COALITION OF

Wound Care Manufacturers

September 6, 2022

Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services,
Department of Health and Human Services,
Attention: CMS-1770-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 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment Policies; Medicare Shared Savings Program Requirements; Medicare and Medicaid Provider Enrollment Policies, Including for Skilled Nursing Facilities; Conditions of Payment for Suppliers of Durable Medicaid Equipment, Prosthetics, Orthotics, and Supplies (DMEPOS); and Implementing Requirements for Manufacturers of Certain Single-dose Container or Single-use Package Drugs to Provide Refunds with Respect to Discarded Amounts [CMS-1770-P]

Dear Administrator Brooks-LaSure,

On behalf of the Coalition of Wound Care Manufacturers ("Coalition"), I am pleased to submit comments in response to the CY 2023 proposed Medicare Physician Fee Schedule (CMS-1770-P). The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including but not limited to skin substitutes – which are the subject of significant revisions in this proposed rule.

CMS has proposed to:

- Treat all skin substitute products as supplies in the physician office setting and pay for them as part of the practice expense relative value units (RVUs) for the procedure with which they are used;
- Discontinue separate payment for skin substitutes, whether based on average sales price (ASP) + 6%, wholesale acquisition cost (WAC), or invoices;
- Discontinue skin substitute Q-codes and establish A-codes for all skin substitute products. The conversion to A-codes would be automatic for most products, though for human cells, tissues, and cellular and tissue-based products (HCT/Ps), a re-application would need to be submitted, including a letter from the Food and Drug Administration (FDA) Tissue Reference Group (TRG) by January 1, 2024.

The Coalition is adamantly opposed to these proposals which change the way skin substitutes have been coded and reimbursed in the physician's office for over 30 years and believe these seismic

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changes will lead to significant limitations on the access to care for numerous patient populations including but not limited to: minorities, patients in rural areas and patients with diabetes. This decrease in access to care may result in the likelihood of increased infection and amputations for these patients.

CMS has stated that their objectives in making these changes are to

- Ensure a consistent payment approach for skin substitute products across the physician office and hospital outpatient department setting;
- Use a uniform benefit category across products within the physician office setting, regardless of whether the product is synthetic or comprised of human or animal based material, so [CMS] can incorporate payment methodologies that are more consistent;
- Ensure that all skin substitute products are assigned an appropriate [Healthcare Common Procedure Coding System] HCPCS code;
- Maintain clarity for interested parties on CMS skin substitutes policies and procedures.

However, we submit that **the proposal does not achieve any of the CMS objectives identified** as discussed below. CMS has not, in any way, described what will happen after 2023, including (1) how the products will be paid in 2024, (2) the methodology it would use to calculate the bundled payments, or (3) the amount of money that would be included in the bundle for CTPs. In fact, CMS is required to establish proposed PE relative value units (RVU) for skin substitute application procedure codes 15271-15728 in order for skin substitutes to be paid as "incident to" supplies that are bundled into the Medicare PFS payment. Yet, CMS failed to do so in this proposal and absent this significant detail, stakeholders are not in a position to provide meaningful comments on CMS' proposal.

CMS has also indicated in this proposal that the Agency is seeking consistency and clarity for this product category. Yet there is nothing consistent or clear with any of the changes being proposed. CMS changing the consistently issued, used and known Q code designation, the terminology to describe these products from skin substitutes – which is a term known world-wide - to a term that is WAY too broad and confusing, and changing the way these products are reimbursed in the physician's office is causing alarm and concern as the impact to patient access is real and significant.

Additionally, there are some inconsistencies in the timeline that significantly impact manufacturers which need clarification prior to implementation as well as possible gaps in care based on the timeline provided.

As such, the Coalition urges CMS to withdraw its policy (or at the very least delay implementation) until a proposed rule can be issued containing the necessary details to provide meaningful comment on such a significant change in policy including but not limited to proposed PE RVUs for procedure codes 15721-15278 inclusive of skin substitutes and an impact analysis based on evidence.

