COALITION OF

Wound Care Manufacturers

November 6, 2014

Novitas Solutions
Medical Policy Department
Union Trust Building
Suite 600
501 Grant Street
Pittsburgh, PA 15219

Submitted electronically to: jackie.dunn@novitas-solutions.com

RE: DRAFT Local Coverage Determination (LCD) for Application of Bioengineered Skin Substitutes to the Lower Extremity for Chronic Non Healing Wounds (DL27549)

Dear Ms. Dunn:

On behalf of the Coalition of Wound Care Manufacturers ("Coalition"), I am pleased to submit the following comments in response to the draft LCD entitled, "Application of Bioengineered Skin Substitutes to the Lower Extremity for Chronic Non Healing Wounds ((DL27549)). The Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds including those products that are subject to this draft LCD. Since our members have a vested interest in the provision of quality, coverage and payment of Cellular and/or Tissue Based Products for Wounds (CTPs), this draft policy is of interest and concern to us. The Coalition appreciates the opportunity to offer our comments.

The Coalition commends Novitas in their decision to allow for these products to be covered based on the clinical decision making process of the clinician treating a patient with a chronic non-healing wound. However, the Coalition believes that the draft is confusing and contains inconsistent language. We highly recommend that any inconsistencies and/or confusing language be addressed and corrected prior to issuing this policy in final. The Coalition is a non-clinical, non-voting member of the Alliance of Wound Care Stakeholders. We are aware that they submitted comments on the clinical inaccuracies in this draft policy. We support their comments and request that Novitas implement their recommendations prior to this policy becoming final. Specifically,

- Novitas uses the term "bioengineered skin substitutes" in the title as well as throughout the draft to describe the products subject to this draft LCD. This term is not a technically accurate term and does not describe the technology that is either currently or will be in the marketplace for products that contain living cells or constitute tissue-based products intended for use in the management, treatment, or healing of skin wounds. Historically, these products have been referred to as "skin substitutes" in reference to their initial use as substitutes for skin grafts in clinical procedures. However, over time, the usage of these products shifted toward chronic

5225 Pooks Hill Rd. • Suite 627S
Bethesda, MD 20814
301 530 7846 T • 301 530 7946 F
marcia@nusgartconsulting.com
www.nusgartconsulting.com

ulcers where grafts are infrequently used and not standard of care. Moreover, newer products in this category may look nothing like skin and, indeed, have not been designed to function as skin replacements. Thus, there is a need to define terminology in the context of skin wounds as opposed to skin grafting procedures. As such, the Coalition recommends that Novitas adopt the term voted upon by the Alliance of Wound Care Stakeholders - "Cellular and/or tissue based products for wounds**"** ("CTPs") which does accurately describe and is broad and inclusive of both current and future technology.

- Clinicians use CPTs for non-healing wounds to achieve closure and avoid complications. The Coalition questions whether most of the products listed in this policy will be covered, even with including the patient's medical necessity documentation as part of the clinical decision-making. We recommend that Novitas utilize more straightforward language in the LCD. It is currently unclear whether Novitas will cover products listed in the policy and how Novitas will judge the supportive clinical evidence for each product used. If this is the case, then we would also recommend that Novitas clearly identify what evidence they are seeking and if a product meets those criteria, then it would be covered. While the Coalition definitely supports expanded treatment options for clinicians based upon their clinical decision-making – it is unclear in this policy whether this would in fact happen.

