ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

August 12, 2019

Administrator Seema Verma
Centers for Medicare and Medicaid Services
Department of Health and Human Services
Attention: CMS-6082-NC
Mail Stop C4-26-05
7500 Security Boulevard
Baltimore, MD 212244-1850

Re: CMS-6082-NC- Patients Over Paperwork – Request for Information

Submitted Electronically via www.regulations.gov

Dear Administrator Verma:

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we are submitting comments to CMS' Request for Information regarding Patients over Paperwork related to reporting and documentation requirements, coding and documentation requirements for Medicare or Medicaid payments as well as prior authorization procedures. The Alliance is a not-for-profit multidisciplinary association of specialty societies, patient associations, and business entities whose mission is to promote evidence-based quality care and services for people with chronic wounds (diabetic foot ulcers, venous stasis ulcers, pressure ulcers, arterial ulcers and other hard to heal wounds). Over the years we have seen and experienced several issues related to documentation requirements as well as coding and documentation requirements that are not only a burden to our practicing clinicians, but also they have impacted patient care. We appreciate the opportunity to provide our suggestions for change. A complete listing of our members can be found at http://www.woundcarestakeholders.org/about/members).

GENERAL COMMENTS

Wound care is a national epidemic masked by co-morbidities. Chronic wounds impact nearly 15% of Medicare beneficiaries (8.2 million patients). If we include wounds as a secondary diagnosis, the cost for wounds may range from $31.7 billion to $96.8 billion (Nussbaum, Carter, Fife et al. ISPOR, *Value in Health* 2018).

Patients with chronic wounds heal differently and require treatment that is individualized. Variations in wound characteristics, such as depth, location, size, presence of ischemia/infection, malnutrition, etc., determine what care and treatment modalities are necessary to heal a specific patient's wounds. These patients have high rates of readmission, total cost of care, lengths of stay, and antibiotic utilization. Those with chronic wounds often have multiple co-morbidities such as diabetes, heart failure, chronic kidney and vascular disease, and their bodies respond differently at various times to various wound healing components.

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The age of the wound, severity of the underlying venous disease and comorbid conditions, frequency of debridement, patient follow-up intervals, and receipt of and compliance with supportive measures such as 4-layer effective compression bandaging (for venous leg ulcers) or off-loading devices (for diabetic foot ulcers), are important factors in wound healing.

With wound care being costly to the Medicare program as evidenced above, the Alliance offers specific information and recommendations for your consideration to help ease the burden on providers, allowing them to be able to provide the necessary care to their patients, and reduce costs to the Medicare program.

SPECIFIC RECOMMENDATIONS

NCCI Edits

The Alliance requests changes to the Correct Coding Edits for physicians and for the Medicare hospital outpatient Prospective Payment System (PPS) for select procedures related to the treatment of complex wounds [e.g. venous, arterial, diabetic and pressure ulcers and complicated surgical wounds]. We submit that the edits described below are impeding delivery of evidence-based treatment for these wounds and forcing increased numbers of provider visits to provide the appropriate care for their patients. We believe this is more costly to the Medicare system and needs to be corrected.

The Alliance is concerned that the current edits impede the application of evidence-based wound care at a single patient encounter. Because of the edits, clinicians and facilities are forced to choose between appropriate care delivery and adequate compensation for the care they deliver. The current CCI edits are contrary to best practice care as documented in evidence-based guidelines for the treatment of diabetic foot wounds, venous ulcers and many other complex wounds. We believe our request for edit changes will ensure adequate treatment is provided for the optimal healing of complex wounds. There are general and specific issues to be raised with respect to this issue.

General NCCI Edit Issues

Specifically, the grafting procedures [CPT® 15000 series] have edits in place when a total contact cast or compression therapy is applied during the same procedure visit. Total contact casting and compression therapy are distinct, separate procedures. Grafting may precede the application of a total contact cast or compression therapy for wounds which are not progressing with standard wound management or for large wound defects which need to be closed. These procedures are commonly required during the same office or clinic visit.

