ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

May 12, 2025

The Honorable Russell Vought
Director
Office of Management and Budget
725 17th Street NW
Mailbox: *MBX.OMB*
Washington, DC 20503

Submitted electronically via www.regulations.gov

RE: Request for Information: Deregulation [Docket No. OMB-2025-0003-0001]

Dear Director Vought,

On behalf of Alliance of Wound Care Stakeholders ("Alliance"), Chair Dr. Matthew G. Garoufalis, Vice Chair Kara Couch and I are pleased to provide our recommendations on the Administrations' request for information regarding deregulation. The Alliance has provided suggestions for deregulation as well as recommendations to streamline or correct current regulatory and sub-regulatory provisions. The recommendations made are in the best interest of patients and will be less burdensome for clinicians and manufacturers. The Alliance is a nonprofit multidisciplinary trade association of physician medical specialty societies, clinical and patient associations, wound care provider groups, wound care clinics and wound care product manufacturers 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.[i]

The Alliance has provided below the regulations, sub-regulations and other issues of concern, in no specific order of importance.

Withdrawal of FDA Proposed Rule re: Reclassification of Certain Antimicrobial Wound Dressings

When the FDA last year released a proposed rule[ii] and companion amendments[iii] on classification of certain antimicrobial wound dressings, the Alliance flagged to the Agency the many gaps and ambiguities in the policy, the reduced availability of wound dressing products that could result if it is implemented, and the harm this could cause to patient care. While this proposed regulation has not yet gone into effect, it is on the docket to be finalized in October 2025 and we respectfully request it is not be finalized but simply withdrawn.

Wound dressings and washes that contain antimicrobials and other chemicals with *antiseptic* properties are an important tool for managing chronic wounds. These wound dressings act as antimicrobial barriers to minimize bacterial contamination of a wound and are an important part of wound management strategies employed by clinicians. Further, because the chemicals being used in these products are generally not *antibiotic* medicines,

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but *antiseptic* chemicals like silver and hypochlorous acid, their use does not carry the same level of concern about antibiotic resistance that use of antibiotic medicines pose.[iv]

The antimicrobial wound dressings and washes that are on the market today have all been reviewed and cleared by FDA pursuant to the 510(k) process. Unfortunately, FDA's proposed rule would upend regulation of these products by revoking prior FDA clearances and requiring new 510(k) submissions for most products under new standards that are unduly burdensome and confusing.[v] There is no reasonable basis for creating such disruption as these products, many marketed for decades, generally have excellent profiles with respect to their safety and the benefits they provide. Further, the new regulations could impede innovation going forward for new products.

As a result, FDA's proposal would create new regulatory classifications affecting hundreds of 510(k)s and the many respective product lines they cover and will create much greater confusion about requirements for wound dressings, resulting in the **unnecessary withdrawal of many important products from the market to the detriment of clinicians and their patients**. Furthermore, these regulatory actions may result in clinicians using more antibiotic products, exacerbating the very resistance problems that FDA is trying to address through regulations on antiseptic-based wound dressings and washes.

The proposal itself would also likely lead to product shortages, exits of manufacturers from the market, reduced innovation, and harm to patients and the public health. Further, the disruptions caused by the proposed rule have the potential to drive up use of antibiotic medicines in the management of chronic wounds, increasing the potential for growing antibiotic resistance.

For these and other reasons detailed in our originally submitted comments[vi], the Alliance respectfully requests that Docket No. FDA–2023–N–3392 – Proposed Rule; Medical Devices; General and Plastic Surgery Devices; Classification of Certain Solid Wound Dressings; Wound Dressings Formulated as a Gel, Creams, or Ointment; and Liquid Wound Washes & Docket No. FDA-2023-N-3275 – Proposed Amendment; Proposed Order; Effective Date of Requirement for Premarket Approval Applications for Certain Solid Wound Dressings; Wound Dressings Formulated as a Gel, Cream, or Ointment; and Liquid Wound Washes Containing Medically Important Antimicrobials be withdrawn. As you will see in the docket, we were not alone in our concerns – other stakeholders, including individual clinicians, clinician organizations, wound care product manufacturers, and trade associations also raised concerns similar to those the Alliance put forward.

Prior Authorization (PA)

The PA process requires physicians and other qualified health care providers to obtain pre-approval for medical treatments or tests from the insurer or its pharmacy benefits manager before the plan will cover the cost of the treatment or test and before clinicians can render care to their patients. The process for obtaining this approval is lengthy and typically requires physicians and other qualified health care providers or their staff to spend the equivalent of 2 or more days each week negotiating with insurance companies — time that would be better spent taking care of patients. PA is often imposed on services that are very unlikely to be over-utilized and are eventually approved 90-100% of the time. In these cases, and others, PA not only prevents seniors from receiving medically necessary, sometimes lifesaving, care in a timely manner but expends unnecessary time and money for plans, providers, and caregivers. Additionally, in numerous cases, it has been demonstrated that Medicare Advantage (MA) contractors implement their commercial coverage requirements for services, often in

contradiction to Medicare coverage requirements.

CMS has recognized throughout rulemaking that PA is burdensome.[vii] The Alliance agrees. PA is a substantial burden for patients and providers due to the immense amount of time required to complete a request, the lack of transparency obtaining an authorization, payers' failure to respond in a reasonable time, and partial approvals which lead to a continuous cycle of repeated requests. Additionally, managed care organizations (for-profit organizations) are not held accountable for the prior authorization decisions that are being made. Yet, most PA requests, as stated above, are ultimately approved. This means that the time spent for providers obtaining a PA or managing the PA process only creates a delay in providing care to their patients and a huge undue burden in ensuring the PA is approved. It is also vital that PA denials be transparent so that clinicians can understand the reasons for denial. PA must also be efficient so that undue delays in care do not occur. We also warn against the extensive use of AI in PA denials which are not supervised or reviewed by individuals with clinical expertise. Use of AI tools for PA should be transparent with the criteria being made available to practitioners.

PA should not be required when there are coverage policies in place and the requirements of the policy have been met. Currently, we are aware of a wound care example to highlight this problem. Autologous blood derived products were issued a national coverage determination (NCD 270.3). As a result of the coverage policy, CMS covers this therapy and Medicare managed care organizations are required to cover this therapy for their subscribers. Yet, despite the NCD 270.3 being issued, some Medicare managed care organizations are denying this therapy. When it's denied, it is requiring several appeals to correct the payment. In addition, a substantial number of Medicare Advantage Plans are still requiring a prior authorization. For the same service, Medicare Part B does not require prior authorization. The therapy is ultimately being approved, but these actions slow down a patient's ability to receive it in a timely manner, which defeats the purpose of the national coverage policy being issued.

