ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

October 2, 2020

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

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

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

Dear Administrator Verma:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), I am pleased to submit comments in response to the proposed CY 2021 Hospital Outpatient Prospective Payment System and changes to the Quality Reporting Programs. In addition to submitting these comments, the Alliance would like to request a meeting with CMS to further discuss the packaging of Cellular and/or Tissue Based Products for Wounds (CTPs) as CMS continues to consider options for changing the current payment methodology.

The Alliance is a nonprofit multidisciplinary trade association representing physician specialty societies, clinical and patient associations whose mission is to promote evidenced-based quality care and access to products and services for people with chronic wounds. Our comments focus on provisions within this proposed rule which impact wound care. Our specific comments follow.

Recommendation: Use of Terminology- "CTP" instead of "Skin Substitute"

The Alliance agrees with CMS when it states in the CY 2014 OPPS final rule: "skin substitute products do not actually function like human skin that is grafted onto a wound; they are not a substitute for a skin graft. Instead, these products are applied to wounds to aid wound healing and through various mechanisms of action they stimulate the host to regenerate lost tissue…"

We believe that the term "skin substitutes" is clinically and technically inaccurate and should be replaced with the more inclusive descriptor "Cellular and/or tissue based products for skin wounds (CTPs)". This term accurately describes all technologies in this sector and is broad and inclusive of both current and future

5225 Pooks Hill Rd | Suite 627S | Bethesda, MD 20814
T 301.530.7846 | **C** 301.802.1410 | **F** 301.530.7946
marcia@woundcarestakeholders.org

technology.

The Alliance adopted this term in 2013 after a year long effort - working with leading wound care scientists, clinical organizations, and business entities - to develop a more appropriate term to represent this product sector. Thus, we will be using the acronym "CTPs" when referring to "Cellular and/or tissue based products for skin wounds" in this document.

The Alliance believes that the term "skin substitute" is misleading and inaccurate for the following reasons:

- The FDA does not allow these products to be called ''skin substitutes'' because they do not actually substitute for skin.
- Both CMS and AHRQ had concerns with the term and did the following:

    - AHRQ in its 2012 final technology assessment on skin substitutes inferred that these products were not "skin substitutes" since *"A true 'skin substitute' would act like an autologous skin graft in adhering to the wound bed while providing the physiological and mechanical functions of normal skin."*
    - CMS abandoned the term in the code descriptors for these products in 2010 when the Agency agreed that these products are not skin substitutes and instead issued Q codes for each individual product by its brand name.

- ASTM, the international standard setting organizations thought so highly of this new 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." The workgroup that created this standard 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. It is now not only used by them but by those who do wound care research. We recommend that CMS review this document so we have included it as an attachment to these comments for the ease of CMS staff.
- Payers in their LCDs are using this term. Several MACs refer to CTPs either in the title or body of their LCDs.
- This term has been adopted by the wound care community and is currently used by physicians and clinicians when speaking at national wound care conferences and in clinical studies published in scientific journals.

As stated above, the ASTM adopted the CTP nomenclature and we believe that it is only a matter of time before the AMA CPT panel makes an editorial change to reflect this terminology. As such, the Alliance recommends that CMS not utilize the term "skin substitute" and instead use the more clinically correct term "cellular and/or tissue based products for skin wounds (CTPs)".

Issues Related to New C code- C1849- for Synthetic Skin Substitutes

Inclusion of Synthetic CTPs in the Definition of "Skin Substitutes"

CMS has proposed to include synthetic products in its description of CTPs in addition to biological products supported by the paper, "Regenerative medicine in dermatology: biomaterials, tissue engineering, stem cells, gene transfer and beyond" by Dieckmann et al. This paper confirmed that these products can be composed of synthetic as well as biologic products.The Alliance agrees that synthetic CTPs should be placed in the description, especially when CMS changes the nomenclature to CTPs so as to be clinically accurate.

The Alliance has been on the record over the years for including synthetic products in a definition for CTPs. For example, the Alliance included synthetics in our classification system during our 2012 meeting with CMS to educate its coding, coverage and payment staffs on CTPs. Just as importantly, we call to CMS's attention the ASTM F3163-16 for the Classification of Cellular and/or Tissue-Based Products for Skin Wounds (CTPs) standards guide noted above which was published in 2016. Many of the Alliance scientific members participated in the workgroup whom, along with FDA staff, created it.Within this standard, the ASTM includes synthetic CTPs within the classification for these products. The standard states:

"CTPs are defined primarily by their composition and comprise 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."

