



December 16, 2019

Honorable Representative Diana DeGette  
2111 Rayburn House Office Building  
Washington, DC 20515

Honorable Representative Fred Upton  
2183 Rayburn House Office Building  
Washington, DC 20515

Dear Representatives DeGette and Upton,

On behalf of the Alliance for Wound Care Stakeholders (“Alliance”), we are pleased to offer our recommendations on how reform of Medicare coding, coverage and payment could better support patients’ access to innovative therapies. The Alliance is a nonprofit multidisciplinary trade association of physician specialty societies, clinical and patient associations whose mission is to promote evidence-based quality care and access to products and services for people with chronic wounds (diabetic foot ulcers, venous stasis ulcers, pressure ulcers and arterial ulcers) through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. We believe your initiatives are extremely important and would like the opportunity to meet with you to discuss our concerns and recommendations in January 2020.

Since appropriate coverage, coding and payment is the key for innovation of medical devices and biologicals uses in the chronic wound care industry, the Alliance has been at the forefront to submit comments to CMS and its contractors and commercial payers and MEDPAC to advocacy for sound policies. Some of our concerns and recommendations include the following:

## **1. Contractor coverage issues that need revising from 21<sup>st</sup> Century Cures**

The Alliance believes that one issue that must be resolved is that the scope of a Medicare Administrative Contractor’s (MAC) Coverage Article (LCA) versus information that is contained in a Local Coverage Determination (LCD). An LCA cannot substitute for an LCD and cannot restrict Medicare coverage. Yet the MACs are in fact placing policy within coverage articles in order to circumvent the notice and comment period. For 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 in the policy 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.” 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.

We recommend that Cures 2.0 close the loophole regarding the MACs use of LCAs to restrict coverage without the appropriate notice and comment period.

## **2. Transparency in Coverage and Coding**

### *Coverage*

Obtaining coverage is critical for manufacturers to bring their products to market. Without it, there is a stifling of innovation. Unfortunately, there is little transparency in how much and what type of evidence is necessary for both commercial and government payers to give positive coverage decisions for devices and procedures. This is such a critical problem for our physician specialty society and clinical association members, researchers and manufacturers, that we are convening an Evidence Summit in Washington DC April 1-2 2020 to shed some light on these requirements. Information about the meeting can be found on our website <https://www.woundcareholders.org/meetings/wound-care-evidence-summit/event/1>. We would welcome you as a speaker for our meeting on either day. We can discuss this more fully when we meet in January.

### *Coding*

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.

## **3. The Use of Real World Evidence**

One of the areas in which you are seeking specific feedback with regards to Cures 2.0 is in the use of Real World Evidence (RWE). The Alliance has long been a proponent of RWE – especially in wound care. We demonstrated this in our article [“Consensus Principles for Wound Care Research Obtained Using a Delphi Process”](#) (Wound Rep Reg (2012) 20 284–293 © 2012 Wound Healing Society) where one of our principles are “National or formal wound registries should be developed with real-world data collection.”

Patients with chronic wounds have serious co-morbid conditions that distinguish them from the patients of wound care RCTs. Several factors can be defined that increase the duration and cost of wound care including wound etiology, as well as specific patient factors. These patient factors likely impact the effectiveness of advanced therapeutics in ways that cannot be ascertained by RCTs.

Currently, Medicare contractors request RCTs for coverage of products in their wound care Local Coverage Determinations (LCDs). However, RCTs are not practical in wound care delivery. Patients

with chronic wounds have serious co-morbid conditions that distinguish them from the subjects of wound care RCTs. Several factors can be defined that increase the duration and cost of wound care including wound etiology, as well as specific patient factors. These patient factors likely impact the effectiveness of advanced therapeutics in ways that cannot be ascertained by RCTs.

RCTs are not able to evaluate the effectiveness of a wound care product or intervention, since more than half of patients are excluded from participation which greatly diminish the applicability of RCT results to the greater population as well as evidence-based medicine. We believe that the practice of wound care should be based on real-world evidence, which is the direction in which the FDA is currently moving, and we hope that more focus is placed on the use and incorporation of this type of data collection and hope that Cures 2.0 addresses this issue.

In 2005, the US Wound Registry (USWR) was created. The USWR is an ideal tool for comparative effectiveness research in wound care because it includes real world patients often excluded from RCTs and reflects actual practice. The USWR evaluated the exclusion criteria of all major randomized controlled trials (RCTs) performed in wound care over a decade (1998-2008). It compared those exclusion criteria with the co-morbid conditions, wound characteristics and medications documented among 3,201 patients in 18 hospital based outpatient wound centers. Its findings were that **approximately 75% of real world patients would have been excluded from every major wound healing RCT that brought new products to market over that decade at the “first pass” before study related laboratories or tests would have been performed.**

Through its work, the USWR has confirmed what the Alliance has been stating our comments to regulatory agencies and Medicare Administrative Contractors (MACs) - **RCTs are not able to evaluate the effectiveness of a wound care product or intervention, when more than half of patients are excluded from participation, greatly diminishing the applicability of RCT results to real world populations and evidence based medicine.**

In terms of improving health outcomes, the best way to ensure that outcomes are achieved is to collect data to determine gaps in practice and then implement performance based payment. We believe that registry data can be utilized to ascertain this information. However, while CMS has implemented the Merit-Based Incentive Payment System (MIPS) and alternative payment models (APMs), there are no performance-based measures specific to wound care. We have provided more information below on this issue; however, we have concerns that when clinicians can “cherry pick” the measures they report (and are not mandated to report on the specific services being performed) – and other care providers are involved who cannot report or may only voluntarily report – there is a disconnect between what is being done and what should be done when performance- based payment is not specifically tied to the services being performed.

We strongly support the continued development of quality measures that assess wound care outcomes, as wound care clinicians should be required to report on measures that relate to the care being delivered. While the Alliance recognizes there are some quality measures specific to wound care, because wound care is not a “specialty,” clinicians currently can “cherry pick” the quality measures they report. The ramifications of such selection are:

- Those that report are providing the care to wound care patients and therefore reporting on the wound care quality measures as they use them to score positively.
- Since reporting on wound care quality measures is not mandatory under MIPS, clinicians who will not score well on the wound care quality measures will choose to report other measures that are more favorable to their performance.
- When all clinicians do not report measures and only those that will score well do, CMS comes to the conclusion, albeit erroneous, that there are no gaps in practice when they look at the data for those clinicians who reported.
- CMS will eliminate measures when the agency finds these measures are “topped out.” However, the only manner by which the agency can ensure that high-quality wound care is being delivered is to require that wound care measures are reported.

As such, any provider that delivers wound care services should be required to report on wound care quality measures. **If this requirement is mandatory, then additional measures will need to be created to ensure that any care in treating a patient with a wound is being represented in the quality measure set being reported.**

The documentation of the specific, significant burden of chronic wounds in the Medicare population illustrates the need for CMS and health policy makers to **include wound- relevant quality measures in all care settings as well as develop episode of care measures, chronic care models, and reimbursement models to drive better health outcomes and smarter spending in the wound care space.**

As stated above, we would appreciate the opportunity to meet with you and your staff to discuss our concerns and recommendations on the critical issues of coding, coverage and payment. We will contact you in January 2020 to set up an appointment to discuss this important matter. If you have any immediate questions or would like more information, please feel free to contact me or our Executive Director, Marcia Nusgart.

We wish you the happiest of holidays!

Sincerely,



Karen Ravitz, JD  
Senior Health Care Policy Advisor