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

September 13, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1772-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted Electronically to Regulations.gov

RE: Medicare and Medicaid Programs; CY 2023 Hospital Outpatient Prospective Payment System [CMS-1772-P]

Dear Administrator Brooks-LaSure,

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are pleased to submit comments on the CY 2023 proposed Medicare Hospital Outpatient PPS (CMS-1772-P). The Alliance is a non-profit 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 and utilize "skin substitutes" or rather the more technically and clinically correct term, "cellular and/or tissue based products for skin wounds (CTPs)" – which are subject to provisions within this proposed rule. Please be aware that while the ASTM definition of CTPs is inclusive of synthetic products, some Alliance members who manufacture synthetic products would also recommend the inclusion of synthetics to the descriptor e.g. Cellular, Synthetic and/or Tissue-based Products (CSTPs) as they believe it would more adequately encompass the evolving field of products in this space. That said, throughout this letter the Alliance will utilize the term "CTP" when addressing this product sector in our comment letter as we have since 2013 and validated when ASTM published its original standard guide for "Categories and Terminology of Cellular and/or Tissue-Based Products (CTPs) for Skin Wounds in 2016.[i] A list of our members can be found on our website: www.woundcarestakeholders.org.

The Alliance has significant concerns with proposals related to CTPs and has focused a majority of our comments on those provisions. CMS has struggled since CTPs have been packaged on how to pay for them in the hospital outpatient setting and has continued to have a payment mechanism in place which continues to have access to care issues for those with larger wounds.

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CTPs are a valuable and successful advanced treatment option for patients with chronic non healing ulcers including diabetic foot ulcers (DFU) and venous leg ulcers (VLU). In fact when CTPs are used on patients with diabetic ulcers on the lower leg or foot, there are lower incidence of amputations.[ii iii iv v vi vii viii ix x xi xii xiii xiv] These products have been used successfully to treat patients and have multiple peer reviewed published studies supporting their use.[xv xvi xviixviii xixxx xxi xxii xxiii xxiv] (Only a sample of studies that validate these statements have been cited and provided below). While CMS continues to pursue health equity goals, it is worth noting that there remains a significant disparity in amputations across racial groups, as persons of color are more likely to suffer amputations from a diabetic foot ulcer.[xxv] This proposed rule will ensure the continuation of this disparity as access to care will be significantly impacted should the CTP proposals move forward.

Furthermore, the Alliance is extremely concerned with the incremental and gradual changes being proposed without the Agency providing a full road map of the payment policies for CTPs in the outpatient setting. We submit that the proposed OPPS policies do not provide needed clarity as to the specifics of CMS's intended path for CTPs furnished; instead the Agency seems to be issuing incremental proposals in a piecemeal fashion. Consequently, without any substantive policy proposals laid out, these changes being proposed actually impact the future of CTPs being furnished in the Provider Based Deptartments (PBDs) and limit appropriate patient access to these products

The Alliance is happy to be a resource for the Agency as it addresses these issues. Our specific comments follow.

OPPOSITION TO CMS RENAMING THE TERM "SKIN SUBSTITUTES" TO "WOUND CARE MANAGEMENT PRODUCTS"

The Alliance agrees with the Agency that the term "skin substitute" is misleading and inaccurate to describe the class of products that are the subject of this proposed rule. We have been advocating for this change for over 10 years. In fact, as the Agency stated, skin substitutes do not substitute for skin. They have evolved and the term is no longer representative of the products in the marketplace or what the products are designed to do. However, the Alliance **strongly disagrees with the Agency that "skin substitutes" should be renamed "wound care management products."** The Agency has indicated that the reason for the change of nomenclature is to provide a "more accurate and meaningful term" which will help address confusion among interested parties about how these products are described and how they are paid for. Yet, CMS goes through great lengths describing this term by stating what is and is not included. The Agency also had to explain that the E/M codes would not be implicated by this terminology. If the Agency has to go through such lengths to explain what the nomenclature means – it will not help to provide any clarity especially when clinically the term includes more products than the class of product it is meant to describe.

