COALITION OF

Wound Care Manufacturers

September 13, 2021

Ms. Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services
Department of Health and Human Services
Attention: CMS-1751-P
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 21244-1850

Submitted electronically to regulations.gov

Re: CMS -1751-P, CY 2022 Medicare Program; CY 2022 Revisions to Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies

Dear Ms. Brooks-LaSure,

On behalf of the Coalition of Wound Care Manufacturers ("Coalition"), I am pleased to submit comments in response to the CY 2022 proposed physician fee schedule. The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including skin substitutes. As a result of provisions contained in this proposal related to wound care and specifically synthetic skin substitutes and NPWT we have a vested interest in this proposed rule and offer the comments below.

The reductions which are contained in this proposed rule are significant and negatively impact not only providers of wound care services and the patients that they treat but also manufacturers. Of specific concern are provisions related to:

1. Synthetic skin substitutes
2. Proposed Reductions
    a. Reduction in non-facility RVUs among several wound care services, including debridement (97597, 11042-11045) and application of skin substitutes (15271-15278)
    b. Disposable Negative Pressure Wound Therapy
    c. Cut in Compression Application
3. Mandatory ASP reporting

SPECIFIC COMMENTS

Synthetic Skin Substitutes

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Creation of New G Codes and Payment for Synthetic Skin Substitutes

The Coalition strongly opposes:

(a) The creation of new G codes for the application of synthetic skin substitutes;
(b) Considering synthetic products "incident-to" supplies;
(c) The packaging of skin substitutes in the physician office; and
(d) Using contractor pricing for synthetic skin substitutes.

All products defined as skin substitutes should be treated the same from both a coding and payment standpoint. However, the creation of new codes for synthetic skin substitutes is not consistent with the issuance of Q codes for ALL other skin substitutes. The creation of a new payment methodology by packaging synthetic skin substitutes in a physician office is not consistent with the payment for ALL other skin substitutes nor is the categorization that synthetic skin substitutes are "incident to" supplies. Finally, the use of contractor pricing is also not consistent with the way manufacturers provide information for pricing of their skin substitutes – most of whom provide ASP pricing to CMS. These changes are inconsistent, unnecessary, not transparent, and would cause considerable confusion and unnecessary burden to providers and A/B MAC contractors in the physician office setting.

In the 2020 Hospital Outpatient PPS rule, CMS expanded the definition of skin substitutes to explicitly include synthetic products. In that rule, CMS stated "Our new description defines skin substitutes as a category of biological and synthetic products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers." Despite recognizing that synthetic skin substitutes fall into the same category as other skin substitute products, CMS has still chosen to treat synthetic products significantly different than other skin substitutes.

We strongly disagree with treating synthetic skin substitutes differently than all other skin substitutes – especially given their inclusion in the definition of a skin substitute by CMS. Either synthetic skin substitutes are skin substitutes or they aren't. CMS has already stated that they are and therefore synthetic skin substitutes **should follow the existing coding and payment pathways under the PFS**. This will negate the need to establish another new set of proposed G codes (and determine pricing) for the application of synthetic skin substitute products in the office setting. There is an established framework already in place for coding and paying for skin substitutes in a physician office setting. Therefore, it is unclear why CMS is diverging from these existing processes for synthetic skin substitute products which CMS has determined fits within the definition of a "skin substitute" product as stated earlier.

The Coalition urges CMS to not move forward with the issuance of the G codes for synthetic r skin substitutes. Instead, CMS should simply follow and adhere to the already established system of issuing Q codes and the current payment mechanism for skin substitutes since CMS has already placed synthetic skin substitutes within the definition of a "skin substitute." There is no need to create a new and inconsistent pathway for synthetic skin substitutes.