In summary, prior authorization is burdensome to clinicians and a substantive majority of prior authorizations are approved whether outright or when denials are overturned. PA delays care and access to products, tests and/or services for patients. As such, the Alliance recommends that CMS should mandate their MA contracted plans do a comprehensive review of the evidence and readjust their guidelines on PA so that PA:

- Can be applied in a manner that is consistent with medical standards of care.
- Can be efficient so undue delays do not occur (PA decisions need to be issued more quickly).
- Decisions are transparent and reasons are provided to providers when denials are issued.

Furthermore, the Alliance recommends that CMS conduct oversight of their MA contractors to ensure that MA contractors are following/adhering to Medicare coverage policies.

Therapeutic Shoes for Patients with Diabetes

The growing rates of obesity, poor diet, and lack of physical activity, among other factors, have contributed to a more than 3-fold increase in the number of adults living with diabetes in the Americas in the past 30 years, according to a report by the Pan American Health Organization, and this number is expected to continue rising.[viii]According to the CDC, more than 29 million Americans live with diabetes. As a result of the increased number of patients with diabetes, there has been a rise in the number of patients with diabetic foot ulcers making diabetes the leading cause of non-traumatic lower-limb amputation. Diabetes is a complex, chronic

condition requiring continuous medical care with multifactorial risk-reduction strategies to prevent amputations including the use of therapeutic shoes. A meta-analysis demonstrated that therapeutic footwear was associated with a reduction in amputations in high-risk individuals who had previous ulceration, partial amputation, severe deformity, or Charcot deformity.[ix]

The current process and Medicare contractor requirements[x] for determining eligibility for Medicare's Therapeutic Shoe Program for Patients with Diabetes, and for furnishing this medically necessary benefit, are unnecessarily burdensome and frequently bogged down. This is leading to frustration on the part of the certifying physician, nurse practitioner, podiatrist, other qualified health care providers, the prescribing doctor, the supplier and the patient.[xi]

Under §1861(s)(12) of the Social Security Act (42 U.S.C. 1395x(s)(12)), Medicare covers diabetic shoes prescribed and furnished by a qualified health care provider including a podiatrist or nurse practitioner when the physician managing the patient's diabetes certifies the need for shoes, among other requirements. Again, however, in the implementation of these requirements, the Medicare DME MACs have imposed undue burdens on providers by exceeding statutory requirements. Specifically, through DME MAC Policy Article A52501, MACs are requiring that the physician managing the diabetes. The relevant language reads:

> *obtain, initial, date (prior to signing the certification statement), and indicate agreement with information from the medical records of an in-person visit with a podiatrist, other M.D or D.O., physician assistant, nurse practitioner, or clinical nurse specialist that is within 6 months prior to delivery of the shoes/inserts …"*

This "co-signing" requirement serves no purpose in furthering patient safety or improving care for patients but rather creates obstacles that prevent patients with diabetes from receiving medically necessary diabetic footwear. Providers often report that this documentation requirement is unnecessarily burdensome, leading to delays or denials of care for patients who need it most. The delays have been associated with re-ulceration and even amputation while patients wait for indisputably necessary therapeutic shoes.

The Alliance believes that this outdated practice serves as a barrier to care and needs to be removed. As such, the Alliance recommends that the DME MACs should be instructed to remove the following sentence from "Therapeutic Shoes for Persons with Diabetes - Policy Article" (A52501):

"Obtain, initial, date (prior to signing the certification statement), and indicate agreement with information from the medical records of an in-person visit with a podiatrist, other M.D or D.O., physician assistant, nurse practitioner, or clinical nurse specialist that is within 6 months prior to delivery of the shoes/inserts, and that documents one of more of criteria a – f."

This would permit podiatrists, nurse practitioners, and other qualified health care providers to be able to prescribe medically necessary therapeutic shoes for persons with diabetes without the need to go back to the physician to verify the need. This will allow for patients to receive the care needed without delay.

The Merit Based Incentive Payment System (MIPS)

CMS had good intentions when it implemented MIPS in 2017. The aim was to streamline disparate quality

reporting programs to reduce the reporting burden, but instead, MIPS has increased the burden of quality reporting. A JAMA Health Forum study found that physicians spent an average of $12,800 per practitioner, and over 200 hours a year to comply with MIPS. CMS itself estimates that MIPS in 2025 would impose health-system burdens equating to 586,877 hours and cost more than $70 million. Despite the fact that practitioners can lose up to 9% of their Medicare payments in penalties, a 2022 study in JAMA Association Between Individual Primary Care Physician Merit-based Incentive Payment System Score and Measures of Process and Patient Outcomes | Health Care Safety | JAMA | JAMA Network found that the Quality Payment Program (QPP) was "approximately as effective as chance in terms of identifying high versus low quality performance."

The burden of MIPS unfairly impacts small and rural practices across the country which have fewer resources to divert from patient care to comply with bloated, and ever-changing MIPS requirements. The unfair impact of MIPS is evidenced by the fact that in 2024, 45% of solo practices, 31% of small practices and 18% of rural practices were penalized under MIPS, compared to 14% of practitioners overall. Even more worrisome, according to CMS's 2022 report on the program, nearly 30% of physicians in solo practice got the maximum 9% penalty. These penalties have occurred despite the fact that there is no evidence to show that MIPS has improved even one healthcare outcome and there is abundant evidence to show that it has decreased the quality of medical care, particularly for the most vulnerable patients.

The American Medical Association (AMA) has proposed a new, budget-neutral incentive payment system that every state medical society and more than 100 national specialty societies have endorsed including many of the Alliance clinical associations and specialty societies that are impacted by MIPS. It is called the Data-Driven Performance Payment System. This system would reduce MIPS's regulatory burden by:

- Awarding multicategory credit and ensuring MIPS Value Pathways are clinically relevant so patients can compare quality and cost across physician practices.
- Reducing unnecessary quality-measure reporting burden and eliminating arbitrary scoring rules that drive up the cost of compliance with MIPS and discourage reporting on new and substantially revised measures.
- Fixing the long-standing inaccuracies with the MIPS cost measures and nullifying their negative impact on Medicare physician payment and patient access to care until these issues can be properly addressed.
- Sharing timely critical MIPS performance data and Medicare claims data with physicians to facilitate better quality and lower costs.

With regard to the development of cost measures, we are particularly concerned with the proposed 2024 Non-Pressure Ulcers Episode-Based Cost Measure (MUC2024-100). Several Alliance members served on the Clinical Advisory Panel for this cost measure and were vocal in their lack of support for the final measure which would hold wound care practitioners responsible for the cost of care delivered by practitioners who are unknown to them, months after the patient had left their practice. Errors in the various codes included in the measure were not addressed by the contractor (Acumen) prior to finalization of the draft measure, and the detailed, written concerns of experts were dismissed by Acumen. While the Alliance supports the development of a wound-care relevant cost measure, field testing of the draft measure demonstrated critical errors. This cost measure should not be implemented. Furthermore, even if this cost measure is implemented (after revisions and additional field testing), the lack of wound care relevant, national quality measures still would make it impossible to develop a useful MIPS Value Pathway (MVP) relevant to non-pressure ulcers.