Furthermore, CMS also indicated that this new term more accurately describes the suite of products that are currently referred to as "skin substitutes" while providing enough specificity to not include bandages or standard dressings, which are not considered skin substitutes. While CMS is correct that bandages are not considered skin substitutes, there are a wide range of additional products and services that are considered "wound care management" products and services. This list includes but not limited to: disposable negative pressure wound therapy, Unna Boots, multilayer dressings, total contact casts, casting and strapping products, selective debridement, surgical debridement agents, low-frequency non-contact non-thermal

ultrasound, support surfaces, topical oxygen therapy products, and surgical dressings. In addition, the distinction between the CPT active wound care management codes and the application of skin substitutes will also cause confusion. CPT active wound care management codes 97597-97610 describe very different procedures from the application of skin substitutes 15271-78, but CMS's proposed terminology change to "wound care management" or "wound care management products" sounds very similar and would also lead to confusion. So realistically, changing to the wound care management product nomenclature would actually cause more confusion in the industry than the CTP or skin substitute nomenclature that currently exists and does not provide the type of clarity that CMS is trying to achieve.

In order to create less confusion, a more accurate term describing the entire suite of products currently marketed as well as prospective ones, **the Alliance recommends that CMS adopt the term "Cellular and/or Tissue Based Products for Skin Wounds" or CTPs.** This nomenclature is already known and being utilized by clinicians, speakers at conferences, in publications as well as several of the CMS A/B MAC contractors and private payers' LCDs.

Additionally, as noted earlier in this comment letter, ASTM International (the well-respected standards setting development organization) thought so highly of the cellular and/or tissue based products for skin wounds (CTP) terminology that in February 2016 it published a definitive standard (F3163-16) devoted to the nomenclature for these products titled "Standard Guide for Classification of Cellular and/or Tissue-Based Products for Skin Wounds." It was updated in 2022 (F3163-22.) The workgroup that created this standard as stated above included FDA (who agreed with the term), scientists, engineers and clinicians who worked collaboratively to ensure that the standard is inclusive of all the products in this space. As stated above, according to the ASTM standards document, the definition of a CTP is as follows, "*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.* [xxvi]

The CTP nomenclature is already being utilized, and includes all products that CMS is trying to describe and provides the clarity that the Agency is seeking. CMS should adopt the term "cellular and/or tissue based products for skin wounds" (CTPs) in place of the words skin substitutes.

Recommendation: The term cellular and or tissue based products for skin wounds (CTPs) is clinically and technically accurate to describe this class of products. In fact, this term provides the clarity that CMS is seeking by very clearly identifying the products that are included within the definition. As such, **the Alliance recommends that CMS not utilize the confusing and overly broad term "wound care management products" and instead use the more clinically accurate term "cellular and/or tissue based products for skin wounds (CTPs)" or as we stated earlier in our comments Cellular, Synthetic and/or Tissue-based Products (CSTPs).**

REQUEST FOR CMS TO PUBLISH ASPS FOR ALL CTPS AND MAINTAIN ASP PRICING METHODOLOGY FOR CTPS

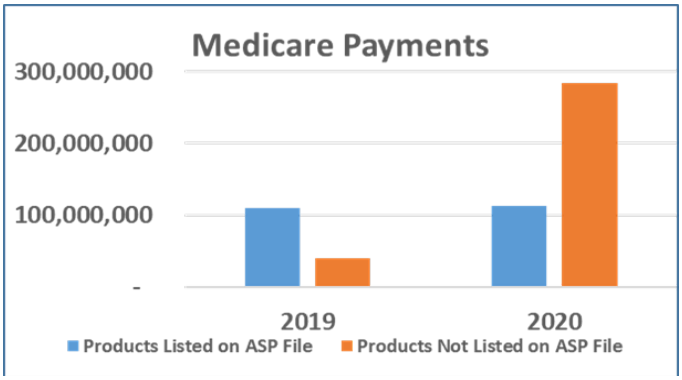
In the CY 2023 proposed OPPS rule, CMS indicated that if the CY 2023 physician fee schedule proposal that no longer requires manufacturers of CTPs to submit ASP pricing is finalized, the Agency would be bound by this decision and therefore would not accept ASP pricing for inclusion in the payment methodology in the

outpatient setting. We believe that not including ASP for calculating payment in the outpatient setting will be detrimental to the Agency and will move away from long standing requirements placed on CTPs to report ASP.