The Coalition however, would be remiss if we did not address the payment methodology proposed in this rule, despite the fact that we do not agree with its adoption. CMS has proposed to package synthetic skin substitutes, have them contractor priced and then cross walk the payment methodology to the Hospital Outpatient PPS (HOPPS). The Coalition would like to point out that there are significant flaws with the HOPPS payment for skin substitutes – so significant that for the past four years CMS has been proposing new payment methodologies for skin substitutes. Inherent

in the flaws is that the data for calculating the payment is flawed and the payment is not equitable. For example, the current system does not provide payment for add on codes despite that fact that additional product is being utilized nor is there the same payment being provided when application of a skin substitute is applied to a patient's leg versus their foot for the same size wound. These type of inequities are creating problems in the clinical treatment of patients with wounds and should not be duplicated in the physician office setting. Therefore, if CMS moves forward with packaging synthetic skin substitutes, despite not only industry but clinical opposition to do so, then the Coalition recommends the following:

- Set national payment rates for codes describing application of synthetic skin substitutes- the application of these products should NOT be contractor priced.
- Pay separately for add-on codes in addition to base procedure code, and include the cost of the additional synthetic skin substitute in the payment for the add-on codes; (this recommendation was voted on and unanimously accepted by the Advisory Panel on Hospital Outpatient Payment August 23, 2021)
- Provide payment equitably. Payment for the same size wound should be made no matter the anatomic location it is being applied as the same amount of product and resource time is being used. (This recommendation was voted on and unanimously accepted by the Advisory Panel on Hospital Outpatient Payment August 23, 2021)

Clarification Needed Regarding the Requirement to Consult with the FDA Tissue Reference Group (TRG) or Obtain a Determination Through a Request for Designation (RFD) on Whether a Skin Substitute is Appropriately Regulated

In the proposed rule, CMS is requiring that "Manufacturers of HCT/Ps should consult with the FDA Tissue Reference Group (TRG) or obtain a determination through a Request for Designation (RFD) on whether their HCT/Ps are appropriately regulated solely under section 361 of the PHS Act and regulations in 21 CFR part 1271 (85 FR 86058)." However, this requirement is located within the section addressing synthetic skin substitutes – which is completely inappropriate. Most synthetic skin substitutes have gone through or are currently going through the FDA 510 (k) process. As such, it is unclear as to whether CMS believes that these products still need to go to the TRG or obtain and RFD – which again would not be appropriate. Any reference to the TRG or RFD should be removed from the discussion of synthetic skin substitutes. Additionally, since this proposal has not yet been finalized, any company that has applied for a HCPCS code in 2021 should be granted their code without further delay. The lack of transparency by the Agency by not issuing coding decisions is unacceptable.

If the Agency wants to make obtaining a determination from the TRG or an RFD from the FDA a requirement for obtaining a HCPCS code, there should be a separate provision in the proposed rule which provides greater detail as to what products are in fact subject to this requirement. The placement of this information in this rule has created confusion among stakeholders and many questions remain including but certainly not limited to:

- Does this requirement only apply to HCT/Ps?
- Since this requirement is located in the synthetic skin substitute section does this requirement apply only to synthetic skin substitutes?
- Is this requirement prospective and only applicable to those products with applications being submitted once this proposal is finalized?
- This requirement has not yet been finalized yet – but it appears that CMS is deferring issuance of Q codes until this information has been received. Can the Agency move forward

with a requirement that has not yet been finalized? If so - this seems to be a violation of the Administrative Procedures Act.

The Coalition would appreciate that CMS includes the answers to these questions in the final rule so all stakeholders can benefit from the response. In addition, the Coalition recommends that any reference to the TRG or obtaining an RFD be eliminated from this proposal. If CMS determines that this information is necessary for obtaining a Q code then a more detailed proposal should be included in the next rule making cycle. The placement of this information in the synthetic skin substitute section of this rule has been confusing and it is still unclear to stakeholders which products are required to get this information and which are not. Until further information is provided and more clarity gained, the Coalition recommends eliminating this language from the proposal. Further, the Coalition recommends that products with applications submitted to the HCPCS workgroup be processed immediately. The continued deferral for a requirement that has not been finalized is not only disruptive, we submit it is a violation of the APA.

Proposed Reductions

CMS had made a number of proposed reductions in the CY 2022 rule in the name of budget neutrality. A focus on budget neutrality now, in the wake of a pandemic, is damaging and short-sighted and will negatively impact patients. In particular we are concerned about the following:

