in a prospective payment system defeats the goals of such a payment system. However, only when the payment is adequate to cover the cost of the product is this the case. The CMS response may be true for procedures, such as debridement, but can not be logically applied to procedures that have expensive products packaged into them.

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. When CMS originally packaged the CTPs 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 presented CMS with data to show that the product costs were higher than the allowable amounts in the packaged rates. However, CMS did not correct the allowable rates for the base codes, and caused a bigger financial problem when it packaged the add-on codes. The incorrect product allowable in the base codes and the packaged add-on codes prevent 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 outpatient departments.

Since CMS requires providers to purchase the right size product to match the wound/ulcer size, the outpatient department 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 products. 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 outpatient departments will experience when they have to purchase product for wounds/ulcer between 26 and 99 sq. cm. and larger than 100 sq. cm.

That is why last year the Hospital Outpatient Payment Panel committee unanimously recommended that CMS pay for the application of CTP add-on codes and include an adequate allowable amount for the

additional product into each add-on code and why the Alliance is respectfully requesting that the Panel once again recommend that CMS assign the existing CPT add-on codes (15272 and 15276; 15274 and 15278) to appropriate APCs allowing for payment and recommend to CMS that they issue an exception for the payment of CTP add-on codes.

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

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 ulcers. Patient A has a 75 sq. cm. wound/ulcer and Patient B has a wound/ulcer measuring 125 sq. cm. The CPT code 15271 is appropriately assigned to APC 5054, for the patient with the 75 sq. cm wound and 15273 is appropriately assigned to APC 5055 for the patient with the 125 sq. cm. wound as the PBD has to purchase more product for the patient with the 125 sq. cm. ulcer/wound.

However, if the application of CPTs were both provided to Patient A and Patient B with the same size wound/ulcer, but in this case, the CTP application was on their foot instead of the leg, the CPT code for Patient A would be 15275 and the application code for Patient B would be 15277. Both would be assigned to the same APC-5054. However, the PBD utilized 50 sq. cm. more product when billing application code 15277 for Patient B. 15277 should have been assigned to APC group 5055. The PBD purchased the same amount of product – whether the ulcer/wound was located on the patient’s leg or their foot and as such, 15277 and 15273 should both be assigned to APC 5055 to provide patients with access to medically necessary CTPs.

While the Panel unanimously agreed, CMS did not adopt this recommendation in the CY 2022 rulemaking cycle. Instead, the Agency, in its response to comments, stated that the codes describing the application of high and low cost graft skin substitutes for adults (15271 and 15275 and their corresponding C codes) are assigned to the same APC 5054. Because they are currently included in the same APC group, OPPTS payment for them is the same and this payment policy is consistent with the recommendation from the HOP panel and other commenters.

However, that is not correct. The Panel unanimously recommended that CMS reassign codes in the last rulemaking cycle as the Panel (and the Alliance) believes that it is not logical for CMS to have assigned 15275 and 15277 to the same APC group in the first place. When clinicians perform 15277, the outpatient departments must purchase 4 times more product than when a clinician performs 15275. CMS correctly assigns 15271 and 15273 to different APC groups, 5054 and 5055 respectively. Therefore, CMS should be consistent and assign 15277 to APC group 5055.

Again, this is why the Panel unanimously recommended that CMS reassign 15277 to APC group 5055 and why the Alliance is recommending that the Panel once again urge CMS to 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.

The Alliance appreciates consideration of the Panel requesting CMS to move forward with these recommendations.

Sincerely,

A handwritten signature in black ink that reads "Marcia Nusgart R. Ph." The signature is written in a cursive, flowing style.

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