Our rationale for CMS to use ASP methodology is that it would allow the Agency to continue to ensure that there is differentiated payment for differentiated products. Furthermore, the Agency would not be overpaying at list or invoice price. According to the data in Tables 1-3 below, when ASP pricing is used for products contained in the Part B pricing data file, there were savings associated with those products as opposed to those not on the Part B pricing data file. If the Agency is interested in controlling costs and providing savings to the Medicare Trust Fund, while applying a consistent payment policy across all CTP products, it should maintain ASP pricing and all products should be published within this data file. The Alliance acknowledges that synthetic products are not part of the category defined as drugs or biologics, and as such, are not currently required to report ASP. Therefore, synthetics are not reimbursed based on ASP payment methodology. As such, to accommodate all products, the Alliance recommends that CMS also require synthetics to report ASP. To illustrate the savings impact that the Medicare Trust Fund would realize if CMS would publish all CTP products on the Part B Drug file, we have provided below 2019 and 2020 data analyzed from the Medicare Part B National Summary Data File from one of our Alliance members.

Table 1 represents Medicare payments of CTP products. As demonstrated, Medicare payments for products not on the ASP Part B file increased significantly from 2019 to 2020.

Table 1: Medicare Payments of CTP Products



As shown in Table 2, payments for CTP products listed on the ASP file increased by 2%. However, products not listed on the ASP file increased 597% or $243 million dollars in 2020.

Table 2: CTP Product Percent Increase

	Medicare Part B Payment*	
	% Increase 2019 vs 2020	$ Increase 2019 vs 2020
Products on Medicare Part B ASP File	2%	$2,406,233
Products not on Medicare Part B ASP File	597%	$243,417,824

Moreover, in Table 3, we demonstrate that the payment per unit actually decreased by 5% for products listed on the ASP file, while the payment per unit for products not listed on it increased 59% per unit.

Table 3: CTP Medicare Payment Per Unit

	Payment Per Allowed Service (UNITS)		
	2019	2020	
Products Listed on ASP File	$ 82	$ 77	-5%
Products Not Listed on ASP File	$ 146	$ 232	59%

Congress recently mandated ASP reporting for all products paid as drugs and biologicals under Section 1847A effective January 1, 2022, under the Consolidated Appropriations Act.[xxvii] By packaging payment and eliminating the ASP reporting requirement for these products, we believe CMS would be undermining Congress' intent to apply a broad, ASP-based payment framework to all drugs and biological products, including CTPs.

Recommendation: The Alliance highly recommends that CMS publish ASPs, and pay per the ASP methodology, for all CTPs in order to achieve the savings and consistency discussed above.

PROVIDER BASED DEPARTMENTS PAYMENT ISSUES IMPACTING MEDICARE BENEFICIARIES ACCESS TO CTPS

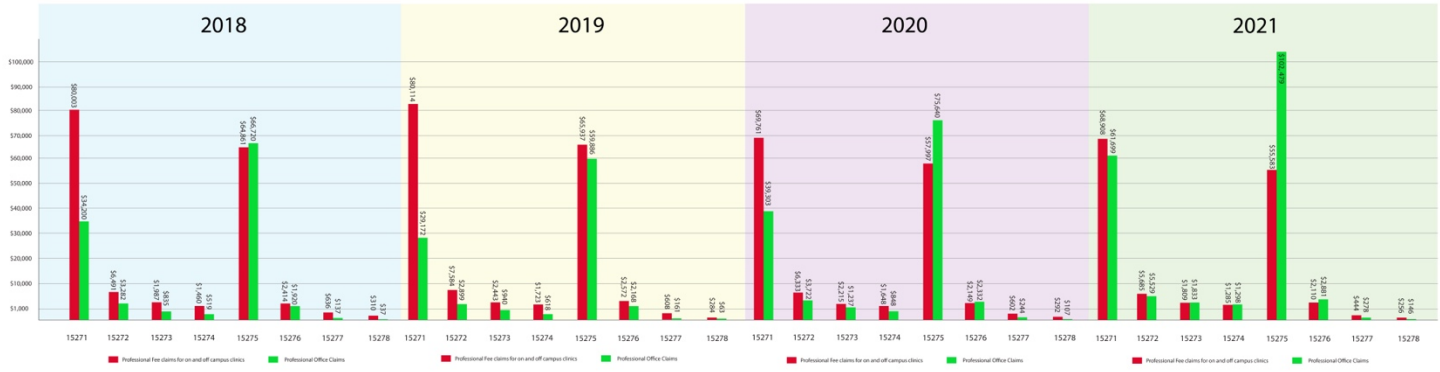
Ever since CMS determined that CTPs needed to be packaged in the hospital outpatient setting, the Alliance has been on record regarding our concerns in that the payment methodology was unworkable since the data being utilized to set the rates was not accurate. The Alliance submitted data to the Agency which unfortunately was not used. We are once more voicing our concerns with the packaging of CTPs and their consequent payments. We submit that since CMS has not analyzed the impact of packaging CTPs and the application add-on codes on patient care, we continue to be concerned that CMS has not provided detailed information regarding the impact of these changes on payment rates or patient access.