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Specific Issues

Consistent Payment Across Settings

CMS has proposed to treat all skin substitute products as supplies in the physician office setting and pay for them as part of the practice expense relative value units (RVUs) for the procedure with which they are used. Yet while CMS has gone through great lengths in explaining what they want

to do, there are no details on how CMS set rates and what methodology will be used. In addition, CMS has not provided any details on the PE RVUs that will be used. While packaging in the physician's office may be similar to that in the HOPD, this is where the consistency ends since the rate setting mechanisms are and will be different and will equally disrupt patient care and access. The creation of a new payment methodology by packaging skin substitutes in a physician's office is not consistent with the payment for skin substitutes nor is the categorization that skin substitutes should be "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 an unnecessary burden to providers and A/B MAC contractors in the physician office setting.

If CMS is interested in a consistent payment approach that will not impact patient access but will provide cost savings to the Medicare Trust Fund, the Coalition recommends that the Agency will continue to use ASP +6, and will publish ALL products and their pricing on the Medicare Part B Pricing Data File.

Prior to 2014 when CMS bundled payment in the hospital outpatient setting, CMS did have a consistent payment approach to skin substitutes. CMS paid separately for the application of the skin substitute and for the skin substitute itself using the same payment methodology as biologicals—ASP + 6%. In creating the packaged payment system, CMS broke from the consistent payment methodology and beginning in 2014, were packaging skin substitutes under the hospital outpatient PPS while separately paying for them in the physician's office. The change in 2014 resulted in an increased number of patients receiving care in the physician office setting as the payment methodology in the outpatient hospital setting was flawed and hospital outpatient departments began losing too much money on treating patients with larger wounds.

We believe that packaged payment for skin substitutes in the physician's office does not mesh with Medicare's statutory framework. As CMS is aware, in the hospital outpatient setting, CMS has implemented a Congressionally-authorized prospective payment system that packages payment for a wide range of drugs, biologicals, supplies, and other procedures in a single payment amount. Medicare's statutory payment framework for drugs and biologicals billed by a physician however does not authorize the same comprehensive packaging policy found in the hospital OPPS. If CMS is trying to create a consistent payment across settings, the Agency should simply revert back to separate payment for skin substitutes utilizing ASP pricing since there is already a framework in place, implementation would be very easy and would be complimentary to section 1847A(f)(2) which requires ASP reporting effective January 1, 2022 for "products that are payable under this part as a drug or biological – which would include skin substitutes.

Moreover, if CMS is trying to achieve consistent payment having these products be contractor priced with each contractor setting its own price based on list or invoice pricing for a given skin substitute, the Agency will not achieve its goal. Our concerns are that not only will there be huge variations nationally in the way in the rate being paid, but there would also be no transparency in rate setting. However, CMS using ASP pricing could establish uniform pricing based on all the skin substitutes ASP not only being reported but also published on the quarterly ASP pricing files. This would allow for pricing consistency and would achieve CMS's goal of reducing out of pocket co-payments since CMS would not be paying for skin substitutes based on list or invoice pricing but rather on vetted sales price, inclusive of discounts. Using ASP is a more transparent means of pricing these products and at the same time CMS can also achieve cost savings in the process. 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.

The Coalition is a member of the Alliance of Wound Care Stakeholders. In its comment letter, the Alliance very clearly shows 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 it. If the Agency is interested in controlling costs and providing savings to the Medicare Trust Fund, it should maintain ASP pricing and all products should be published within this data file.

The Coalition recommends that CMS should withdraw its policy to package payment and utilize ASP +6 for all skin substitutes and publish all data in the pricing data file.

Clarity in Coding by Assigning Appropriate HCPCS Codes

CMS has made a determination to reverse over 12 years of issuing "Q" codes for skin substitutes by now issuing "A" codes to the entire product sector and require those products already in the marketplace with known "Q" codes to either reapply for an "A" code or have one issued to them depending on the make-up and designation of the product. CMS must recognize that it cannot make a broad brush sweeping change to call all skin substitutes "supplies" and issue them "A" codes in the name of "clarity." We believe there is nothing clear about this change and it creates more confusion.