Hospital Outpatient Prospective Payment System for CTPs

In 2013 CMS determined that skin substitutes also known as Cellular and/or Tissue based Products for skin wounds (CTPs) should be bundled in the hospital outpatient setting and set out a regulatory framework to do so.[xii] The Alliance was not in favor of this proposal. We believed that the policy would create perverse incentives to price products high, thus eliminating low cost product choices. Furthermore, the payment methodology was flawed from the beginning – which we also provided substantive feedback. As a result of the payment methodology flaws, the Alliance has noticed a shift in the site of service in which CTPs are being provided – from the hospital outpatient provider department (HOPD) to the physician office and now also to mobile clinics.

The lack of access to care in HOPDs for larger wounds (over 25 sq cm) has been demonstrated in a published study in the Journal of Medical Economics, "*Chronic wound prevalence and the associated cost of treatment in Medicare beneficiaries: changes between 2014 and 2019*."[xiii] The key findings of the study which validates the shift from patients being treated in HOPD to the physician's office are:

- **Shifts in site-specific spending**: HOPD fees saw the largest reduction ($10.5 billion to $2.5 billion) although home health agency expenditures decreased from $1.6 billion to $1.1 billion. Physician offices saw an increase from $3.0 billion to $4.1 billion and durable medical equipment increased from $0.3 billion to $0.7 billion.
- **Decreasing overall cost**: Despite the increase in prevalence, healthcare expenditures associated with chronic wound care *decreased* over the study period. The researchers used three different methods to estimate expenditures. Regardless of the method used, there was a reduction in expenditure, with the most conservative method showing a decrease from $29.7 billion to $22.5 billion. This is particularly surprising since overall Medicare costs increased over the same time frame.
- **Shifts in wound types and cost:** The largest changes were increases in arterial ulcers (0.4% to 0.8%) and skin disorders (2.6% to 5.3%), although the authors suggest that the movement from ICD-9 to ICD-10 over the study time period may factor into the changing prevalence of certain types of wounds. As in 2014, surgical wound complications were the most expensive in 2019, with pressure ulcers the second most expensive. For most wound types there were decreases in expenditures, but the "generic" chronic ulcers and venous leg ulcers registered small-to-moderate increases.

CTPs are a medically necessary advanced treatment option for patients with chronic non-healing wounds. There are published scientific studies showing their effectiveness in wound healing, including the reduction of amputation and infection when they have been used. [xiv], [xv],[xvi], [xvii] The outlook for patients with wounds based on our study findings suggests that any ongoing access to care problems could worsen because the population is aging. This, along with a concurrent rise in the number of patients with diabetes, will result in an increase in the cost of treating patients with chronic non healing wounds and potentially an increase in the number of amputations. Furthermore, the impact of the inability to provide CTPs in the HOPD, as a result of the flawed payment methodology, has contributed to their proliferation in the office-based and mobile care settings.

To address these concerns, most recently on August 26, 2024, the Alliance provided 5 recommendations to the Advisory Panel on Hospital Outpatient Payment in which the Panel overwhelmingly voted to recommend that CMS adopt.[xviii] These recommendations, have not yet been implemented by CMS. However, if implemented, they will help correct the flaws that exist in the payment methodology as well as inappropriate APC assignments for CTPs which have impacted access to care in HOPDs. Specifically, the Panel recommended:

1. CMS assign the existing CPT® add-on codes (15272, 15274, 15276, and 15278) and HCPCS codes (C5272, C5274, C5276, and C5278) to appropriate APC groups allowing for separate payment and issue an exception to separately pay for these add-on codes.
2. CMS assign the CPT and HCPCS codes for the same size wound, regardless of anatomical location on the body, to the same APC groups.
3. CMS assign all cellular and/or tissue-based products (CTPs) with either HCPCS codes of Q or A to the low-cost APC groups until a manufacturer provides cost information to CMS.
4. CMS realign both the high-cost and low-cost application procedure codes to higher paying APC groups that reflect the current average sales prices of all CTPs. Manufacturers are required to submit average sales prices, and this pricing should be used to map to an appropriate APC for all CTPs, whether they are issued a HCPCS A code or Q code.
5. CMS not assign CTPs that are not in sheet form (e.g., gel, powder, ointment, foam, liquid, or injected) to any APC group, because these products are not allowed to use the current application codes of HCPCS codes 15271-15278; C5271- C5278; which drive the APC group assignment. CTPs that are not in sheet form track to services and procedures, such as clinic visits and debridement of chronic wounds, and therefore [the Panel recommends that they] should not map to any APC.

The Alliance has reiterated the Panel's recommendations below and provided the rationale for them. We urged CMS to implement all of the Panel's recommendations in order to fix the regulatory payment methodology flaws it established in 2013.

1. CMS Assign The Existing CPT® Add-on Codes (15272, 15276, 15274, and 15278) and HCPCS codes (C5272, C5276, C5274, and C5278) To Appropriate APC Groups Allowing For Separate Payment And Issue An Exception To Separately Pay For These Add-on Codes.

Rationale for Recommendation

The first barrier to access relates to the packaging of the add-on codes. When the payment for CTPs were packaged into the payment for the application, the add-on codes were also packaged. The regulation, 42 C.F.R. § 419.2(b)(18) provides for packaging of "certain services described by add-on codes" and thus is not a blanket requirement applicable to all add-on codes. For example, in the CY 2023 final rule, CMS decided to adopt a policy that Software as a Service (SaaS) add-on codes are not among the ''certain services described by add-on codes'' for which we package payment with the related procedures or services under the regulation at 42 CFR 419.2(b)(18)".vi CMS should adopt the same policy for the above-identified CTP add-on codes so that they are paid separately like the SaaS codes.

In addition, packaging CTP add-on codes adversely impacts beneficiaries suffering from larger wounds and ulcers. **Because the add-on codes represent wounds and ulcers that require the purchase of additional product or a larger product, patients with wounds/ulcers larger than 25 sq. cm. up to 99 sq. cm. and also wounds/ulcers greater than 100 sq. cm**., packaging means there is no separate payment to account for the larger wounds and ulcers. That disincentivizes hospitals to offer medically necessary CTPs in HOPDs to beneficiaries with larger wounds and ulcers. **The reason for this is that** the packaged OPPS rates for the base codes are not adequate to allow the HOPD to purchase the sizes of CTPs necessary to apply to wound/ulcer sizes that are aligned with the add-on code descriptions.