In the hospital outpatient setting 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 by clinicians in the Provider Based Departments (PBDs). The reason 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. PBDs cannot nor are they willing to incur prohibitive costs and financial losses if they provide CTPs to patients with larger medically necessary wounds/ulcers. Instead, these patients are being treated in either the operating room (OR) defined as same day surgery in which the 2 midnight rule would apply for packaging or they are treated in physician offices. Treating the patients in the operating room (OR) can be problematic for the following

reasons: not all patients can undergo anesthesia (or want to), surgeons do not like to do "minor" CTP applications in the OR as there are significant hurdles that have to be navigated in terms of pre procedural testing and anesthesia clearance, OR time can be very hard to obtain in the current climate of over flowing hospitals and finally, there is a significant cost incurred when shifting this procedure to the OR. Thus, a majority of patients have been treated in the physician office for these larger wounds.

To validate this, the Alliance analyzed Medicare claims data from 2018 – 2021 and according to the data provided in Table 4, there has been a steady increase of claims submitted by physician providers. In fact, procedure codes 15271 – 15277 were billed more frequently in the physician office than in PBDs and for more of the larger sized wounds (wounds over 25 sq. cm. – 99 sq. cm. as well as wounds over 100 sq. cm.). There has been an increase every year in the number of claims, largely due to physicians being able to treat larger and more complex wounds in the office and being reimbursed appropriately for their work.

Table 4 Medicare Claims Data for CTP Application Code Claims 2018-2021



*Medicare data analysis completed by Dobson and DaVanzo
** The data in Table 4 is also being provided in larger font as Attachment A

We were also able to confirm based on the same Medicare data analysis completed by Dobson and DaVanzo that **outpatient facilities under the prospective payment system are losing money on these larger wounds**. In fact, **the current APC payment rate of $1,749 to treat a patient with a larger wound does not even cover the cost of a majority of CTPs in the market place today.** Thus, the steady shift/increase in the number of claims submitted in this physician office setting.

Therefore, the Alliance once again proposes two easy solutions for CMS to implement:

- Assign the existing CPT add-on codes (15272 and 15276; 15274 and 15278) to an appropriate APC group that provides adequate payment for the additional product needed for those applications to larger size wound/ulcers (The Alliance believes that this would allow for adequate work and product acquisition payment) and issue an exception for the payment of skin substitute application add-on codes.
- Assign the application codes for 100 sq. cm wounds/ulcers on the feet to the same 5055 APC group as the application codes for 100 sq. cm wounds/ulcers on the legs.

The Alliance presented these recommendations in our presentation to both the August 23, 2021 and August 22, 2022 Advisory Panel on Hospital Outpatient Payment (HOP) meeting. We appreciate that the Panel both years voted to approve them. Here are their recommendations that were recently posted on the CMS website:

> *Skin Wound Procedures*
>
> *1.The Panel recommends that CMS assign the existing add-on codes HCPCS code 15272, Application of skin substitute graft to trunk, arms, legs, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure); HCPCS code 15274, Application of skin substitute graft to trunk, arms, legs, total wound surface area greater than or equal to 100 sq cm; 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 (list separately in addition to code for primary procedure); HCPCS code 15276, Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; each additional 25 sq cm wound surface area, or part thereof (list separately in addition to code for primary procedure); and HCPCS code 15278, Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area greater than or equal to 100 sq cm; 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 (list separately in addition to code for primary procedure); to an appropriate Ambulatory Payment Classification (APC) group allowing for payment and issue an exception for the payment of the add-on codes for cellular and/or tissue-based products for skin wounds.*
>
> *2. The Panel recommends that CMS assign APCs for the same size wound regardless of anatomical location on the body.*

We request that CMS includes these important recommendations in the OPPS final rule.

We believe that these two issues are so important that we have provided additional detail for each one of these recommendations.

Payment for Application of Add-on Codes

When the payment for CTPs was packaged into the payment for the application, the add-on codes were also packaged. 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 CTPs in the PBDs. The reason is that the add-on codes that are packaged into the OPPS packaged rates are not adequate to allow the PBDs to purchase the additional sq. cm. of CTPs necessary to cover the wound surface of all wound/ulcer sizes.

