ALLIANCE OF
WOUND CARE
STAKEHOLDERS
POWER THROUGH COLLECTIVE ADVOCACY

April 22, 2015

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: Local Coverage Determination (LCD) for Application of Bioengineered Skin Substitutes to the Lower Extremity for Chronic Non Healing Wounds (L27549)

Dear Ms. Dunn:

The Alliance of Wound Care Stakeholders ("Alliance") is a nonprofit multidisciplinary trade association of health care professional specialty societies and associations whose mission is to promote quality care and access to products and services for people with wounds through effective advocacy and educational outreach in the regulatory, legislative, and public arenas. In reviewing the final LCD for the Application of Bioengineered Skin Substitutes to the Lower Extremity for Chronic Non Healing Wounds, L27549, we realized that there some issues that we would like to have clarified. Many of our members utilize Cellular and/or Tissue Based Products for Wounds (CTPs) in their practices as an adjunctive therapy when treating a patient with a chronic non-healing wound. As such, we have a vested interest in this policy and would appreciate receiving a written response to our issues.

First, the Alliance would like to applaud Novitas on utilizing the more clinically appropriate term for skin substitutes-- cellular and/or tissue based products for wounds (CTPs). While we appreciate that Novitas is giving more discretion to clinicians to choose the product that they would like to use to treat their patients, as mentioned above, there are areas in which we would like to seek clarification. These include the following:

1. There are 6 products that have HCPCS codes that are not listed in this policy. Was this an oversight? Are these products not covered? Moreover, if new products enter the marketplace, will they be covered? What criteria do these companies need to meet in order to obtain coverage? Do clinicians need to show adequate clinical evidence in order to use these new products?

2. It appears that podiatrists are still not able to apply these products based on the language provided in the LCD - is this intended? Please clarify whether podiatrists are permitted to apply these products under this LCD.

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

3. The title of this policy, "Application of Bioengineered Skin Substitute Material to Diabetic Foot Ulcers and Venous Leg Ulcers of the Lower Extremities", implies that the coverage of these products is solely for treatment of diabetic foot ulcers and venous leg ulcers in the lower extremities. If a clinician utilizes these products to treat patients who have ulcers in other areas of the body –does this policy not apply in these circumstances? Similarly, if a patient has a pressure ulcer on their heel - would this policy apply? Finally, please clarify that treatment of chronic non-healing wounds in other areas of the body, such as a pressure ulcer on their sacrum or buttocks, will still be covered based on reasonable and necessary criteria.

4. If a patient continues to use tobacco products on a regular basis after their 4 weeks of wound care – Please clarify that the CTP product will be considered non-covered. This seems to be a bit extreme and without merit. Can you please site the studies/evidence used to make this decision? We understand and support the efforts to provide counseling but believe that to deprive patients of these products to help treat their wounds if they are not able to stop smoking will impact patient care.

5. There is language contained in the LCD (that we have provided in red below) that we would appreciate clarity. Specifically your policy states, "Evaluation of the clinical literature indicates that studies comparing the efficacy of bioengineered skin substitute to alternative wound care approaches with patients' autologous skin are limited in number, apply mainly to generally healthy patients, and examine only a small portion of the skin substitute products available in the United States……Therefore, all products with FDA clearance/approval or designated 361 HCT/P exemption used in accordance with that product's individualized application guidelines will be equally considered for the purpose of this LCD and may be considered reasonable and necessary".

Many of the products listed for coverage under this policy are HCT/Ps and do not require 510K clearance or PMA approval. PMA and 510K products are approved with specific indications for use and have FDA approved package labels. These products will receive an approval letter from the FDA. However, HCT/Ps have a different FDA pathway and while they have package instructions for use, they do not receive FDA approval nor do many of these products have clinical studies. Since the FDA determined that these products – which are minimally manipulated, intended for homologous use, are not combined with other articles and do not have a systemic effect – are safe and thus may be marketed without any FDA pre market review, clearance, or approval. As such, these products will not have any FDA approved package instructions. Therefore, is Novitas stating in its policy that these products are not covered as they do not have FDA approval or published evidence? Can you please provide more information regarding what you mean in this paragraph in order to provide transparency and clarity?

6. The Novitas' LCD states the following:

> "The utilization of bioengineered skin substitute non-compliant with medical necessity or designated guidelines for that specific product may necessitate review or non-coverage as not medically necessary. Labeling for most skin substitute grafts include language suggesting multiple applications; however, Medicare does not expect that

every ulcer in every patient will require the maximum number of applications listed on the product label or allowed for reimbursement. Utilization rates that exceed peer norms, identified through data analysis may prompt prepayment or post payment medical review."

We are concerned that HCT/Ps are intended for homologous use and therefore do not have labeling for an application schedule. Throughout its policy, Novitas implies that all products will be included for coverage that have an FDA clearance/approval or designated 361 HCT/P exemption used in accordance with that product's individualized application guidelines. However, as stated above, not all products do. We question then, are all products really covered under this policy if a clinician documents the reasonable and necessary criteria?

7. The Novitas policy states, "1 skin graft will be allowed for the episode of care not to exceed 10". If a patient has a larger wound where two grafts are needed, is this permissible under this policy?

Conclusion

On behalf of the Alliance of Wound Care Stakeholders, we appreciate the opportunity to seek clarification on Novitas' recently implemented LCD. We would like for Novitas to provide clarification to our members and look forward to hearing back from you on these issues. If you have any questions or would like further information, please do not hesitate to contact me.

Sincerely,

Marcia Nusgart R.Ph.

Marcia Nusgart R.Ph.
Executive Director