Furthermore, CMS is making a determination that is contradictory to its own language contained in prior rulemaking in which CMS repeatedly states these products either are biologics or should be treated as such. This change is also contrary to some of these products having biologic designation on their own by meeting regulatory requirements and a recognition by the clinical community that these products are biologicals. The CMS goal of providing clarity is not being achieved by making this change. In fact, it is quite the opposite. Clinicians recognize that these products are not supplies. In studies performed by clinicians, these products are described as biologics or having biologic effect in the wound bed. These products are NOT disposable as they are affixed by a physician or a nurse practitioner and once affixed, these products are absorbed into the wound. They are NOT removed. So, to issue a code that has a supply designation and to call these products "supplies" is technically and clinically incorrect. Q codes have long been recognized as the ones issued for skin substitutes no matter the pathway these products have come through the FDA and into the marketplace. CMS has also long recognized and treated skin substitutes as biologics, thus the Q code designation. As CMS stated in its own regulations, "HCPCS Q-codes are typically assigned to drugs and biologicals and are used to describe skin substitutes…"[1] CMS has also stated multiple times that skin substitutes are biologicals. Two of these examples are the in 2020 Hospital Outpatient PPS rule, in which 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." and in the CY 2014 OPPS/ASC final rule with comment in which the Agency also described skin substitutes as "…a class of products that we treat as biologicals"[2] Despite recognizing that skin substitutes are biologicals, CMS has ignored its own descriptors of this product category and has downgraded them to a supply without providing any rationale as to why they believe that these products – that have biological effect – should be termed a supply.

It is apparent that CMS does not understand the technological components that make up skin substitutes. Thus, for consistency's sake and not to cause confusion in the marketplace for an

[1] *See* 78 FR 74932 "…
[2] 86 FR 63563

already recognized, coded and paid for product sector, CMS should simply continue to issue Q codes to skin substitutes as the Coalition has been on record recommending for the past two years.

"Skin Substitutes" versus "Wound Care Management Products" Terminology

The Coalition categorically opposes the change in nomenclature from "skin substitutes" to "wound care management products." CMS stated that the reasons that a proposed name change was included in this rule was due to the evolution of this product category over time and that skin substitutes "do not actually function like human skin that is grafted onto a wound." However, we maintain that it is a term that is well vetted through the AMA, is in language that has been used for years and remains pertinent in the Current Procedural Terminology (CPT) codes, such as 15271-15728, and is a term that is well known, used and accepted by clinicians as well as public and private insurers. "Wound care management products" is way too broad a term, encompasses more products than what would be considered skin substitutes (e.g., disposable negative pressure wound therapy, selective debridement, surgical debridement agents, surgical dressings, low-frequency non-contact non-thermal ultrasound, support surfaces, topical oxygen therapy products, as well as Unna Boots, multilayer dressings, total contact casts, casting and strapping products), and is confusing. The term wound care management products does not provide the clarity that CMS is seeking. In fact, CMS had to go through great lengths in this proposed rule to not only distinguish wound care dressings and bandages from skin substitutes (87 FR 46028) but also CMS acknowledges in the proposed rule potential issues with the use of the term "care management" and its likely conflation with AMA CPT evaluation and management (E/M) codes.

The Coalition recommends that CMS either keep the current skin substitute nomenclature or use the nomenclature that the ASTM has created and is already widely used "Cellular and/or tissue-based products for skin wounds (CTPs)".[3] The ASTM states that "*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".* [4] While synthetics are not in the title, it is very clear from the definition included in the standards document that in fact they are a CTP. The CTP term will better achieve CMS's goal of more accurately describing the entire suite of products but without the possible misinterpretation as other medical products or services.