To highlight this issue -if a patient has a 24 sq. cm. diabetic foot ulcer, the facility would be paid the base code (CPT 15721 mapped to APC 5054) for the application of the skin substitute as well as the product. However, if that same patient has a wound/ulcer that is 64 sq. cm., the facility would be paid for the base code (which reimburses up to 24 sq. cm.) but would not be paid for the remaining 40 sq. cm. of product needed because it is part of the add on code (15272) which is not reimbursed since it is packaged and does not map to an APC. A facility should not be required to absorb the cost of a medically necessary product to treat their patient and the patient should not have a barrier to access when medically indicated.

CMS's policy to unconditionally package add-on code procedures has completely undermined the AMA CPT coding framework, it has not ensured that hospitals are reimbursed for all medically-necessary services performed, and it ultimately has impacted beneficiary access to important medically necessary and indicated

CTPs in provider based departments (PBDs). Add-on codes are distinct clinical procedures that have been valued by the AMA independently from the primary procedure and that 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 CTPs, that are required when performing an add-on service, which ultimately has adversely impacted patient access to these services in a PBD. The Alliance believes that **packaging all add-on codes is indiscriminate and does not promote payment accuracy or advance patient care and creates barriers to access.**

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, procedures that require the purchase of a product require 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.

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.

In summary, because the OPPS does not pay for most add-on codes and because the payment for the CTP is packaged into the base application code, OPPS does not provide adequate payment for PBDs to purchase an adequate amount of CTP products for wounds/ulcers between 26 and 99 sq. cm., and over 100 sq. cm. Therefore, the Alliance urges CMS to adopt the Panel's recommendation:

• Assign the existing CPT add-on codes (15272 and 15276; 15274 and 15278) to an appropriate APC group (which the Alliance believes will pay for the additional work and the additional product).

• Issue an exception for the payment of CTP application add-on codes.

In addition to the add on codes for 15272 and 15276; 15274 and 15278, the Alliance also recommends that the CMS assign existing CPT add on codes (C5272, C5276; C5274 and C5278) to an appropriate APC group.

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. It simply 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.

While the Panel unanimously agreed to this recommendation in 2021, CMS did not adopt it in the CY 2022 rulemaking cycle. In the response to comments, CMS seemed to be confused about the code descriptions for 15277 and C5727 as it appears that the Agency seemed to think these codes were only for the application of CTPs to children. Actually, **all the CTP application code descriptions for wounds/ulcers equal to or greater than 100 sq cm are identical: "100 sq cm wound surface area, <u>or</u> 1% of body area of infants and children; and "each additional 100 sq cm wound surface area, <u>or</u> part thereof, <u>or</u> each additional 1% of body area of infants and children, or part thereof." Therefore, CMS's response does not appropriately address the Panel's recommendation**. Again, these codes are pertinent to adults as well as infants and children as the descriptor states.

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 be assigned to APC 5055 and 15271 and 15275 continue to be assigned to APC 5054. The Alliance recommends that CMS adopt the panels' recommendation in the final rule.

<u>RETIREMENT OF HCPCS C1849</u>

The Alliance supports the retirement of HCPCS C1849 since we never supported its creation. The

Alliance has already gone on record opposing the issuance of HCPCS C1849 and supports the retirement of that code.

ELIMINATION OF HCPCS Q CODES TO DESIGNATE CTPS

The Alliance categorically opposes the elimination of Q codes being issued to CTPs and do not support HCPCS coding changes from "Q" codes to "A" codes. "A" codes designate supplies, and CTPs are not supplies. CMS indicates that it is proposing to move an entire class of products out of the HCPCS codes that have been issued to them for over 12 years – HCPCS Q codes – to new A codes in order to uniformly classify these products in the HCPCS code set and to eliminate confusion. However, the only confusion is in fact CMS's proposal to eliminate Q codes for an entire class of products that have been issued them for decades.

