



Comments on Novitas Draft LCD
Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers
(DL35041)
April 29, 2022 Public Meeting – Oral Testimony

Good Morning. My name is Marcia Nusgart and I am the Executive Director for the Alliance of Wound Care Stakeholders. Thank you for the opportunity to provide the Alliances comments on the draft Skin Substitute LCD and the accompanying LCA. The Alliance is a non-profit multidisciplinary trade association of physician medical specialty societies and clinical 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. These comments were written with the advice of Alliance clinical specialty societies and organizations that not only possess expert knowledge in complex chronic wounds, but also in wound care research. A list of our members can be found on our website.

Before I being to discuss the issues with the LCD/LCA the Alliance is concerned with Novitas using the term “skin substitutes”. 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 chronic ulcers. 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 ulcers where skin 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 chronic non healing ulcers as opposed to skin grafting procedures.

As such, the Alliance recommends that Novitas adopt the term “Cellular and/or tissue based products for wounds” (“CTPs”) which does accurately describe and is broad and inclusive of both current and future technology. We would respectfully point out that other organizations, contractors and the wound care clinical community have adopted this verbiage. To underscore its importance of this nomenclature, the ASTM has updated its standard guide to define CTP nomenclature.

In terms of the provisions contained in the draft, the Alliance has many concerns with the draft LCD as it is currently written which we will address in our written comments. However, for the purposes of this public meeting, I have narrowed our concerns down to four. First, many of the statements and limitations in the policy do not seem to have the scientific evidence to support them. We have great concerns that a thorough evaluation has not been done since Novitas has not only omitted known published evidence, but old evidence was cited and often the evidence cited contradicts statements in the policy that the evidence was used to support. 2. Utilization parameters that have been provided in this draft LCD seem arbitrary, will negatively impact patient care and are not supported in the evidence provided by Novitas. 3. There is conflicting, confusing and/or incorrect information contained in the draft LCD which is not only problematic but at times also clinically incorrect. Finally, we have some significant procedural issues with the release of this draft LCD.

So if I may take a couple of minutes to elaborate briefly on each of these points.

1. Evidence –

We will provide a more detailed discussion of the evidence in our written comments but one example by which the evidence utilized in the policy contradicts statements made in the policy is in reference to the number of applications of a CTP permitted under this policy. The draft policy permits 2 applications of a CTP however the literature cited in the policy directly contradicts this limitation. Rather, the evidence cited in this policy is dependent on the product being utilized and the number of applications ranges from 1 – 8.9 based on the studies cited in this policy. We can not find any evidence supporting 2 applications as being clinically justified and would appreciate Novitas advising us as to where this evidence is located. As you are aware 21st Century Cures requires evidence to be utilized to support the positions taken in an LCD. We have not found any to justify this change in policy language and believe that allowing only 2 applications is not clinically appropriate.

2. Utilization

Furthermore, the limitation of 2 applications in an episode (defined as 12 weeks) being not medically reasonable and necessary is not only contradictory to other statements in the draft policy that products should be used based on their labeling instructions it is not supported in the literature as noted above.

The FDA labelling for some products requires reapplication every 7 days, while the FDA labelling for other products requires reapplication every 2-3 weeks. So, it is very likely if a product requirement is to reapply the product 5 times every 3 weeks – the clinician will be over the number of applications under this policy all while following the FDA labelling for the product usage.

Moreover, if the LCD limits treatment to 12 weeks, some of these products will not be able to be used since some of them, according to their FDA labeling, require multiple treatments in a span of time that would exceed 12 weeks. The Alliance is concerned that clinicians would always have to justify utilizing the product chosen to treat their patients – even though they are following the FDA labeling for the products covered under this policy. This in itself is problematic however even more troubling is that the 2 application limitation is not founded on any evidence in literature. The Alliance is in complete disagreement with the 2 application limitation and urges Novitas to simply include a statement that the products should be applied in accordance with their FDA labeling of the product which places the responsibility on the physician/clinician to apply the product correctly and documentation in their files should be sufficient to show that the physician/clinician was following guidelines for the product being utilized.

3. There are many examples of Incorrect/inconsistent or confusing language contained throughout this LCD. I will provide just a few examples.

- a. First - with respect to hemoglobin (Hgb) A1C, the draft LCD reads that “adequate glycemic control of hemoglobin A1C defined by this policy as <7% is recommended to reduce the incidence of DFUs and infections.” We disagree with this statement clinically for chronic wound care patients as these patients can die when their A1C goes below 7%.

Among diabetics, controlling Hgb A1C may reduce long term complications if implemented early. However, among Medicare beneficiaries with diabetes, HgbA1C should be interpreted with care.

The American Diabetes Association (ADA) “Standards of Medical Care in Diabetes” includes the ADA’s current clinical practice recommendations and is intended to provide the components of diabetes care, general treatment goals and guidelines, and tools to evaluate quality of care.

For older adults with complex/ intermediate conditions (multiple coexisting chronic illnesses or 21 instrumental ADL impairments or mild-to-moderate cognitive impairment), a reasonable A1C goal is <8%.

However, for older adults with very complex conditions or who are in poor health (LTC or end stage chronic illnesses or moderate cognitive impairment or 21 ADL impairments), the ADA cautions clinicians to avoid reliance on A1C and states that glucose control decisions should be based on avoiding hypoglycemia and symptomatic hyperglycemia. (Some prospective studies have shown an increased death rate among older adults whose Hgb A1C was less than 7.4%).

The Alliance will provide detailed recommendations in our written comments, but Novitas should revise this section of the policy to comport with clinical evidence as well as with clinical practice recommendations by the American Diabetes Association and the National Committee on Quality Assurance.

- b. There is very inconsistent language throughout the LCD re: what is a chronic non healing wound. In some places the LCD defines this as a wound that has not healed in 1-3 months; in other places it says greater than 4 weeks, and yet in other places, there are other measurements of time. 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. The Alliance recommends that Novitas utilize the standard by which all policies have been written and use the 30 day or 4 week timeframe and not the 1-3 month measure of a chronic non -healing wound which was stated in this policy. The range is too long and creates ambiguity. The literature supports the 30 day or 4 week timeframe and is the standard which all clinicians follow prior to proving any advanced therapy to their patients.

The title of the LCD is skin substitutes for the treatment of DFU and VLU so why does this policy constantly refer to pressure ulcers - which have completely different etiology - and other types of “wounds”? There is no reason for this and it causes confusion given the limited nature of this policy. We request that Novitas only refer in its LCD the types of chronic ulcers that are subject to this policy and delete reference to any other wound or ulcer type as well as the term “wound” as DFUs and VLUs are chronic non healing ulcers. Wounds are something altogether different and not the subject of this LCD.

4. The last issue is procedural. We are disappointed that Novitas did not engage any stakeholders – including convening a meeting of its CAC to create questions and discuss the evidence for this draft LCD. Many of the clinical errors in this policy as well as the incorrect use of the evidence would have been caught prior to this draft being released.

We recommend that in the future, the Alliance can serve as a resource for the Novitas medical directors in that we:

- Serve as unbiased multidisciplinary knowledgeable clinical resource for information and as a collaborator
- Can address any wound care related subject matters
- Consist of physicians, surgeons (general, vascular and foot/ankle), podiatrists, physical therapists, nurses, dieticians
- Can help Novitas with:
 - Technical questions
 - Creating educational seminars for staff
 - Convene an educational seminar on CTPs as we have done with CMS staff in the past

We hope that you will utilize our expertise to help ensure that this policy is well balanced and clinically accurate. Thank you.