Clarification/Inconsistencies

CMS has indicated that it will discontinue all existing HCPCS "Q" codes for skin substitute products and assign those products a HCPCS "A" code. This process would require manufacturers of HCT/P products that have not already been provided with a recommendation from the Food and Drug Administration's (FDA) Tissue Reference Group (TRG) to submit a HCPCS Level II re-application within 12 months of the effective date of the final rule (that is, January 1, 2023). For manufacturers of products described as a 361 HCT/P, a recommendation letter from the TRG is required for submission of the HCPCS Level II application. There are over 150 unique HCPCS Level II codes that describe skin substitutes. However, it is clear that the FDA will not be able to accommodate this timeline to provide applicants with the required TRG letter of recommendation in a time frame that will afford manufacturers the opportunity to reapply for their HCPCS code during

[3] Standard Guide for Classification of Cellular and/or Tissue Based Products (CTPs) for Skin Wounds. ASTM International. Current edition approved Feb15, 2022. Published March 2022 Last previous edition approved in 2016 as F3163-16DOI:10.1520/F3163-22

[4] Ibid

the biannual process. It is currently taking the FDA over 9 months to issue these letters and the requests that are being made now are largely for manufacturers who are required to obtain these letters in order to be issued a new HCPCS code. To ensure that the FDA can issue the letters timely, CMS should assess FDA's progress in advance of next year's PFS rulemaking and report that data in the CY 2024 proposed rule. At that time, CMS should consider whether timelines need to be adjusted to best accommodate the resources at FDA and the applicant to ensure no discontinuation or gap in products available to Medicare beneficiaries.

Impact to Patient Access

The proposed changes to the way skin substitutes will be coded and paid for will create inappropriate incentives to delay treatment of patients with multiple ulcers (e.g., treat one ulcer per visit), to use lower quality products, and to use an insufficient amount of product to treat these ulcers completely. As evidence has shown, advanced therapies including skin substitutes have been shown to heal diabetic foot and venous stasis ulcers and reduce the number of infections and amputations while saving money.[5] Meanwhile, as a result of the payment changes, physicians will no longer be able to afford these advanced therapies and will likely not provide them in their offices any longer or at least in a limited capacity which will undermine healthcare outcomes for Medicare beneficiaries generally and particularly for underserved populations such as African Americans, Latinos, and Native Americans, who are at higher risk for these ulcers because they disproportionately suffer from diabetes and obesity. [6]

Lastly, CMS's proposed approach to reimbursement of skin substitutes will stifle the incentive to innovate and bring to market the kind of new medical products that require millions of dollars of research and development and a lengthy FDA approval process.

Conclusion

The Coalition urges CMS to delay the implementation of this proposed rule related to skin substitutes. It is not well thought out and will have a severe impact on patient access and increase amputation rates – especially to the minority community. Additionally, CMS has not done its due diligence in providing the stakeholder community enough information to provide meaningful comment. 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 not only adopt the Coalition recommendations but to also adopt the Alliance recommendations. Both of our recommendations are in the interest of patients who will be negatively impacted if this proposed rule goes forward as currently written.

The Coalition appreciates the ability to comment on this proposed rule and hopes that the Agency

[5] David G Armstrong MD, PhD, DPM, MS; William H Tettelbach MD, FACP, FIDSA, FUHM, FAPWCS, CWS*; Thomas J Chang DPM; Julie L De Jong MS; Paul M Glat MD, FACS; Jeffrey H Hsu MD, FACS; Martha R Kelso RN, LNC, HBOT; Jeffrey A Niezgoda MD, FACHM, MAPWCA, CHWS; Travis L Tucker MA, MBA; Jonathan M Labovitz DPM, FACFAS, CHCQM, "Observed impact of CTPs in lower extremity diabetic ulcers-lessons from the Medicare Database (2015-2018)JOURNAL OF WOUND CARE, NORTH AMERICAN SUPPLEMENT VOL 30, NO 7, JULY 2021

[6] Disparities in Outcomes of patients admitted with diabetic foot ulcers, Published online 2019 Feb 4. doi: 10.1371/journal.pone.0211481

will consider our requests as it finalizes the CY 2023 Physician Fee Schedule. If there are any questions, I can be contacted at Karen.ravitz@comcast.net or 301 807-5296.

Thank you for your consideration.

Sincerely,

Karen Ravitz, JD
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Coalition of Wound Care Manufacturers