According to CMS, Q codes are not appropriate for these products because they are used to identify separately payable drugs and biologicals. CMS's stated rationale for the change from Q codes to A codes is inconsistent with one of its stated objectives in the treatment of skin substitute products (maintaining clarity for interested parties) and is incorrect factually. We ask CMS to recall from the 2014 OPPS Final Rule (CMS-1601-FC) that CMS responded to stakeholder feedback by stating the Agency was not conflating the two benefit categories of CTPs and surgical dressings; and, further, that CMS assigns A codes to surgical dressings and Q codes to drugs and biologics which are used to describe CTPs. CMS has a long-standing precedent of assigning A codes to dressings and Q codes to individual skin substitute products that submit new HCPCS code applications. Therefore, we recommend that CMS's latest proposals that Q codes be eliminated in the future and that skin substitute products which are already appropriately assigned Q codes should apply instead for an A code (meant for surgical dressings) is inappropriate**.**

In terms of maintaining clarity for interested parties on coding for skin substitute products, CMS's proposal does just the opposite. Historically, CMS made the decision to issue Q codes in 2010 when CMS abandoned the term "skin substitutes" in the code descriptors for these products and instead required an individual product/brand specific descriptor. At that time, the Agency agreed that these products were not "skin substitutes" and instead issued Q codes for each individual product by its brand name – rather than the "J" codes that they were being issued. Q code designation for these products are more appropriate. Thus, for more than a dozen years, most skin substitute products have had HCPCS codes in the Q41XX or Q42XX series, which has enabled physicians, providers, contractors, and coders to know where to look in the HCPCS code set for such products.

CMS has disturbed this clarity in coding by first assigning certain CTP products A codes within the past year and now by proposing to move all CTP products to A codes. These actions taken and proposed create confusion and unnecessary work for all involved, instead of maintaining clarity. CMS is forcing physicians, providers, coders and Medicare contractors to change their mindsets and their systems to a new set of codes. Further, the proposal would further burden the HCPCS process, which based on consistent missing of time frames for release of code decisions, seems over-burdened already. The proposal would significantly increase the number of HCPCS applications the Agency will have to process. Clarity would be maintained by having all skin substitute products assigned Q codes, and that would spare considerable resources for all these components of the system.

The rationale for CTP products not maintaining Q codes is factually incorrect. The Q codes do not just include separately payable drugs and biologicals. There are dozens of Q codes for cast supplies and about 10 codes for hospice or home care services. Moreover, if one thinks about what is contained in the set of Q codes, CTP products make sense to be included therein. The majority of CTPs are either biological or have strong biological components, and in many cases are the result of humans who have donated their tissue. CMS has stated numerous times in rulemaking that these products "*stimulate the host to regenerate lost tissue.*" This class of products are therefore most accurately captured by a Q code.

The CMS proposal to transition to A codes not only creates unneeded work and confusion in light of the many years of the use of Q codes for such products, but A codes for skin substitutes do not capture the therapeutic significance of these treatments.

CTPs are not supplies both for technological reasons and also on how they are used clinically.

First, CTPs are affixed to a wound and become incorporated into the wound bed. This demonstrates that they are not supplies that are used and disposed of. To better understand this concept as well as this product category, we have provided an excerpt from the Wounds International Journal which describes CTPs.[xxviii] Specifically, the journal states,

> *CTPs provide an extracellular matrix (ECM) to a chronic wound, which plays an important role in tissue regeneration and is the major component of the dermal skin layer. The composition of ECM includes proteoglycans, hyaluronic acid, collagen, fibronectin, and elastin. As well as providing a structural support for cells, some components of the ECM bind to growth factors, creating a reservoir of active molecules that can be rapidly mobilized following injury to stimulate cell proliferation and migration. In many chronic wounds, increased levels of inflammatory cells lead to elevated levels of proteases that appear to degrade the ECM components, growth factors, protein and receptors that are essential for patient healing.*
>
> *Recognition of the importance of the ECM to wound repair has led manufacturers to introduce CTPs that work with the patient's body to replace the ECM. These CPTs comprise a reconstituted or natural collagen matrix that aims to mimic the structural and functional characteristics of native ECM[4]. When placed in the wound bed, the three-dimensional matrix provides a temporary scaffold or support into which cells can migrate and proliferate in an organized manner.*
>
> *These products are not passive – they are not gauze or a band aid. They are not a surgical dressing. These products (in contrast to dressings/supplies) are not applied by a patient or caregiver and are typically not removed post-application. There is biologic effect that takes place as a result of the incorporation of these products into a wound bed.*

Furthermore, CTPs have regulatory requirements placed on them that NO other supply has, specifically, tissue tracking requirements. There are rigorous requirements that clinics have to adhere to in order to pass their Joint Commission accreditation inspections.[xxix] [xxx] [xxxi] These include but are not limited to documenting:

- Who delivered the CTP
- What time the CTP was delivered
- What condition the CTP arrived

- How the CTP is being stored
- Where they are stored
- Monitoring and logging daily temperatures in storing the CTP
- Each staff member who has come into contact with each tissue needs to be tracked and documented
- Maintain a 10 year implantation record retention

If PBDs fail to comply with these requirements, they could be in jeopardy of losing their accreditation.. No supply has the same type of documentation requirements as CTPs or have any specifically identified Joint Commission requirements as stringent as CTPs. The reason – CTPs are not supplies and are not treated as such through the accreditation process.