Evidence-based treatment of a grafted diabetic ulcers requires offloading the graft area such as with application of a total contact cast [CPT® 29445] to protect the investment of the graft and optimize healing. Evidence-based treatment for a grafted venous ulcer requires the application of compression therapy [CPT® 29580, 29581] to support venous return which reduces inflammation for optimal healing of the graft site.

The grafting procedure codes do not include a RVU allocation for professional time for either total contact casting or compression therapy application, nor do they include an allocation for the medical supplies needed for these treatments. The AMA revisions for 2012 to the Skin Replacement Surgery CPT® codes [15271 -

15278] for grafting also will not have allocations for compression therapy or total contact casting, therefore these codes need to be considered as part of this edit change review. For example, this includes the instances when the compression products are used on the same day as the application of skin substitutes (the new codes are: 15271-15278).

Debridement typically is medically necessary for several weeks during treatment of complex wounds with devitalized tissue and may be performed prior to an application of a total contact cast or compression therapy. This is to ensure all necrotic tissue is removed from the wound to prevent wound deterioration, infection and slowing of the healing process. Removal of devitalized tissue from complex or chronic wounds is evidence-based wound care and is often required prior to the application of a total contact cast procedure [CPT® 29445] or application of compression therapy [CPT® 29580, 29581].

However, the current CCI edits, both in the physician office and the outpatient client setting, deny billing and payment for both procedures when performed at the same site at the same patient visit. Currently a surgical debridement (CPT® 11042-11047) or active wound care debridement (CPT® 97597-97598) if billed as the primary procedure during the same visit as a total contact casting procedure (CPT® 29445) or compression therapy [CPT® 29580, 29581], has an edit in place. Edits indicate the second procedure is either included in the first or not billable. Debridement codes do not include an RVU allocation for professional time or supplies for either total contact casting or compression therapy application because neither are the 'usual' associated medical procedures after every debridement.

Diabetic foot wounds are among most common complications of diabetes mellitus. Delayed healing of diabetic ulcers can decrease patient mobility, reduce quality of life, and increase the risk of amputation. Sixty to seventy percent of diabetics have nerve damage which allows them to continue to traumatize their injured foot. As such, offloading a diabetic foot wound with total contact casting has been shown to be a gold standard for healing diabetic foot ulcer quickly, which avoids complications and the risk of amputation, while saving significant health care dollars.

With one percent of the population suffering from leg ulcers with three percent for those 60 years of age or older, healing these wound efficiently with debridement of devitalized tissue, when required, is critical. Improving venous return with compression, the cornerstone of evidence-based treatment for these frequently occurring chronic wounds, has been well documented in the literature and is cost-effective.

The CCI edits need to be corrected to allow the correct medical management for complex wounds which require debridement and/ or grafting and the application of total contact casting or compression therapy, as indicated in evidence-based guidelines and the literature.

Specific NCCI Edit Issues

Issue 1:

There are issues in the Physician CCI edits when debridement [CPT® 11042-11047, 97597, 97598] is the primary procedure, and a secondary total contact casting procedure [CPT® 29445] is used.

In the CPT® instructions under Application of Cast and Strapping, the section defines the appropriate use of cast and strapping codes and states:

The listed procedures apply when the cast application or strapping is a replacement procedure used during or after the period of follow-up care, or when the cast application or strapping is an initial service performed without a restorative treatment procedure(s) to stabilize or protect a fracture, injury, or dislocation and/or afford comfort to a patient. Restorative treatment or procedure(s) rendered by another physician following the application of the initial cast/splint/strap may be reported with a treatment of fracture or dislocation code.

A physician who applies the initial cast, strap, or splint and also assumes all of the subsequent fracture, dislocation or injury care cannot use the application of casts and strapping codes as an initial service, since the first cast/splint or strap application is included in the treatment of fracture and/or dislocation codes.