Thus, the Alliance is in agreement with the CMS proposal to include synthetic CTPs in its definition.

Concerns with Coding and Payment of New C Code - C1849

The Alliance has significant concerns with the Agency's proposed establishment of the code C1849 ("Skin substitute, synthetic, resorbable skin substitute per square centimeter) to define an entire class of non-branded products and its placement in the OPPS high cost payment package:

- We are concerned that the Agency issued a C code in the outpatient setting for a CTP which should have been given a Q code by the HCPCS Workgroup through the HCPCS coding process. CTPs are to be issued unique product codes which are brand specific based on a "per sq.cm" size (unless the product is an injectable or micronized). The product currently identified in the C1849 code, Restrata, applied for a HCPCS Q code but was issued an "A" code by the HCPCS work group. If CMS believes that Restrata should be a CTP based on the proposed new definition, then the Agency should re-evaluate its HCPCS coding decision and issue it a brand specific "Q code". We believe that CMS should be consistent and follow the same process of assigning "Q" codes to a synthetic CTP that it has used for coding all other established CTPs. The pathway to obtain a Q code through the HCPCS coding process is well established. Therefore, we question why CMS would issue a C code for a product in a category in which Q codes are required and why CMS did not publish directions for other synthetic products to follow the same quarterly HCPCS application process for a "Q" code just like other CTPs?

- We believe that the use of this C code may lead to confusion in the marketplace since the assignment of a "C" code rather than a "Q" code may cause the Provider Based Department to believe these products have pass-through payment – which they do not.

- The code descriptor for this C code is too broad and thus all synthetic products that are or will becoming into the marketplace may be defined by and placed into this new code. Currently, there are several which are being utilized in the hospital inpatient setting that did not have a pathway to obtain a Q code previously. By creating such a general code, CMS will not be able to identify what product is being utilized since the code is not product specific. Thus, the assignment of one HCPCS code, C1849, to all synthetic and resorbable CTPs does not provide the information needed to appropriately assign each unique brand of synthetic and resorbable CTP to the correct APC package.

- The CMS draft rule proposes to include all brands of synthetic CTPs into this one HCPCS code and to automatically assign that one code to the high cost APC package, which is not consistent with the handling of all other CTPs. We believe that CMS should follow the same processes of assigning codes and assigning each specific brand of synthetic CTPs to the high cost/low cost APC packages that are already in place for all other CTPs. This will prevent the Agency from overpaying for synthetic products that are truly low cost. Just like the other categories of CTPs, some brands of synthetic CTPs should be appropriately assigned to the low-cost package and some should be appropriately assigned to the high cost package.

To ensure consistency in the HCPCS coding and payment processes for CTPs, the Alliance recommends:

1. Since CMS has proposed that synthetic products should be included in the definition of "skin substitutes", then CMS should issue Q codes by brand names for all synthetic resorbable products. This should include all synthetic products that are entering the marketplace as well as CMS revisiting the products that are currently in the A6460 and A6461 codes (Synthetic, resorbable wound dressing…) and reassign them Q codes or request that the companies reapply through the HCPCS coding process to be reassigned Q codes when appropriate.
2. Any new CTP product entering the marketplace – including synthetic CTPs should be assigned to the low-cost package until the manufacturer has submitted its average sales price (ASP) or Wholesale Acquisition Price Cost (WAC) information to the CMS. If the manufacturer's quarterly ASP/WAC information shows that the product should be in the high cost package, the CMS should make that reassignment. From that point on, the synthetic products should follow the current OPPS payment methodology based on claims **and** pricing data.
3. CMS should eliminate the new code C1849 skin substitute, synthetic resorbable per sq cm. as it is not an appropriate code for this product sector especially since these products should be issued Q codes by CMS. This non-brand-specfic coding convention does not follow precedence and is not an appropriate code. Individual CTP products are each issued *specific* Q codes by CMS which adequately allows for *individual* product identification, high or low-cost placement into appropriate pricing categories, and product coverage considerations.
4. Creation of the new C1849 code defines a number of unknown "synthetic" CTP product brands and has an unintended consequence for product coverage. By grouping all synthetic products into the C1849 code, it will force blanket coverage (or non-coverage) policy positions among all products within that grouping, not only for CMS and MACs, but private payers as well.

The Alliance adamantely opposes the creation of the new C1849 code.