Recommendation: The Alliance opposes the proposal to have all CTPs be issued HCPCS A codes. **HCPCS A codes are inappropriate as these products are not supplies. We strongly recommend that all CTPs be assigned a Q code when meeting the requirements of the HCPCS application and all CTPs inappropriately issued an A code beginning in 2021 should be re-assigned a proper Q code.**

CPT 15275

In addition to the CPT provisions identified above, CMS proposed to designate CPT code 15275 (Application of skin substitute graft to face, scalp, eyelids, mouth, neck, ears, orbits, genitalia, hands, feet, and/or multiple digits, total wound surface area up to 100 sq cm; first 25 sq cm or less wound surface area) as permanently office-based under the ASC payment system and to reduce the rate to $89. The Alliance does not support this proposal. The very reason there are few claims for application of CTPs in the ASC is because the reimbursement is so low that it has created access to care issues to this advanced therapy. Surely the Agency can recognize that this is what happens when facilities are not being reimbursed properly and supports the very concerns that the Alliance has addressed in this comment letter. As stated above, the rate of $89 doesn't even cover the resources used by clinicians to apply the CTP let alone the CTP itself. Therefore, it is imperative that CMS provide adequate reimbursement for CTPs to be provided in ASCs.

340B-Acquired Drugs

For CY 2023, CMS proposes to continue their current policy of paying ASP minus 22.5 percent for 340B-acquired drugs and biologicals, including when furnished in nonexcepted off-campus PBDs paid under the PFS. But in light of the Supreme Court's recent decision in *American Hospital Association v. Becerra,* the Agency indicated that they intend to apply a rate of ASP + 6 percent to drugs and biologicals in the final rule for CY 2023. However, it is unclear what that will look like as when CMS undoes the current policy, it will need to make a corresponding adjustment to the conversion factor to preserve budget neutrality.

While the Alliance supports the Agency's position that it "fully anticipates" reverting to its prior policy of paying Average Sales Price (ASP) plus 6% for 340B-acquired drugs in CY 2023 and urge it to finalize this policy in the OPPS final rule, we strongly recommend that in doing so CMS:

- Revert to the prior lawful policy of paying ASP plus 6% for CY 2023, regardless of whether a drug was acquired through the 340B program;

- Promptly repay any hospital the difference between ASP plus 6% and what they were actually paid for drug claims as a result of this unlawful policy for CYs 2018-2022;
- Hold the entire hospital field harmless for this illegal policy for CYs 2018-2022, which means no recoupment of funds received during this period.
- Not invoke budget neutrality to recoup funds as it would be wrong to penalize any hospital for the Agency's own past mistakes in implementing an unlawful policy.

In order to address the possibility of budget neutrality, CMS put out an Alternative Addendum B, which illustrates the payment rates without the 340B adjustment. The packaged rate for CTPs is already problematic as we described above as the rate does not even cover the cost of the products being used. The Alternative Addendum actually reduces the rate which will cause more access to care issues in the PBD. Below is a chart that shows the Addendum B rates and the Alternative Addendum B rates posted by CMS.

2023 Proposed Payment Rate for Skin Substitute Procedure Codes

Code	Addendum B Rate	Alternative Addendum B Rate
15271	$1,761.64	$1,702.37
15273	$3,303.07	$3,191.94
15275	$1,761.64	$1,702.37
15277	$1,761.64	$1,702.37
C5271	$589.66	$569.82
C5273	$1,761.64	$1,702.37
C5275	$589.66	$569.82
C5277	$589.66	$569.82

As stated above, the Alliance recommends that CMS not invoke budget neutrality to recoup funds as a result of unlawful policy. We strongly encourage CMS to ensure no further harm is done to any hospital by promptly paying 340B hospitals the funds they are rightfully owed and not cause further financial losses by implementing the Alternative Addendum B Rate.