Restorative fracture and/or dislocation procedure CPT® codes include debridement and an initial cast in the RVU calculations for payment. Therefore, the current edits make sense for application of restorative fracture and/or dislocation procedures. However, neuropathic tissue injury (wound) or neuropathic Charcot fractures conditions have no initial fracture and/or dislocation procedure (code) that is required, hence the cost for a surgical debridement is not calculated into the total contact casting CPT® 29445 code. **Not every application of a total contact cast requires a debridement; therefore it has not been included in the CPT RVU calculations. Without this change, providers are forced to debride the wound at one visit and apply the total contact cast at another visit to adequately manage their patient's medical condition and be appropriately be compensated. This needs to be corrected to ensure cost effective and timely treatment.**

Issue 2

In the CCI OCE edits for hospital clinics, debridement codes [CPT® 1104X series and CPT® codes 97597, 97598] when used with total contact casting [CPT® 29445] have similar edits as those for CCI Physician edits.

The Alliance recommends removing the current OCE edits for debridement codes CPT® 11042-11047, 97597, 97598 when used in conjunction with total contact casting CPT® code 29445.

Issue 3

The CCI OCE edits and CCI Physician edits for the applications of zinc paste and multi- layer compression [CPT® codes 29580 and 29581] for treatment of venous ulcer injury, include edits disallowing billing with grafting procedures [15XXX series] during the same visit.

This is not consistent with evidence-based clinical practice for venous ulcer injury which includes the application of compression therapy to support adequate venous return and reduce edema; both are required for a successful graft take and promotion of healing for a venous ulcer.

The Alliance recommends removing the current edits for grafting procedures [15XXX series] and ensure the Skin Replacement Surgery CPT codes [15271 -15278] for grafting are not assigned edits when used in conjunction with compression CPT® code 29580 and 29581 during the same visit.

Issue 4

All grafting procedures codes [CPT® 15XXX series] have edits disallowing use with total contact casting [CPT 29445] for both the Physician CCI edits and the ODE outpatient clinic.

If a grafting procedure is performed for a diabetic or neuropathic injury and a total contact cast is applied immediately to offload the site from further injury, the edit will not allow billing of the total contact casting procedure [CPT® 29445]. This is not consistent with evidence-based clinical practice and would force a second visit to the clinic to adequately offload the grafted area. Grafting and total contact casting are distinct procedures. Grafting codes do not have physician time or supply RVUs calculations included for total contact casting.

The Alliance recommends removing the current edits for grafting procedures [15XXX series] and ensure the Skin Replacement Surgery CPT codes [15271 -15278] for grafting are not assigned edits when used in conjunction with total contact casting, CPT® code 29445.

Issue 5

The Alliance believes Modifier -59 is appropriate for identifying the application of compression therapy or total contact casting, as separate, distinct procedures after either wound debridement [CPT® 11040 series and 97597, 97598] and/ or after grafting procedures [CPT® 15000 series]. This has not been universally applied to billing procedures by the Medicare contractors. The professional time or expense allocation RUVs for total contact casting or compression therapy are not included in the debridement procedures or grafting procedure codes.

The Alliance recommends immediately approving the use of Modifier -59 by all Medicare contractors to the current edits described in this request and maintain active use.

The CCI edits need to be corrected so as to allow the correct medical management for complex wounds which require debridement and/ or grafting and the application of total contact casting or compression therapy, as supported in evidence-based guidelines and the literature.

The Alliance requests that the edits provided are removed to ensure providers can deliver appropriate care at a single patient encounter rather than schedule multiple visits to provide appropriate evidence-based treatment. This will allow more cost efficiency and provide savings for Medicare and the patients.

HCPCS Coding Reform

Since CMS aims to increase quality of care, lower costs, improve program integrity, and make the health care system more effective, simple and accessible, we would ask that the Agency consider our recommendations

for reform of the process used by it to assign new Healthcare Common Procedure Coding System (HCPCS) Level II billing codes to durable medical equipment, prosthetics, orthotics, and supplies (DMEPOS).

