ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

SUMMARY OF COMMENTS AT MAY 20, 2014
CMS HCPCS PUBLIC MEETING
AGENDA ITEM #10 ATTACHMENT 14.010

I am Marcia Nusgart and serve as the executive director for the Alliance of Wound Care Stakeholders which is a multidisciplinary nonprofit association of health care clinical organizations whose mission is to promote quality care and access to products and services for people with wounds. The Alliance is a membership organization and receives membership fees from the clinical associations, non-clinical associations and business entities.

The Alliance strongly agrees with the preliminary coding decision in which CMS determined not to establish four new HCPCS codes or to categorize skin substitute products among the suggested four new A codes – which would be classified as dressings for the following reasons:

1. Skin substitutes or the more clinically appropriate term, Cellular and/or tissue based products for wounds (CTPs) are not surgical or wound dressings in the way they function, their clinical indications or their technology
2. CTPs are tied to a different payment method than surgical dressings – they are separately payable by their average sales product of a given product so that CMS is able to identify them and track them so as to set the packaging rates

To the first point, a surgical or wound dressing is a material that is utilized for covering and protecting a wound and helps shield the wound against the environment without exerting any direct biological effect. CTPs are products that all contain viable or non-viable cells and/or are derived from biological tissue with intrinsic biological activity, are usually not removed from the wound, are uniquely utilized for their biological influence on the healing process – whether they have a positive influence on the healing process without incorporation OR have the ability to stabilized or support healing through incorporation in whole or part into the regenerating tissue. None of the products in this category are dressings as suggested by the requestor.

In the 2014 CMS Hospital Outpatient PPS final rule, CMS states,

> *"Skin substitutes are a class of products that we treat as biological….. The term ''skin substitutes'' refers to a category of products that are most commonly used in outpatient settings for the treatment of diabetic foot ulcers and venous leg ulcers. Although the term ''skin substitute'' has been adopted to refer to this category of products in certain contexts, these products do not actually function like human skin that is grafted onto a wound; they are not a substitute for a skin graft. Instead, these products are*

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applied to wounds to aid wound healing and through various mechanisms of action they stimulate the host to regenerate lost tissue."

Furthermore, CMS states,

"We acknowledge that there are differences in composition among the various skin substitute products and that is why each is assigned a distinct HCPCS Q-code (or HCPCS C-code in some cases). If all of the products were identical, we would only need one code to describe all of them. Skin substitutes are those products that are used in wound healing procedures and that are typically assigned a HCPCS Q-code in the Q4100 series (or assigned a HCPCS C-code if OPPS pass-through payment status applies)".

To our second point, while CMS establishes individual Q codes for these products, there are several additional important reasons to have product specific codes assigned to them. CMS determines the pricing for these biological products based on the Average Sales Price methodology. Section 1847A of the Social Security Act states that a manufacturer is required to provide the unit of measure for their specific product along with the Average Sales Price for their products. Furthermore, the Carriers Claims Processing Manual Chapter 17 section 20.1.2 further elaborates that "the payment limit for a biological product will be based on the pricing information for products marketed or sold under the applicable FDA approval. As appropriate, a unique HCPCS code will be assigned to facilitate separate payment. Finally, a facility is required to utilize HCPCS codes on their claim forms to identify all services and products used in a procedure." Since these products, as CMS has stated in their own regulations, have different mechanisms of action – they need to be identified on the claim forms uniquely by their individual HCPCS Q code.

In summary, the Alliance is in agreement with the CMS HCPCS Workgroup's preliminary coding decision. We recognize that there may be questions from the Workgroup on the difference between surgical dressings and CTPs. We would once again welcome the opportunity to discuss any concerns and again serve as a resource for you in answering any questions in order to clarify the issues.