



Alliance of Wound Care Stakeholders Comments Regarding for the USP Drug Classification (USP DC) 2021

My name is Marcia Nusgart and I serve as the founder and executive director of the Alliance of Wound Care Stakeholders. Dr. Matthew Garoufalis and I had the pleasure of speaking to USP staff Diane Kwan and Donna Bohannon on October 6 2020 to address the need for the USP to include a subcategory under dermatology for wound care in the USP DC. I am again attaching the presentation that we used at that time.

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 including diabetic foot ulcers, venous stasis ulcers, pressure ulcers and arterial ulcers. We achieve this through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. Our clinical specialty societies and organizations not only possess expert knowledge in treating complex chronic wounds, but also in wound care research.

Wound care is a national epidemic masked by co-morbidities. A landmark study, “An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds” published in *Value in Health* January 2018 stated that 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 per year.¹ The importance of this study is it shows that the **hospital outpatient settings** drove the greatest proportion of costs – demonstrating a **major shift in costs from hospital inpatient to outpatient settings**.

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.

Therefore, it is imperative that if someone develops a diabetic foot ulcer, pressure ulcer or venous stasis ulcer, it needs immediate attention. One of the first lines of treatment is the use of surgical dressings and drugs applied to the chronic wound. It is our understanding that in the USP DC and the USP MMG wound care products are in the “Dermatological, Other” category and this includes a long list of products for a variety of conditions with varying severity. We respectfully request that the USP add a subcategory titled “wound care” under dermatology rather than keeping these products in the “Dermatological, Other category” for the following reasons:

1. Distinguish the products that are used to treat chronic wounds due to severity and increased morbidity, mortality and economic burden associated with them.

¹ Nussbaum, Carter, Fife et.al. An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds, *Value in Health* Jan.2018.

2. Wound care products are distinct technologically and functionally from products typically used in dermatology that are often used to treat cosmetic and/or non-fatal conditions.
3. Ensure patient access to these important wound care products. With no subcategory for wound care, there may be access limitations placed on wound care prescription treatments. We know that on page 21 of Section 30.2.1- Formulary Categories and Classes of the CMS Part D Benefits Manual, it states that Part D sponsors are only required to place two drugs in each category/subcategory on the formulary. The consequence of this could be that leaving wound care products in the large and diverse “Dermatological, other” subcategory rather than in a distinct “wound care” one could result in a Part D plan excluding all wound care products on its formulary and still be compliant.

We appreciate your taking our request into consideration. Please call on us if we can be of help to you on this issue. I can be reached at 3015307846 or marcia@woundcarestakeholders.org.