We submit that the HCPCS Level II Coding Process needs reform since it currently is not transparent, understandable or predictable. Over many years, this has created strong barriers to appropriate coverage and reimbursement for new technologies and products. The current process has a chilling effect on innovation that drives researchers and R&D investments away from DMEPOS, ultimately compromising access to quality care for millions of Medicare beneficiaries and other individuals. Although this process is administered by the Centers for Medicare and Medicaid Services, this badly flawed process impacts Medicare and all payers using the uniform code set. Reform is needed to ensure the goals of a meaningful code set are met, namely, uniformity in billing, appropriate coverage and reimbursement policies, and patient access to quality care.

The Alliance has worked with CMS officials responsible for the HCPCS code set over the past decade to improve this process. Unfortunately, to date only incremental changes have been made that do not address the more significant deficiencies with the process. The need to make these improvements stems from a longstanding history of concerns with the HCPCS Level II coding process. Despite repeated discussions with CMS staff over the years, our concerns with the HCPCS Level II coding process persist—leaving clinicians, manufacturers, payers and most importantly, patients, with a coding system that inadequately describes the products that are being provided and billed.

A prioritized list of recommendations that we would like CMS to consider in making improvements include the following:

1. Increase transparency of coding decisions and adopt procedural protections to enable stakeholders to participate in the coding decision process, including a mechanism for stakeholders to respond to coding decisions. We further recommend the creation of a HCPCS Level II Coding Advisory Committee to assist the HCPCS Coding Workgroup;

2. Clearly separate the criteria used to establish a new HCPCS code (or verify use of an existing code) from criteria used to establish a coverage policy for the product(s) described by that code. Coverage criteria should never be considered when making coding decisions;

3. Establish a transparent appeals process to provide an independent review or reconsideration of coding decisions; and

4. Improve the coding verification process used by the Medicare Pricing, Data Analysis and Coding contractor (the "PDAC"), as well as the CMS-initiated code revision process (e.g., for internal or modifying code descriptor).

LCDs vs LCAs

A baseline issue that the Alliance believes must be resolved is the scope of a Medicare Administrative Contractor's Coverage Article (LCA) versus information that is contained in a Local Coverage Determination (LCD). A LCA cannot substitute for an LCD and cannot restrict Medicare coverage. yet the

MACs are in fact placing policy within a coverage article in order to circumvent the notice and comment period.

Congress has defined an LCD as "a determination by a fiscal intermediary or a carrier under part A or part B, as applicable, respecting whether or not a particular item or service is covered on an intermediary-or carrier-wide basis under such parts, in accordance with section 1395y(a)(1)(A) of this title." 42 U.S.C. §1395ff (f)(2)(B). Section 1395y (a)(1)(A) refers to the "reasonable and necessary" standard for Medicare coverage. Neither the Medicare statute nor CMS's regulations ever mention Coverage Articles.

CMS has developed specific LCD procedures for a MAC to follow whenever it proposes to exclude an item or service in all cases rather than when a MAC is denying a claim on medical necessity grounds on a case-by-case basis; these LCD procedures include a formal public notice-and comment process. The most recent version of the LCD procedures is set out in Chapter 13 of the Medicare Program Integrity Manual, which implements the revisions to the LCD process enacted by Congress in the 21st Century Cures Act; the Manual revisions took effect on September 26, 2018. Most notable is that Coverage Articles are not discussed in this or any previous iteration of the Program Integrity Manual, nor is there any exception that would allow a Coverage Article to change Medicare coverage or would allow a Coverage Article to be a substitute for an LCD to deny coverage.