To remedy this issue, the Alliance urges CMS to take the approach taken last year with SaaS add-on codes. We

request that CMS identify the CTP add-on codes as not being among the services described by the add-on codes that are subject to packaging and pay separately for the CTP add-on codes. The Panel likewise recommended that CMS separately pay for the CTP application add-on codes. The allowance of payment for the add-on codes is an easy remedy for CMS to implement and there has been precedent set by CMS providing this exception to other procedures which require the purchase of additional product (e.g., chemotherapy).

Additionally, the Alliance recommends that APC groups 5053, 5054 and 5055 be retained but additional APC groups should be created to appropriately address the costs to purchase the appropriate amount of product for wounds/ulcers 26-50 sq. cm., 51-75 sq. cm., 76-99 sq. cm., and each additional 100 sq. cm. Again, currently, the CPT codes are assigned to APCs based on the wound size - smaller wounds (under 25 sq. cm) or larger size wounds (over 100 sq. cm). The current system makes CTPs for patients with wounds /ulcers that are in between 25 sq. cm. and 100 sq. cm. as well as those over 100 sq. cm. cost-prohibitive for HOPDs since they are not reimbursed for the extra product that would be needed to treat the patient's medically necessary wounds/ulcers.

In order to appropriately pay HOPDs now for the various sizes of products required for the wounds and most importantly, so that patients with larger wounds can gain medically necessary access to CTPs, each base code for the application of the products must track to separate APC groups and each add-on code must also track to separate APC groups. The OPPS payment rates for the add-on code APC groups should include payment for the additional product that must be purchased. If CMS is not agreeable to this recommendation, we recommend that the additional product necessary be billed separately (in addition to the APC payment for the application) to allow the HOPD to afford the purchase of the extra product required to treat the larger wounds/ulcers.

2. CMS Assign The CPT And HCPCS Codes For The Same Size Wound, Regardless Of Anatomical Location On The Body, To The Same APC Groups.

Rationale for Recommendation

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.

The HOPD purchases the same amount of product – whether the wound/ulcer was located on the patient's leg or on their foot, and as such, 15277 and 15273 should both be assigned to APC group 5055 to provide patients with the same size wounds/ulcers regardless of the anatomic location with access to medically necessary CTPs.

In the past, CMS officials stated that CMS assigns different APCs to wounds on the foot versus the legs because of the two times rule. However, we believe that the two times rule should not apply here. These wounds are using the same resources and the same amount of product and thus the costs would be the same. Therefore, the two times rule would not apply. If CMS believes that the two times rule should be invoked, we submit that data needs to be provided to support the continuation of these codes being placed in different APCs.

The Alliance continues to **urge CMS to adopt the Panel recommendations and 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.** These codes apply to adults as well as children and should be assigned to APC 5055 as the same resources are used regardless of anatomic location of the wound.

3. CMS Assign All New CTPs, With Either HCPCS Codes of "Q" or "A" to the Low-Cost APC Package Until a Manufacturer Provides Cost Information to CMS.

Beginning in 2013 when CTPs were packaged in HOPDs, CMS mapped CTPs assigned HCPCS "Q" codes into an appropriate APC group based on pricing data that had to be submitted by the manufacturer. CMS identified the pricing information that it required the manufacturer to submit to determine the placement of the product in the high or low cost group. If the cost was not provided to CMS, the product would automatically be placed in the low cost group as stated in the regulations. CMS currently places some CTPs assigned "Q" codes into the high or low-cost package based on the Median Unit Cost (MUC) or the Per Day Cost (PDC) and then the product is mapped to an appropriate APC group.

CMS began to issue HCPCS "A" codes to CTPs with FDA 510(k) clearance and has automatically placed all of these products into the high-cost package without receiving any pricing data to validate their placement in the higher APC grouping.

The Alliance is concerned with this action by the Agency for the following reason: **CMS is not following its own guidance on this issue. The mapping of CTP products to the appropriate APC group should be based on the assignment of the product to either the high or low-cost category - which is currently determined by pricing data provided by the manufacturer.**

By automatically placing the CTPs assigned "A" codes into the high-cost APC group without receiving pricing information from the manufacturer, CMS is potentially paying high-cost rates for CTPs that are actually low-cost.

During the August 23, 2023 HOP Panel meeting, CMS cited incorrect information in its presentation which may impact whether the Agency adopts this Panel recommendation. Specifically, CMS officials stated that "under current regulation, there is a requirement that skin grafts described as synthetic "A" codes be assigned by default to the high cost bucket consistent with the hold harmless policy that once a product is assigned to the high cost bucket they will remain there. This is why the "A" codes are being assigned to the high cost group."

Respectfully, this statement is incorrect. First, not all "A" codes assigned to CTPs are synthetics. In fact, many HCPCS "A" codes were issued to products that are not synthetic but simply went through the 501(k) process. So, in fact, **not all products that are automatically being assigned into the high cost package are synthetics.**

Further, while CMS officials are correct in stating that CMS does assign products that were placed in the high cost package in a particular calendar year to remain there if already assigned to that group based on the hold harmless language**, CMS is automatically placing new products that have never been placed in the high cost package into that bundle without the manufacturer providing pricing data as required.** This is causing many products that should be in the low cost bucket to be paid higher than they should. There is added cost to the patient and does not help to protect the Medicare Trust Fund. Any manufacturer that has not provided pricing information on its product to CMS should be placed in the low cost bucket. There should be no exceptions.

Finally, synthetic products are like all other CTPs in that they are required to apply and receive a unique HCPCS code**.** When synthetics were first addressed in the OPPS regulations, CMS claimed that there was no payment mechanism for them and as such, issued a temporary C1849 code for any synthetic in the marketplace**.** All synthetics that were in the marketplace at that time were then grouped into that one code and assigned into the high cost bucket whether they were appropriate to be there or not. The placement into the high bucket for ALL synthetics was based on data from one company. Currently, the "C" code for these products been discontinued and instead, CMS is requiring that all synthetics obtain a unique HCPCS code. As such, automatic assignment of new products being issued an "A" code to any product into the high cost group is an unfair way

to bolster one specific type of CTP over another, which negatively affecting market competition and potentially limiting beneficiary access to other more clinically beneficial treatments. Determining the placement of products in the high-cost bucket should be contingent with pricing data, as has long been CMS's policy.