- As a result of the proposed reduction in the CY 2022 Conversion Factor from 34.8931 to 33.5848, providers – including the clinicians that we interface with – are facing large payment cuts across the board, unless Congress intervenes. It is of particular concern to our members that there is a reduction in non-facility RVUs among several wound care services, including debridement (97597, 11042-11045) and application of skin substitutes (15271-15278) in CY 2022. The Coalition is very concerned that the impact these payment cuts and reductions in RVU valuations could negatively impact patient access to critical and essential wound care services and treatments that are necessary to salvage patient limbs and lives. The medical community is still actively dealing with the threat of the COVID-19 Public Health Emergency (PHE) – this is not the time to be issuing significant cuts.
- CMS is also proposing to reduce the payment of Disposable Negative Pressure Wound therapy (dNPWT), CPT codes 97607 and 97608, by 22%, when performed in physician office settings. The Coalition has significant concerns about this reduction as physicians will find it difficult to continue to use this therapy. The option to use dNPWT provides numerous benefits the patients and improves their quality of life. dNPWT is portable, light weight and allows for patients to be mobile rather than house bound while using this therapy. If this therapy is not an option in physician offices moving forward, these patients may lose access to this advanced therapy to help treat their wounds. While we understand that the decrease is largely due to practice expense payment changes due to repricing of clinical labor time, the drastic nature of this cut along with cuts for many other device and equipment-intensive services will negatively impact patient care. As such, the Coalition asks that CMS not implement the proposed clinical labor time **unless** updated pricing information can also be obtained for medical equipment and supplies.
- The application of multilayer compression (CPT 29581 and 29584) is costly due to the acquisition cost of the multi-layer compression bandages, and due to the need for a clinician who is appropriately trained and skilled in applying multi-layer compression bandages to perform a procedure which is very time consuming. Multiple specialty society guidelines (i.e. Society of Vascular Surgeons, the Wound Healing Society, and Wounds International) discuss this type of compression as a standard of care for treating patients with chronic edema such as lymphedema, and ulcers due to venous insufficiency (VLU). The Coalition

is extremely concerned that the cut in the reimbursement for the application (which must be adequate to purchase the product and to pay the clinician) will make it cost prohibitive for physician offices to provide this standard of care to their patients which will result in negative outcomes for their patients. As such, the Coalition opposes cuts to fees associated with the CPTs codes for compression application.

Mandatory ASP Reporting

The Coalition supports the provision in the proposed rule in which all drugs and biological manufacturers should be required to report ASP. However, as we have stated for numerous years, **CMS should be required to publish all reported ASP in the national Part B Data file.** The proposed rule estimates that 6319 products report ASP yet only 640 (10%) of these HCPCS are listed in the national data file. Currently, many manufacturers report ASP but clinicians do not chose products unless they are published in the data file. The Coalition believes that publishing any reported ASP for drugs and biologicals (1) creates a level field for all manufacturers; (2) prevents overbilling of the Medicare Trust Fund; (3) decreases Medicare beneficiary financial responsibility; (4) ensures clinicians select products based on clinical efficacy and (5) assures transparency in the program. Since the CMS is requiring the reporting of all Medicare part B drugs and biologicals ASP, the Coalition recommends that CMS also be required to publish all ASP that is submitted to them in the Part B pricing data file.

Conclusion

In summary the Coalition has the following recommendations:

- CMS should NOT adopt (a) the creation of new G codes for the application of synthetic skin substitutes; (b) considering synthetic products "incident-to" supplies; (c) the packaging of skin substitutes in the physician office; and (d) using contractor pricing for synthetic skin substitutes.
- Since CMS has already placed synthetic skin substitutes within the definition of a what is a skin substitute, CMS should adhere to the already established system of issuing Q codes and the current payment mechanism for skin substitutes for synthetic skin substitutes in a physicians office. There is no need to create a new and inconsistent pathway for synthetic resorbable skin substitutes.
- Any reference to the TRG or obtaining an RFD from the FDA be eliminated from this proposal or at the very least be removed from the section addressing synthetic skin substitutes.
- Skin substitute applications which are under consideration by the HCPCS Workgroup should be issued new Q codes for the October 2021 coding cycle.
- CMS not implement the proposed clinical labor time **unless** updated pricing information can also be obtained for medical equipment and supplies – especially for CPT codes 97607 and 97608.
- CMS should not cut fees for CPT 29581 and 29584 which address compression application.
- CMS should be required to publish all reported ASP in the national Part B Data file if mandatory ASP reporting is finalized.

The Coalition is a member of the Alliance of Wound Care Stakeholders and we agree with their more detailed comments on this proposed rule. We urge CMS to adopt their recommendations.

The Coalition appreciates the opportunity to offer our comments. We are happy to provide any additional information.

Sincerely,

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