The distinction between informal interpretations such as Coverage Articles (that can be issued unilaterally by a MAC and do not require public notice and comment) and formal changes in Medicare coverage or reimbursement is embedded in the Medicare statute. Since 1987, Congress has set a specific standard that requires public notice and comment whenever there is any (1) "rule, requirement, or other statement of policy" that (2) "establishes or changes" (3) a "substantive legal standard" that (4) governs "payment for services". 42 U.S.C. § 1395hh(a)(2). This standard that requires notice-and-comment rulemaking in a wider range of circumstances was endorsed by the United States Court of Appeals for the District of Columbia Circuit. *Allina Health Services v. Price*, 863 F.3d 937 (D.C. Cir. 2017), *cert. granted* (No. 17-1484, Sept. 27, 2018). Although this statute contains an exception to the notice and comment process for Medicare National Coverage Determinations, the logical reason for this exception is that the NCD process (and by analogy the LCD process) already requires public notice and comment as set out in public notices and in Medicare manual provisions.

As an example, Noridian made substantive policy changes in 2018 (reducing coverage) in an LCA. (Use of Amniotic Membrane Derived Skin Substitutes (A56155) and (A56156) They improperly achieved the same goal as an LCD because they state comprehensively that the use of amniotic membrane derived skin substitutes for treatment of any condition other than a DSU or VSU is "not reasonable and necessary and non-covered." There are no exceptions.[2] This new coverage restriction did not go through the notice and comment period that the public is afforded when this type of restriction of coverage is issued in an LCD. The LCA issued by Noridian was not a clarification of an existing policy or CMS regulation already in effect. Rather, the Coverage Article created a new substantive standard for Medicare coverage.

Congress and CMS have specified that when a MAC determines that throughout its jurisdiction it will not cover an item or service, the LCD process that includes public participation is *the exclusive vehicle*. Otherwise, the LCD process that includes public notice and comment could be improperly circumvented or ignored routinely, which is contrary to Congress's and CMS's intent.

When CMS or a CMS contractor intends to create a rule that restricts Medicare coverage or creates a new standard that affects coverage, it must follow a public notice-and-comment process that includes evaluating the information provided by interested parties. While this issue is not a coding or documentation issue, when the process is not followed properly, it does place a burden on providers and the patients that they treat.

Prior Authorization

While the Alliance understands and support the need to reduce improper payments in the Medicare program, and supports appropriate utilization management to promote the delivery of value-based care, we are concerned with the added burden that prior authorization places on clinicians as well as the impact it has on the patients they treat. By its very nature, prior authorization questions the clinician's judgment and furthermore removes the decision making from clinicians and their patients to administrators who do not have first hand knowledge of the patients or their condition.

Prior authorization creates an undue burden on providers, impacts patient access to medically necessary services used by Medicare exponentially increase administrative burden and the possibility of inadvertent error while simultaneously adversely impacting patient access to medically necessary services and creating a systematic focus on volume of services.

Patients often must undergo a prolonged, burdensome process to obtain treatment authorizations. A delay in authorization may severely hinder a patients recovery. It is vital that future approaches that support prior authorization recognize a clinicians ability to render patient-centered care using evidence-based guidelines, clinical judgment and decision-making, and full scope of licensure. This would help ensure timely patient access to medically necessary services and streamlined administrative processes.

Additionally, there is no consistency regarding prior authorization from one jurisdiction to another. Instructions for obtaining prior approval for current and ongoing patients are unclear and inconsistent between one jurisidiction and another. Therefore, to reduce clinician burden and promote standardized data collection, the Alliance recommends that standard language is incorporated within CMS contracts with their contractors requiring them to adopt a prior-authorization process in which all prior authorizations, whether submitted directly to an MA insurer or to a Medicare subcontractor, are submitted through an electronic portal (consistent portal framework) using the same standardized form (developed by CMS, which undergoes official notice and comment so stakeholders can submit their feedback). Under such a process, the MA insurer or subcontractor would be required to approve or deny an authorization within a set timeframe, such as 24 or 48 hours, allowing 72 hours for the provider to appeal, again through a similar electronic portal, or risk being in violation of its contract with CMS. If the insurer or subcontractor fails to reply within the timeframe, then the authorization would be granted. This type of process would allow the payer to use algorithms to be reviewed by stakeholders including professional associations to identify the most blatant instances of abuse and would allow for proper, timely care to beneficiaries.