The Alliance urges the Administration to follow a uniform methodology for placing CTPs into the high or low-cost package to appropriately map each CTP to the correct APC group regardless of the product's code. Methodologically, placement of a CTP with a HCPCS "A" code into the high or low cost package should be based on the MUC or PDC just like CTPs that are issued HCPCS "Q" codes. Not only would this be equitable, but CMS would be following its own guidance. **The notion that A codes are "different" is factually not correct.** There are current 510(k) products that have HCPCS "Q" codes and newer ones that now have HCPCS "A" codes. Moreover, the notion that the hold harmless language applies to all new "A" codes being issued to synthetic products as opposed to only those that have already been placed in the high cost group is simply wrong. The Alliance urges the Administration to adopt the Panel recommendation that **CTPs that are issued HCPCS "A" codes should not automatically be assigned to the high cost package.** This will help to address products potentially being mapped to an incorrect APC group without providing appropriate pricing data and will adhere to CMS regulations.

4. CMS Realign Both The High-Cost And Low-Cost Application Procedure Codes To Higher Paying APC Groups That Reflect The Current Average Sales Prices Of All CTPs.

The Administration should reassign both the high-cost and low-cost application procedure codes to higher paying APC groups that reflect the current average sales prices of all CTPs. To accomplish this, CMS should consistently publish and use the ASP of all CTPs (both products assigned "Q" and "A" HCPCS codes.) NOTE: Although all manufacturers of products paid like drugs and biologicals have been required to submit the ASPs of all CTPs since January 1, 2022, CMS has not published, on the Medicare Part B drug and biological file, all the ASPs reported for CTPs assigned "Q" HCPCS codes and none of the ASPs for the CTPs assigned "A" codes. Because inaccurate product costs were built into the packaged payment for the application of CTPs, the HOPDs have been unable to purchase most low-cost CTPs, even for small sized wounds/ulcers. This improper payment has existed now for over 10 years. Now that all CTP manufacturers are required to submit the ASPs for their products CMS should realign the CTP application procedure base codes and add-on codes to APC groups that reflect the HOPDs' true costs.

We believe that this can be accomplished easily if CMS adopts the Panel's recommendation to realign the application of CTP base codes and add-on codes to appropriate APC groups that reflect current prices of high-cost and low-cost CTPs which the Alliance maintains can be accomplished by:

- Enforcing the requirement that manufacturers of all CTPs report their ASPs every quarter.
- As recommended by the OIG and the Alliance, publish the ASPs of all CTPs (assigned both "Q" and "A" codes) in the Medicare Part B Drug and Biological File.

MACs are assigning the cost to the product which is not only inconsistent but potentially creating higher pricing than is necessary for these products. The Alliance recommends that all **CTPs be required to submit ASP pricing as is currently mandated and CMS publish all ASPs.** Finally, **the Alliance recommends that CMS utilize its enforcement authority to ensure that all discounts and rebates are being provided accurately to the Agency**. While the Alliance recognizes that CMS is looking at different payment methodologies for CTPs and for a consistent payment model across all sites of service, if the Agency is looking to emulate the bundled system in the HOPD as the model across different sites of service, the flaws within the current HOPD payment

model need to be fixed. As such, **we request that all of the Panel's recommendations are implemented in order to fix the regulatory payment methodology flaws CMS established in 2013.**

Real World Evidence

Part of the 21st Century Cures law was intended to accelerate medical product development and bring innovations faster and more efficiently to the patients who need them. Among other provisions, the Cures Act added section 505F to the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355g). Pursuant to this section, FDA created a framework for a program (RWE Program) to evaluate the potential use of real-world evidence (RWE) in regulatory decision-making. Randomized Controlled Trials (RCTs) can provide evidence of efficacy in a "perfect" world. In the case of wound care trials, they enroll only the healthiest patients with the most superficial wounds and thus are almost entirely non-generalizable to the real world. RWE is needed to provide evidence of effectiveness in usual clinical practice and thus fills a vital evidence gap for payers. While the Alliance appreciates that the FDA is moving forward with the Congressional mandate to make use of RWE in expanding indications for use on already approved or cleared devices, the Center for Medicare and Medicaid Services (CMS) and commercial payers have not accepted this type of data for drugs and/or devices, including tissue products and medical devices used in wound care, as primary evidence for the purpose of coverage. They have repeatedly stated they will only accept Randomized Controlled Trial (RCT) evidence as primary evidence coverage considerations. Even if the FDA adopts/permits RWD/RWE for regulatory decision making, unless CMS and commercial payers also accept this type of evidence as primary evidence for coverage purposes, it will still be burdensome and costly for manufacturers to provide one type of evidence for the FDA and another for payers for coverage and payment purposes.

The Alliance held a first of its kind ground-breaking Wound Care Evidence Summit™ in May 2022. During this Summit, RWE was heavily discussed. CMS, FDA, commercial payers and other distinguished guests attended and presented during this meeting. Panel after panel urged payers to adopt RWE as primary evidence for coverage as this type of evidence is more reflective of the patient population being treated. However, the medical directors of the payer panels, while recognizing the benefits of RWE, repeatedly stated they would not use RWE as primary evidence for coverage purposes but only as supplemental evidence to RCTs. This defeats the purpose of the FDA mandate as manufacturers will not conduct different sets of trials – one for the FDA to come to market and another to gain coverage through CMS and commercial payers.

The Alliance highly recommends that the Administration mandate that CMS also adopt the use of RWE as primary evidence for coverage purposes, particularly since it is the only type of evidence that provides data on clinical effectiveness. If the FDA can utilize RWE and deem that a product is safe and effective, CMS and other payers should be able to use RWE to determine that the products are reasonable and necessary for coverage purposes.

Coverage with Evidence Development

Under the Social Security Act, CMS provides coverage for products and services that are deemed "reasonable and necessary" to patients over 65 and disabled populations. CMS may issue an NCD that establishes a single coverage standard on how a product or service approved by the Food and Drug Administration is covered (and thus, reimbursed) in the Medicare Part B program. In 2005, CMS introduced the Coverage with Evidence

Development (CED) paradigm that requires Medicare patients to enroll in a CMS-approved CED clinical study as a condition of coverage for that product or service. **CED has never been explicitly authorized by Congress.**

CED is a process CMS uses when it believes certain products and services are promising but need further research to determine whether these treatments are "reasonable and necessary" for Medicare patients. When CMS invokes CED for an NCD, patients must enroll in a CMS-approved clinical study to obtain Medicare coverage for that product or service. CMS updated the CED regulatory guidance in 2014 indicating its intent to expand and advance CED coverage restrictions, and issued proposed guidances in 2023.[xix], [xx]

Over the years, CMS has employed CED 27 times across 8 therapeutic areas.[xxi] The vast majority of those coverage restrictions have remained in place since the inception of the CED pathway. Only 7 of the 27 CED requirements have been removed. In 4 cases, the CED requirements were removed while the NCD remained in place, taking between 4 to 12 years for such a decision; 3 resulted in removal of the NCD and deferral of coverage decisions to local contractors which took between 10 to 13 years to be removed.[xxii] The remaining 21 items and services continue to be subject to CED, and none have preset time frames for "graduating" from the program and receiving a final coverage determination. Even amongst the products that moved forward from CED, the time elapsed between initiation and completion ranged between four and 12 years. Multiple products that were amongst the first to receive CED continue to be required to generate clinical data today, almost 20 years later.

