ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

September 20, 2018

Richard Migliori, M.D.
Executive Vice President, Medical Affairs and Chief Medical Officer United Health Group
Wendy MacLeod, M.D.
National Medical Director
William O'Bryant, M.D.
Senior Medical Director, Clinical Coverage Review
United Health Care
9700 Health Care Lane
Minnetonka, MN 55343

Via USPS and submitted electronically

RE: Skin and Soft Tissue Substitutes (Policy number 2018T0592A)

Dear Drs. Migliori, MacLeod and O'Bryant;

On behalf of the Alliance of Wound Care Stakeholders ("Alliance"), we request that United Healthcare (UHC) delay implementation of Commercial Medical Policy 2018T0592A, Skin and Soft Tissue Substitutes, scheduled to become effective October 1, 2018. Our concern is that this Policy, if enacted, will cause significant disruption in the care of your members in outpatient, hospital, rehabilitation, skilled nursing and other settings who are currently receiving skin and soft tissue substitutes (hereafter referred to as CTPs[1]) for the management of their chronic wounds. We request a meeting with you to discuss our concerns, address issues regarding improvement in health outcomes with these therapies, and to offer recommendations that will serve to improve the clinical outcomes for your member patients at lower cost of care. Pending your consideration of the information and evidence that we would provide you in this meeting, we respectfully request that the implementation date of this Policy be reasonably postponed.

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). Our members (complete listing found at http://www.woundcarestakeholders.org/about/members) treat patients with hard to heal wounds using advanced treatment modalities that may include CTPs.

Wound care is a national epidemic masked by co-morbidities. Nearly 60 million people in the U.S. are living with diabetes or vascular disease, which are the leading causes of chronic wounds. Over 6.7 million patients suffer from non-healing advanced wounds, leading to unnecessary hospitalization and lower extremity amputations. Patients with chronic wounds have longer lengths of stay,

5225 Pooks Hill Rd | Suite 627S | Bethesda, MD 20814
T 301.530.7846 | C 301.802.1410 | F 301.530.7946
marcia@woundcarestakeholders.org

unplanned readmissions, and costs to treat. The U.S. spends in excess of $50 billion annually on treating chronic wounds, and a staggering $8 billion on amputation procedures alone. Fueled by an aging population, increased obesity, and a rising rate of diabetes, chronic wounds are projected to increase at a compound annual growth rate of nearly 3% over the next five years. While many patients heal with standard care, there are a significant number that require advanced treatment modalities, such as CTPs.

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. 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.[2]

By restricting coverage to only a few CTP options the Alliance believes that the proposed Policy may result in unintended consequences of increased product wastage and higher costs, including higher member patient co-pays. As such, we believe this proposed Policy will have substantial negative impacts on patient outcomes, quality of life, and cost of care. For example, patients with Wagner Grade II and above diabetic foot ulcers (DFUs) are more expensive to treat and are associated with higher risk for major lower extremity amputations[3,4], yet two of the CTPs covered by the proposed Policy are contraindicated by their respective FDA approvals for use on such severe complex wounds. Restricting CTP options that are indicated for the more severe wounds will lead to higher amputation and associated death rates[5,6]. Our practicing clinical members' concern is that by not providing coverage of CTP options that are indicated for the treatment of these more severe wounds, member patients may experience higher amputation and associated death rates. We respectfully ask that UHC pause and consider these clinical implications to its member patients before implementing a policy for CTPs.

The Alliance recognizes that large *n* RCTs on the use of CTPs are limited for the majority of CTP products. However, a major limitation with wound care studies is that patient co-morbidities often exclude subjects from evaluation in RCTs.[7] As RCTs limit co-morbid factors, which cannot be removed in the actual treatment of wound care patients, we suggest that UHC consider alternative clinical study forms in addition to its reliance on RCTs for developing wound care coverage decisions. RCTs only tell a part of the clinical outcomes story, as claims data shows that real world patients are often sicker than patients enrolled in RCTs. Given the historical reliance on RCTs for other UHC coverage decisions, the Alliance can understand how UHC arrived at its policy decision; however, we believe that the utilization of well-designed EHR data and registry data studies, with well matched cohorts for comparative outcomes analysis, would provide real world clinical outcomes data for making UHC coverage policies determinations. Because practicing clinicians are treating sicker patients with multiple co-morbidities that would fall outside of the patient types typically included in RCTs, clinicians often have to rely on this real-world data of retrospective studies based on EHR data or registry data to make treatment decisions.

For all the forgoing reasons, the Alliance respectfully requests that the implementation date of the proposed Policy be reasonably postponed. We further ask that UHC meet with the Alliance so that we can provide UHC with meaningful information and evidence to help guide its Policy on CTPs that we believe, as revised, will result in better clinical outcomes for your member patients at lower cost.

Thank you in advance for your consideration. I can be reached at 301-530-7846 or marcia@woundcarestakeholders.org.

Sincerely,

Marcia Nusgart R.Ph.

Marcia Nusgart R.Ph.
Executive Director

References

1. Please note that the Alliance led a multi-year effort that engaged clinical practitioners, scientists and manufacturers to come up with a consensus agreement to name this class of products Cellular and/or Tissue-based Products (CTPs) for skin wounds, which is a more clinically accurate descriptive term for these products. This was adopted by the standard setting organization ASTM which developed its unique standard guide (F3163-16)
2. *An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds;* Nussbaum, Samuel R. et al., Value in Health, 2017 http://www.valueinhealthjournal.com/article/S1098-3015(17)30329-7/pdf
3. Zhan, L. The Society for Vascular Surgery lower extremity threatened limb classification system based on Wound, Ischemia, and foot Infection correlates with risk of major amputation and time to wound healing. Journal Of Vascular Surgery Volume 61, Number 4.
4. Samson O. Oyibo, Mrcp, Edward B. Jude, Md, Ibrahim Tarawneh, Md, Hienvu C. Nguyen, Dpm, Lawrence B. Harkless, Dpm, Andrew J.M. Boulton, Mda Comparison of Two Diabetic Foot Ulcer Classification Systems The Wagner and the University of Texas wound classification systems DIABETES CARE, Vol 24, Number 1, January 2001.
5. Carls, G., et al. The Economic Value of Specialized Lower-Extremity Medical Care by Podiatric Physicians in the Treatment of Diabetic Foot Ulcers. Journal of the American Podiatric Medical Association March/April 2011, Vol 101, No 2 .
6. National Diabetes Statistics Report, 2017. Estimates of Diabetes and Its Burden in the United States. Center for Disease Control.
7. Carter MJ, Fife CE, Walker D, Thomson B. Estimating the Applicability of Wound-Care Randomized Controlled Trials to General Wound Care Populations by Estimating the Percentage of Individuals Excluded from a Typical Wound Care Population in Such Trials. Adv Skin Wound Care. 22: 316-24, 2009.