To ensure that patients continue to receive high-quality care and avoid rejecting or limiting medically necessary services, CMS should consider exempting from prior authorization patient populations with certain conditions and clinicians who participate in standardized data collection systems and are willing to share outcomes; requiring the use of specific performance-based outcome measures; and/or requiring the collection of patient-reported outcome measures that have clinical utility and importance that are meaningful to a

diverse set of provider types.

Billing for Disposable Negative Pressure Wound Therapy in the Home Health Care Setting

The Alliance would like to raise a concern regarding the process established by the Centers for Medicare and Medicaid Services (CMS) for billing disposable negative pressure wound therapy (dNPWT) in the home care setting. As part of the Consolidated Appropriations Act, 2016, Congress intended to give seniors access to a cost-effective, clinically efficacious, and convenient alternative to traditional, canister-based NPWT. Since the launch of this benefit in 2017, however, home health agencies (HHAs) have struggled to secure payment for dNPWT due to a burdensome CMS billing process.

While the Alliance has raised issues in our comments regarding this issue in the past, CMS did not address this concern in the proposed Home Health PPS rule. As such, we are raising this issue again so the Agency can consider resolving this burden on providers through the Patients over Paperwork initiative. Two decisions made by CMS during implementation of payment for dNPWT at home created unnecessary burdens, slowing adoption by HHAs to the detriment of the patient with a wound. The first is a requirement to submit charges on a TOB 34x—which is rarely used within our industry—instead of the industry standard TOB 32x. This creates a barrier to patient access, due to the additional back office burden placed on HHAs that provide this technology. This is exacerbated by billing software that does not allow for easy billing of dNPWT.

The second problem is that HHAs can receive credit for a home health visit during which dNPWT is applied only if a second condition is treated during the same visit. This creates a disincentive to provide dNPWT, as HHAs do not want to jeopardize prospective payment with treatments that are not counted toward the minimum threshold required for a full episode. HHAs are also required to separate time at the nursing level to differentiate between furnishing dNPWT and time spent on caring for a patient's other conditions, creating additional confusion for nurses.

In order to improve patient access to this technology while reducing provider burden, we recommend that CMS implement a couple of process reforms. First, we recommend that CMS allow HHAs to report—and receive separate payment for dNPWT on TOB 32x. This would allow HHAs to submit only one bill for patients treated with this technology. It would also harmonize billing on the standard billing form. Second, we recommend that CMS count the application of dNPWT as a home health visit. Taken together, these two changes will decrease unnecessary burdens on caregivers, and remove barriers to access for their wound care patients.

Timing of Rules Issued by CMS

Finally, the Alliance appreciates that CMS included a specific question on the timing of rules and how to simplify them to reduce the burdens and barriers to compliance for clinicians. First, the Alliance would like to applaud CMS for providing language in some of the final rules which states, “Final Action” when provisions within a regulation have been issued in final and have been tagged as such by the Agency in the final rule. This allows clinicians to quickly assess what they need to know without reading through the entire regulation – which is confusing and often extremely long. The Alliance recommends that CMS continue to utilize this method in all regulations issued in final by the Agency.

However, the Alliance also would like to address the timing of rules being issued. Often final rules are issued late without adequate time for stakeholders to implement the massive amount of changes that are often reflected in provisions contained in the final rule. CMS seems to be issuing regulations later and later which is causing a huge burden on providers. The Alliance recommends that CMS issue regulations on a more timely basis and furthermore, if significant changes are being made, allow adequate time for implementation. This implementation time schedule should be built into the rulemaking – providing stakeholders the opportunity to comment on the timeframe for implementation.

Conclusion

On behalf of the Alliance of Wound Care Stakeholders, I appreciate the opportunity to provide some of our concerns along with our recommendations. Thank you in advance for your consideration. I can be reached at 301-530-7846 or marcia@woundcarestakeholders.org.

Sincerely,

Marcia Nusgart, R.Ph.
Executive Director