The fact is that CED is seemingly never-ending for innovators who chose this pathway, with more than 30 complex steps required simply to establish a program. Once CMS announces coverage of a product under CED, an organization must step in to sponsor a study to collect the evidence. This involves determining investigators, establishing a governing protocol, getting approval from both an institutional review board and CMS, preparing a database or registry in which data can be submitted, determining funding for the study, identifying and enrolling patients, and general clinical practice. The details behind each of these steps are extensive, and mistakes can be costly. For example, failure to incorporate data collection into clinical workflow may make data submission burdensome for physicians, who may overlook data submission and prevent the study from generating sufficient data to encourage adoption of the technology.

Furthermore, the resources required to facilitate CED can inhibit evidence development. It is not always clear who should bear the costs of participation, or developing systems to collect and input data, or who should be responsible for sharing with data registries. The long, and uncertain time frame for CED chills innovation. Without a set time frame, innovators may be unsure of what requirements must be met to "graduate" from CED and what events may trigger failure. They may also be concerned that failure may trigger an adverse coverage determination by CMS and even threaten FDA licensure.

Finally, it should be considered that even if a product or service is able to "graduate" from CED and an NCD is developed and implemented, access can still be an issue if payment is not adequate to cover the cost of the product or service being provided coverage. An example in the wound care space includes autologous blood derived products. CMS states that the CED process was a success for this product; however, three years after the NCD was issued, there are still significant issues of Medicare beneficiaries gaining access to this technology as a result of inaccurate and inappropriate reimbursement. If reasonable reimbursement does not follow the process and the product is not accessible as a result, it is our opinion that the CED was not successful.

As such, the Alliance suggests that substantive revisions to the CED program need to be made for it to be successful and for innovators to not be in a perpetual CED state. Therefore, the Alliance requests that the issues raised above need to be addressed as CED could be a very good program if there was more transparency and timeframes were identified so that the process is not open ended. It is also imperative that appropriate reimbursement be addressed when a resulting NCD is issued so there is no gap in care or in accessing the products or services that CMS created an NCD from the CED process.

National Correct Coding Initiative

On December 19, 1989, the Omnibus Budget Reconciliation Act of 1989 (P.L. 101-239) was enacted. Section 6102 of P.L. 101-239 amended Title XVIII of the Social Security Act (the Act) by adding a new Section 1848, Payment for Physicians' Services. This section of the Act provided for replacing the previous reasonable charge mechanism of actual, customary, and prevailing charges with a resource-based relative value scale (RBRVS) fee schedule that began in 1992. With the implementation of the Medicare Physician Fee Schedule (PFS), it was important to assure that uniform payment policies and procedures were followed by all Medicare Administrative Contractors (MACs) so that the same service would be paid similarly in all (A/B MAC) jurisdictions. Accurate coding and reporting of services are critical aspects of assuring proper payment.

As such, the Centers for Medicare & Medicaid Services (CMS) developed the National Correct Coding Initiative (NCCI) program in 1996 to promote national correct coding methodologies and to control improper coding that leads to inappropriate payment of Part B claims. The coding policies are based on coding conventions defined in the American Medical Association's *Current Procedural Terminology (CPT) Professional,* national and local Medicare policies and edits, coding guidelines developed by national societies, standard medical and surgical practice, and/or current coding practice.

Procedure-to-procedure (PTP) edits

While there is value in NCCI edits, inappropriately issued NCCI edits should be addressed especially when they conflict with CPT coding given that the policies are based on coding conventions defined in CPT. When edits are issued that negatively impact patient care and create health equity issues but are not corrected, patients suffer. To highlight the problem, the Alliance will provide a wound care specific example in which a procedure-to-procedure (PTP) edit was put in place that conflicts with CPT and standards of care and needs to be corrected.

The Alliance has submitted several letters to the CMS National Correct Coding Initiative (NCCI) Panel requesting the elimination of PTP edits which prohibit the application of a total contact cast [CPT® code 29445] or compression therapy (Unna Boot, multi- layer compression system) [CPT® codes 29580, 29581] after a debridement or grafting procedure during the same office or clinic visit.[xxiii],[xxiv],[xxv] The specific code pairs at issue are:

- CPT 11042-11047 with CPT 29445, 29580 or 29581
- CPT 97597-97598 with CPT 29445, 29580, or 29581
- CPT 15271-15278 with CPT 29445, 29580, or 29581

With the current edits in place, if a grafting or debridement procedure is clinically indicated for treatment of a

wound, CMS would deny payment for the application of the TCC or compression procedure during the same visit. This is problematic as in order to appropriately identify and compensate clinicians for their services, it would necessitate scheduling two procedures on separate dates, requiring a patient to come to the office/clinic more often for evidence-based care. **This is wasteful and more costly for both CMS and Medicare beneficiaries since it creates more copays for them. This is also detrimental to patients since it does not follow the standards of care for offloading and compression for wound care.**

To provide the evidence-based medical care needed for neuropathic and diabetic wounds or Charcot deformities and comply with current NCCI edits, CMS is not compensating physicians for the procedures they are providing. Instead, clinicians are incentivized to add an office or clinic visit to ensure they can perform debridement, if required, along with application of total contact cast or compression. The same is true if a grafting procedure is required prior to the application of a total contact cast or compression. Ultimately, this stagger of procedures leads to increased costs for the health system and each patient, instead of reducing the cost by allowing both medically required procedures at one visit. Due to the edits, clinical providers especially in rural areas cannot afford to apply these evidence-based therapies without appropriate reimbursement. Patient care suffers since their wounds won't heal as fast and they will need to come back to the clinics often which increases costs. In addition, people with disabilities or those who do not have easy access to transportation may not be able to travel to a facility for multiple visits so as to treat their wounds.

To further highlight the problem with this issue, CPT coding guidance allows for debridement (codes 11042-11047, 97597- 97598)) and application of TCC (CPT 29445) on the same date of service - which conflicts with the NCCI edit. The CPT Assistance Guidance states, "Code *29445, Application of rigid total contact leg cast"*, is the appropriate code to report for the total contact cast application. A TCC is used to reduce the pressure and/or shear forces on a lower extremity wound, typically on the plantar surface. The cast improves the ability of the wound to heal. If a wound debridement is performed (codes 11042-11047, 97597- 97598), any primary or secondary dressing materials used to cover the wound would be included in the debridement and would not be separately reported. However, a TCC is not considered a wound dressing and is not included in the debridement procedure. Therefore, the cast application should be coded in addition to the code for the appropriate level of debridement, if performed.