MEASURING DISPARITIES ACROSS CMS QUALITY PROGRAMS

CMS may spend as much as $98 billion a year on the treatment of chronic wounds, and they impact 15% of Medicare beneficiaries.[xxxii] There are profound healthcare disparities in the outcome of chronic wounds, not the least of which is that **persons of color are more likely to suffer amputations from a diabetic foot ulcer. Chronic wounds disproportionately affect minority populations, and primarily affect persons with multiple comorbid conditions and the disabled. Thus, quality measures would be an important tool to ensure appropriate care is being provided and measured. However, we bring these issues to the Agency's attention:**

- There are no national MIPS quality measures relevant to the management of patients with chronic wounds and ulcers, and among the quality programs in all healthcare sectors, there is only one measure relevant to chronic wounds (the counting and staging of pressure injuries).

- The GAO reports that CMS has spent an average of $43 million a year on quality measurement programs over the past 11 years, **none of which was spent to fill the measure gap in chronic wound management**.
- There is no "Meaningful Measures" initiative around chronic wounds, a problem which impacts 5 times more individuals than heart failure and may cost twice as much.

The Alliance has partnered with the US Wound Registry (USWR), a CMS recognized QCDR, to develop a suite of evidence based QCDR quality measures focused on chronic wound care. Three of them were selected for inclusion on *Physician Compare* including: adequate offloading of diabetic foot ulcers at each visit; adequate compression of venous leg ulcers at each visit; and arterial assessment of patients with lower extremity wounds and ulcers at the first visit. Since all wounds are symptoms of disease, they are invariably associated with conditions such as diabetes, heart failure, chronic kidney disease, paralysis, and cardiovascular disease. Physicians practicing wound care full time have no specialty code and since they often provide the plurality of visits for patients with wounds, are allocated the cost of hospital readmission for conditions like diabetes and heart failure.

The Alliance has always supported the use of quality measures since they are a valuable tool to ensure improved patient outcomes. We strongly support the continued development of quality measures that assess wound care outcomes across CMS quality programs, as wound care clinicians should be required to report on measures that relate to the care being delivered. While the Alliance recognizes there are some quality measures specific to wound care, because wound care is not a "specialty," clinicians currently can "cherry pick" the quality measures they report. The ramifications of such selection are:

- Those that report are providing the care to wound care patients and therefore reporting on the wound care quality measures as they use them to score favorably.
- Since reporting on wound care quality measures is not mandatory under MIPS, clinicians who will not score well on the wound care quality measures will choose to report other measures that are more favorable to their performance.
- When all clinicians do not report measures and only those that will score well do, CMS comes to the conclusion, albeit erroneous, that there are no gaps in practice when they look at the data for those clinicians who reported.
- CMS will eliminate measures when the Agency finds these measures are "topped out." However, the only manner by which the Agency can ensure that high-quality wound care is being delivered is to require that wound care measures are reported.

As such, any provider that delivers wound care services should be required to report on wound care quality measures. **If this requirement is mandatory, then additional measures will need to be created to ensure that any care in treating a patient with a wound is being represented in the quality measure set being reported.**

The documentation of the specific, significant burden of chronic wounds in the Medicare population illustrates the need for CMS and health policy makers to **include wound- relevant quality measures in all care settings as well as develop episode of care measures, chronic care models, and reimbursement models to drive better health outcomes and smarter spending in the wound care space.**

CONCLUSION

The Alliance appreciates the opportunity to provide our comments and recommends that CMS delays implementation of the CTP provisions. We continue to be very concerned about the impact on patent access as well as the detriment to patient care should any of the CTP provisions move forward as currently written. The Alliance has and continues to offer to be a resource to CMS as they navigate the very complex issues surrounding CTPs.

Thank you for your consideration.

Sincerely,

Caroline E. Fife, MD, CWS, FUHM Matthew G. Garoufalis, DPM, FASPS, FACFAOM, CWS
Alliance of Wound Care Stakeholders Co-chairs

Marcia Nusgart, R.Ph.
Chief Executive Officer

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[i] *1.1 This guide defines terminology for description of cellular and/or tissue-based products (CTPs) for skin wounds. CTPs are TEMPs (tissue-engineered medical products) that are primarily defined by their composition and comprise viable and/or nonviable human or animal cells, viable and/or nonviable tissues, and may include extracellular matrix components. CTPs may additionally include synthetic components*

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