- Novitas uses the term "Biologic Wound Dressings" interchangeably with "Bioengineered Skin Substitutes". These are two separate and distinct product categories with different functions, regulatory clearances and coding pathways. A wound dressing is a material that is utilized for covering and protecting a wound, helping to maintain an optimal wound environment, and shield the wound against the environment. These products are identified under A-HCPCS codes by product category. Yet, CTPs are designated with a "Q Code" for each individual product based on their unique qualities and function. CTPs all contain viable or non viable cells and/or are derived from biological tissue with intrinsic activity, are usually not removed from the wound, are uniquely utilized for their influence on the healing process – whether they have a positive influence on the healing process without incorporation OR have the ability to stabilize or support healing through incorporation in whole or part into the regenerating tissue. Furthermore, dressings and CTPs are used differently clinically in treating wounds. Dressings are used as standard, conventional treatment. CTPs, however, are used as advanced therapy to influence the cellular response in the wound so as to aid in wound closure, when standard dressings have not been effective. All the products listed in this draft LCD are CTPs and are **NOT** wound dressings as they promote wound healing by interacting directly or indirectly with the wound bed.

- The Novitas policy is problematic in terms of how the products/categories are actually defined. The definitions of "Allografts," "Human Skin Allografts," and "Acellular Matrices" are confusing and misleading. For instance, in the definition of an "Allograft," the draft LCD specifically states "from human skin" which is exactly the same as the second category definition of "Human Skin Allograft". The term "Acellular Matrices" is limited to "derived from other than human skin". There are ample acellular matrices derived from human skin (e.g., Graftjacket, DermACELL, and AlloSkin AC]. Furthermore, it is unclear where amniotic

products that are acellular [e.g., Epifix (MiMedx), AlloWrap (AlloSource) Grafix Core/Prime (Osiris)] fit in to the classifications/definitions contained in the policy. These products are not composed of skin, but rather amniotic membranes. The Coalition recommends the elimination of the definitions contained in the policy. Should Novitas decide to include the language then the Coalition recommends that Novitas correctly define the product categories.

- While Novitas recognizes in the draft policy that HCT/Ps do not require PMA or 510K approval, there is still a statement in the draft policy that seems to preclude these products for reimbursement since they do not receive FDA "approval" for their proposed use. The Coalition is concerned about this and recommends that Novitas edit the draft policy language which reads, "each marketed product is required to have designated FDA approval for Medicare reimbursement for its proposed use" and instead utilize the following language, "each marketed product is eligible for Medicare reimbursement if it is provided in accordance with their proposed use."

- Novitas is inconsistent with their definition of chronic non- healing wounds. In some places Novitas defines a chronic wound as "A wound that fails to show evidence of healing by contraction and advancement of epithelial margins following 6 weeks of optimization", while in other places it states, will cover specialized wound therapy when a venous stasis ulcer fails to respond to documented appropriate care for greater than 2 months. Yet there is also a definition which states, "a chronic wound is a wound that does not respond to standard wound treatment for at least a 30 day period during standard conservative treatment". This inconsistency is problematic. The Coalition recommends that defining a chronic non healing wound as a wound that does not respond to standard wound treatment for 4 weeks is more consistent with the literature, and with all other LCDs and NCDs related to wound products, therapies and devices and as such should be adopted by Novitas throughout this policy.

- The utilization section is also inconsistent throughout the document. Novitas first states that the utilization of 3 or more applications of a skin substitute product in an episode of care (which previously was defined as 21 days) for all indications may be subject to prepayment medical review. However, Novitas also states in the limitations section, "one specific graft will be allowed in a 21 day period – unless it was per FDA guidelines". The LCD further discusses an "episode of care" as a 21day event and that the clinician can only apply one skin substitute per episode OR in compliance with FDA assessments and submitted guidelines for the specific product. This information is not only confusing and inconsistent - it conflicts with the judgment of the clinician based on the response of a wound. The Coalition recommends that Novitas simply revised their policy language to have clinicians follow the FDA labeling with respect to the utilization and application of these products. We also recommend that the documentation in the medical record support the use of the product.

The Coalition appreciates the opportunity to provide our comments. We hope that CMS will work with stakeholders to ensure a more balanced policy that truly is based on the decision making of the clinicians treating the patients with chronic non-healing wounds. If you need more information or have any

questions, please do not hesitate to contact me.

Sincerely,

Karen S. Ravitz, JD
Senior Policy Advisor
Coalition of Wound Care Manufacturers
301 807 5296