Currently, hospital outpatient departments cannot get paid the separate APC for the TCC as there is an NCCI edit in place that prohibits debridement from being performed on the same date of service as a total contact cast - which is contrary to CPT assistant guidance. There is an NCCI edit for this code pair with a modifier indicator of "1" which says the code pair may be paid if an NCCI-associated modifier is on the claim. The existence of an NCCI edit with CPT codes 11042 and 29445, with "CPT Manual or CMS manual coding instruction" as the rationale is improper and has created this problem. With no pertinent CMS instruction, CPT must be the reason for the edit, but CPT guidance in the form of a CPT Assistant article which says CPT codes 11042 and 29445 should both be reported. This prohibits the facility from getting paid for the TCC (CPT 29445) separately which does not align with CPT Coding Guidance.

The Alliance has requested **elimination of the procedure-to-procedure edits which do not allow for reimbursement for the application of a total contact cast (CPT 29445) or compression therapy (CPT 29580, 29581) after a debridement or grafting procedure during the same office or clinic visit.** But this inappropriate edit still remains negatively impacting patient care and access.

The Alliance recommends the NCCI panel not be permitted to issue NCCI edits that conflict with CPT coding guidance or negatively impact patient care. We further request that the Administration request that the NCCI panel eliminate the procedure-to-procedure (PTP) edits which prohibit the application of a total contact cast [CPT® code 29445] or compression therapy (Unna Boot, multi- layer compression system) [CPT® codes 29580, 29581] after a debridement or grafting procedure during the same office or clinic visit. **If the edit is simply removed there would be no need for a modifier and both services could be paid.**

Once again, the specific code pairs at issue are:

- CPT 11042-11047 with CPT 29445, 29580 or 29581
- CPT 97597-97598 with CPT 29445, 29580, or 29581
- CPT 15271-15278 with CPT 29445, 29580, or 29581

Medically Unlikely Edits (MUE)

The National Coverage Determination ("NCD") 270.3 – Blood-Derived Products for Chronic, Non-Healing Wounds (effective April 13, 2021) establishes coverage for autologous blood- derived products "for the treatment of chronic non-healing diabetic wounds ... for a duration of 20 weeks, when prepared by devices whose Food and Drug Administration-cleared indications include the management of exuding cutaneous wounds, such as diabetic ulcers."[xxvi] There is nothing in the NCD that prohibits providers from treating multiple wounds during the treatment period, or that prohibits multiple applications of an autologous blood-derived product to a wound with a large surface area. As such, there are several updates to the Medicare billing guidance for G0465 that we would like to suggest in order to clarify for providers how multiple applications of an autologous blood-derived product should be appropriately identified on the CMS-1500 claim form and how Medicare payment is made for such multiple applications.

The Practitioner Services MUE Table for 2025 (effective January 1, 2025; posted Nov. 25, 2024)[xxvii] maintains the MUE value of 1 (and the associated MAI of 3) for G0465. As stated in our comment letter to CMS,[xxviii] given the frequency at which multiple wounds and large surface area wounds occur, it is untenable for a provider to have to appeal every claim that is submitted with two (2) or more G0465 procedures per patient on the same date of service because the MUE value of 1 has been exceeded. It is not uncommon for patients to have multiple wounds or larger wound sizes, especially patients with diabetes. Given this fact, patients should be able to get all of their wounds treated on the same date of service.

As such, we respectfully request that the Administration request that CMS remove the MUE value of 1 (and the associated MAI of 3), in order to allow a provider to bill for more than one (1) unit of G0465 per day when the clinician is treating multiple wounds or wounds with a large surface area. This would decrease the unnecessary administrative burden for the provider, who will otherwise have to submit appeals for every claim that is submitted with two (2) or more G0465 procedures per patient on the same date of service, not burden the patient to have to come back to obtain additional applications on a different day for a different wound or to continue treating the larger wound, and to allow for consistency with the NCD that does not restrict coverage to only one application of an autologous blood-derived product per day.

Audit Reform

RACs originated under a demonstration project in the Medicare Fee-For-Service Recovery Audit program created by Congress in the Medicare Prescription Drug, Improvement and Modernization Act of 2003. The program was made permanent with the passage of the Tax Relief and Healthcare Act of 2006 which required a national Recovery Audit Contractor (RAC) program to be in place by January 1, 2010. The goal of the recovery audit program is to identify improper payments made on claims for services provided to Medicare beneficiaries. Improper payments may be overpayments or underpayments. Overpayments can occur when health care providers submit claims that do not meet CMS coding or medical necessity policies. Underpayments can occur when health care providers submit claims for a simple procedure, but the medical record reveals that a more complicated procedure was actually performed. Providers that could be reviewed include hospitals, physician practices, nursing homes, home health agencies, durable medical equipment suppliers and any other provider or supplier that submits claims to Medicare.

Under the Medicare program, CMS contracts recovery audit contractors (RACs) to identify overpayments and underpayments made by the Medicare program under Part A and Part B. The RACs are also responsible for the recoupment of overpayments made to providers. However, the RACs have perverse incentives. RACs are paid on a contingency fee basis, which means they are reimbursed based on a percentage of the improper payments they find or collect. The amount of the contingency fee is based on the amount of money from, or reimbursed to, providers. As such, Recovery Audit Contractors were paid by CMS on a contingency fee basis — meaning the more dollars they denied and "recovered," the higher the fees they collected. This model essentially incentivizes RACs to be overly aggressive in their audit approach since again, they are paid based on the number of overpayments they find or collect - whether or not what they are identifying is appropriate and/or correct. In fact, most of the overpayment determinations are reversed at a huge cost to providers, not to mention the time and burden to appeal these determinations that are being placed on providers.

Some of the areas within the audit process that the Alliance believes the Administration needs to address include the following:

- Over-Auditing Penalties: Current audit contractors face no penalties for frequent denials that are later overturned. Stakeholders proposed a performance metric or disincentive if a high proportion of denials are reversed. Stated simply, audit contractors should be held accountable for their overzealous behavior and for frequent denials that are overturned as it just shows that the contractor is not clear on the standards of care, the policies in which they are seeking overpayment, and in judging medical necessity decisions.
- Audit Criteria Transparency: Auditors should have clear and published "success criteria" to avoid subjective or inconsistent standards. Furthermore, when issuing a decision based on medical necessity, the physician that reviewed the claim needs to be identified. In clinical practice, nurses are not permitted to make medical necessity decisions yet in most cases the individuals reviewing the claims on behalf of the audit contractor are nurses, or worse, may have no clinical training at all.