Establishment of New Technology APC Assignment for 0598T

The Alliance is pleased that CMS has recognized the value of the non-contact real time fluorescence wound imaging, for bacterial presence, location, and load, per session by establishing an APC assignment for code 0598T and code 0599T for an additional wound. This new technology is a valued new procedure in carrying out recognition of bacteria at levels known to stall wound healing. This new imaging procedure is a significant improvement over standard of care when assessing and treating wound care patients. We support the Agency's proposal to continue payment for these codes.

Supervision

In this proposed rule, CMS has carved out certain areas in which they believe direct supervision is necessary. The Alliance is not responding to the list that has been carved out but rather we are requesting that Hyperbaric Oxygen Therapy (HBOT) be added to the list of services that require direct supervision.

Under the past OPPS regulations and current clinical practice guidelines which require direct supervision for HBOT, the supervising physician must be immediately available to furnish assistance and direction throughout the performance of the procedure. Should a life-threatening complication arise during a patient's HBOT session, the physician must be present, interruptible and available in order to respond.

Under current general supervision regulations, the supervising HBOT physician may not be present and would have to rely upon untrained individuals to manage life-threatening complications with instruction being given over the phone. In that scenario, the immediate response to an emergency could be left to a medical assistant or basic EMT whose primary responsibility is chamber operation and observation of the patient. The required assessments and medical interventions for life-threatening complications are beyond the scope of this potentially unlicensed individual.

As noted above, the occurrence of a life-threatening complication with HBOT is rare, but when one does occur, it requires that a physician be able to immediately physically assess and intervene.

Because the move of supervision levels from direct to general for HBOT could compromise the quality of care and put patients at risk, most PBDs are still requiring direct supervision due to the nature of the service being provided. However, we should not allow PBDs who are providing HBOT to consider moving to general supervision of HBOT as a cost-cutting measure. Therefore, the Alliance requests that CMS place HBOT on the list of services that are required to have direct supervision. This designation is in the best interest of the patients.

Mapping Evaluation and Mangement to G0463

The CY 2021 proposed Medicare Physician Fee Schedule rule appears to align with the AMA CPT changes for E/M services. However, the CY 2021 proposed Outpatient Prospective Payment System (OPPS) rule does not mention if/how PBDs should assimilate the E/M changes into the mapping of their clinic visit services to G0463. On page 348 of the proposed OPPS rule, CMS proposes to continue with the current hospital outpatient clinic visit payment policy. However, noticeabley absent is any direction regarding G0463

and how provider based departments (PBD) should make decisions on the level of service assigned to this code once the new 2021 E/M guidelines are in place. Specifically, physicians/qualified health professionals (QHPs) are instructed to select the level of office visit E/M based on "time" or "medical decision making." However, the PBDs have not received any instruction.

Ever since the year 2000, PBDs have been following CMS's direction to create a mapping tool and a policy and procedure for the use of the 10 E/M codes to report the resources used by PBDs when they provide clinic visits. Each of those 10 clinic visit codes are assigned a separate charge based on the cost of the resources used for that clinic visit level. This process has now been used for 20 years to code and bill both CMS and all other payers. In fact, even when CMS instructed PBDs to only report their clinic visits with one code (G0463), PBDs continued the mapping process for 2 reasons:

1. To select the correct codes for the other payers
2. To attach the correct charge to G0463 for CMS. Once they map their resources to the correct E/M level and charge, they convert the E/M level and that particular charge to G0463. Therefore, G0463 has 10 different charges – depending on the level of clinic visit services provided. This is important for CMS to see, on the claims, the cost of the resources used by the PBD for each clinic visit provided.

Therefore, the Alliance uges CMS to provide guidance on this issue, and specifically: Will PBDs be allowed to have the option of selecting the appropriate level of clinic visits based on the following:

1. The level of the medical decision making as defined for each service (resources used); or
2. The total time for E/M services performed on the date of the encounter (time).

The Alliance understands that the G0463 code will still be reported by PBDs and CMS will pay one blended rate based upon claims data from 2 years ago. However, we request that CMS provide clear direction about mapping based on "resources used" or "time." If CMS does not provide direction on this major issue, the PBDs could experience some disastrous repayments during Medicare audits through no fault of their own but rather through the vague/lack of instruction provided by CMS – especially if each auditor interprets the clinic visit mapping issue individually. As such, the Alliance recommends that CMS provide further guidance and clarity on this issue.

Conclusion

On behalf of the Alliance of Wound Care Stakeholders, we appreciate the opportunity to submit these comments. We look forward to meet with you to discuss our comments in the upcoming months ahead. If you have any questions or would like further information, please do not hesitate to contact me.

Sincerely,

Marcia Nusgart R.Ph.

Marcia Nusgart R.Ph.
Executive Director