Data and Reporting Processes That Are Duplicative or Overly Complex

In order to allow for smoother processes and eliminate burdensome policies/requirements, the Alliance has

provided an additional suggestion which addresses the question - what data and reporting processes are duplicative or overly complex? This area includes the following:

Pricing Data Analysis and Coding (PDAC) Contractor

The Pricing, Data Analysis and Coding (PDAC) contractor maintains the Durable Medical Equipment Coding System (DMECS). DMECS is an official source for Medicare Durable Medical Equipment, Prosthetics, Orthotics and Supplies (DMEPOS) product code verification and assignment. One of the reasons manufacturers contact the PDAC is when it makes a change to an existing product or even more basic, makes a change to a product stock keeping unit (SKU) number. While the Alliance understands the need for a manufacturer to submit an application when changes are made to an existing product, we maintain that making changes to something that is not related to product or function of the product should not be required to submit a new application. For example, when a manufacturer needs to make a change to a SKU number – without any changes to the product itself – is unnecessary and burdensome for manufacturers to submit an entirely new application to the PDAC. In fact, the current process requires a manufacturer to submit a new application and, in some cases, include a product sample for SKU changes. There should be a more simplified process to submit updates to the PDAC so manufacturers are not required to go through a burdensome process for such a simplistic change that is not related to the product itself.

Conclusion

The Alliance appreciates the opportunity to provide our feedback and recommendations. Should you have any questions or require additional information please feel free to contact the Alliance CEO, Marcia Nusgart, or our senior health policy advisor, Karen Ravitz (karen@woundcarestakeholders.org).

Sincerely,

Matthew G. Garoufalis, DPM, FASPS, FACFAOM, CWS
Chair

Kara Couch, MS, CRNP, CWCN-AP, FAAWC
Vice Chair

Marcia Nusgart R.Ph.
Chief Executive Officer

[i] *A list of our members can be found at: www.woundcarestakeholders.org*

[ii] *88 Fed. Reg. 83,774 (Nov. 30, 2023)*
[iii] *88 Fed. Reg. 83,802 (Nov. 30, 2023)*
[iv] *As discussed in our comments, the proposed rule makes leaps based on very sparse information, often drawn from non-medical sources (e.g., environmental research on heavy metals), to suggest that certain antiseptics might contribute to antibiotic resistance through a mechanism called co-selection. However, not even the rule suggests that this theoretical concern (if real) would be as significant a contributor to antibiotic resistance as antibiotic overuse.*
[v] *The rule incorporates World Health Organization ("WHO") standards, which are problematic given the United States withdrawal from that organization*
[vi] *https://www.woundcarestakeholders.org/images/Alliance_Comments_-_FDA_proposed_rule_-_wound_dressings_-_final_2.27.24.pdf*
[vii] Adv*ancing Interoperability and Improving Prior Authorization Processes Proposed Rule; 2024 MA/Part D Proposed Rule, 87 Fed. Reg. 76238 (Dec. 13, 2022) and CMS-0057-F.*
[viii] *Diabetes. Pan American Health Organization. Accessed August 29, 2024. https://www.paho.org/en/topics/diabetes*
[ix] *Maciejewski ML, Reiber GE, Smith DG, Wallace C, Hayes S, Boyko EJ. Effectiveness of diabetic therapeutic footwear in preventing reulceration. Diabetes Care 2004;27:1774–1782*
[x] *https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52501*
[xi] *Medicare Benefit Policy Manual Chapter 15, Section 140 Subsection (C)*
[xii] *78 FR 74938*
[xiii] *Carter MJ, DaVanzo J, Haught R, Nusgart M, Cartwright D, Fife CE. Chronic wound prevalence and the associated cost of treatment in Medicare beneficiaries: changes between 2014 and 2019. J Med Econ. 2023 Jan-Dec;26(1):894-901. doi: 10.1080/13696998.2023.2232256. PMID: 37415496.*
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[xv] *Skin grafts may help heal diabetic foot ulcers and reduce amputations. Metabolics Hormones and Diabetes 19.04.16 doi: 10.3310/signal-000227*
[xvi] *Frykberg RG, Marston WA, Cardinal M. The incidence of lower-extremity amputation and bone resection in diabetic foot ulcer patients treated with a human fibroblast-derived dermal substitute. Adv Skin Wound Care 2015; 28 (1): 17–20.*
[xvii] *Veves A, Falanga V, Armstrong DG, Sabolinski ML, Apligraf Diabetic Foot Ulcer S. Graftskin, a human skin equivalent, is effective in the management of noninfected neuropathic diabetic foot ulcers: a prospective randomized multicenter clinical trial. Diabetes Care 2001; 24 (2): 290–5.*
[xviii] *https://www.cms.gov/medicare/regulations-guidance/advisory-committees/hospital-outpatient-payment*
[xix] *(CMS. Guidance for the public, industry, and CMS staff National Coverage Determinations with data collection as a condition of coverage: coverage with evidence development. July 12, 2006. Accessed October 10, 2023. https://www.cms.gov/ medicare/coverage/determinationprocess/downloads/ced.Pdf*
[xx] *CMS. Guidance for the public, industry, and CMS staff: coverage with evidence development. November 20, 2014. Accessed October 10, 2023. https://www.cms.gov/medicare- coverage-database/view/medicare-coverage-document. aspx?MCDId=27, CMS. (Proposed) coverage with evidence development. Proposed guidance document. June 22, 2023. Accessed October 10, 2023. https://www.cms.gov/medicare- coverage- database/view/medicare-coverage-document. aspx?mcdid=35&docTypeId=-1&sortBy=title&bc=16)*
[xxi] *Zeitler E, Gilstrap L, Coylewright M, et al. Coverage with evidence development: where are we now? Am J Manag Care. 2022;28(8):382-389. doi:10.37765/ajmc.2022.88870*
[xxii] *Ibid.*
[xxiii] *https://www.woundcarestakeholders.org/images/June_29_2021_Alliance_Letter_to_NCCI_Contractor.pdf*
[xxiv] *https://www.woundcarestakeholders.org/images/NCCI_letter_-_10.3.21.pdf*
[xxv] *https://www.woundcarestakeholders.org/images/ncci_April_3_2022_Letter_to_NCCI_final.pdf*
[xxvi] *https://www.cms.gov/regulations-and-guidance/guidance/manuals/downloads/ncd103c1_part4.pdf*
[xxvii] *https://www.cms.gov/files/zip/medicare-ncci-2025q1-practitioner-services-mue-table.zip.*
[xxviii] *https://www.woundcarestakeholders.org/images/Final_Comments_-_CMS_draft_2025_Physician_Fee_Schedule_-_9.7.24.pdf*