Coalition of Wound Care Manufacturers comments on Novitas Draft LCD skin substitutes for the treatment of diabetic foot ulcers and venous leg ulcers (DL35041)

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Good Morning and thank you for the opportunity to provide comments on the draft LCD on Skin Substitutes for the Treatment of diabetic foot ulcers or DFUs and venous leg ulcers or VLUs and the accompanying LCA. My name is Karen Ravitz and I am the Health Care Policy Advisor for the Coalition of Wound Care Manufacturers. Founded in 2000, the Coalition represents leading manufacturers of wound care products used by Medicare beneficiaries for the treatment of wounds. Our members manufacture cellular and or tissue based products for skin wounds (CTPs) – also referred to as skin substitutes - that are the subject of this draft policy. Therefore, our members have a vested interested in ensuring that this policy is clinically sound and based on evidence.

The Coalition has major concerns with this proposed LCD. Unfortunately, the evidence that has been utilized is either not the most current available, or is used in such a way that is contradictory to the points Novitas is trying to make. Furthermore, the policy is fraught with clinical inaccuracies that ultimately will be detrimental to patient care.

The Coalition recommends that Novitas pull this draft policy, work with stakeholders and the CAC to craft a more accurate and well balanced policy.

Our areas of concern include:

* The use of the clinically inaccurate term “skin substitute” rather than cellular and or tissue based products for skin wounds or CTPs.
* The lack of a consistent and accurate definition of what is a chronic non healing wound – which should be 30 days or 4 weeks as it is already standardized and used by CMS and other A/B MACs.
* Incorrectly describing the application of CTPs as an adjunct therapy rather than an advanced therapy.
* Omitted coverage of products in the LCA including many sheet products.
* Inappropriate use of the term “wound” given the title of this LCD/LCA.
* The use of the terms pressure ulcer, decubitus ulcer, burns, and trauma throughout this policy which specifically states it only addresses DFUs and VLUs.
* Omission of a significant number of ICD-10 codes from the LCA that should have been included in this policy. It is concerning that Novitas only identified codes with the .621 suffix – which is for the foot only and has excluded any patients with a diabetic ulcer even above the ankle.
* Increase in the smoking cessation timeframe prior to the use of a CTP to 6 weeks.
* The requirement for a venous diagnosis to implement treatment.
* The number used for the measurement of hemoglobin A1C – which is too low for this patient population.
* No reference for the ABI of 0.9 so uncertain where this number came from.
* The inability to switch products or use additional applications when medically necessary.
* Inconsistently stating something is recommended and then later being required – for example Venous Clinical Severity Score (VCSS).
* Reference to the Tissue Reference Group or TRG. TRG is used for coding not coverage and a provider should not be required to provide a TRG letter in order to use a product. Providers will not have those letters and not all CTPs? require a TRG in order to obtain a code.
* Reference to synthetic occlusive skin substitutes and singling them out multiple times in the policy.
* The requirement that clinicians utilize the smallest package size available for purchase from the manufacturer that can provide the appropriate amount for the patient despite that fact that the clinician does not control what is purchased or is on hand at their facilities and therefore may not have the smallest package size manufactured.

However, the Coalition will be providing significant written comments on these issues and will not go into detail on them here today. I did want however to highlight a few specific areas which we are extremely concerned and believe Novitas could have benefitted from CAC and stakeholder involvement. These include but are certainly not limited to the following:

First – Under Limitations in the LCD Novitas allows only 2 applications of a specific product. We submit that this is an arbitrary application limitation in this policy that is not based on the evidence in general nor is it based on any evidence cited in the policy itself.

In fact, the evidence cited in this policy either shows the number of applications to be higher than the two permitted under this policy or is very clear that the number of applications should be based on the labeling instructions for the specific product being used.

More specifically, the number of applications cited in the evidence ranges from 1 – 8.9 applications and is based on individual product labeling. The FDA labeling for some CTPs requires reapplication every 7 days, while the FDA labeling 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 while following the labeling instructions for the CTP being used to treat their patient OR they will be required to stop treatment midstream, prior to the wound being healed in order to comply with the requirements of this LCD. This seems counter intuitive and is clinically detrimental to patient care.

Second, Novitas also defines CTPs as surgical supplies. Specifically, the language used in this draft states, “Although skin substitutes have attributes of both biologicals and devices, the current position is that these products are best characterized as surgical supplies or devices because of their required surgical application and their similarity to other surgical supplies”. First, we question whether this is really the current position as the language used in this draft policy is taken directly from the CY 2015 hospital outpatient PPS proposed rule in which CMS was trying to justify moving the pass through application process for skin substitutes from the drug and biologics process to the device process. There were legal reasons why this should not have taken place, but the Agency moved ahead to finalize it as written since CMS wanted to limit the number of products granted pass through status. This being said, that statement was used for a specific purpose with respect to pass through status but has no place in this draft LCD. CTPs are not surgical supplies and should not be referred to as surgical supplies.

This reference is simply clinically incorrect. A CTP promotes wound healing by interacting directly or indirectly with the body tissues. There is direct biological effect in the wound bed as a result. The role of CTPs is not to cover and protect wounds like a surgical dressing but rather to stimulate endogenous healing, although whether or not an individual CTP is capable of exerting effects on wound healing must be determined by adequate evidence. Furthermore, CTPs are distinct from surgical dressings in that:

* The AMA crafted application codes for them in the surgical section of the CPT book because they required specific wound bed preparation. These codes apply to the surgical application no matter whether done in the physician office, provider based departments and apply to all CTPs.
* They must be applied by a physician or nurse practitioner not by a nurse or physical therapist, and
* They must be fixated

A CTP is simply not a supply of any kind.

A wound or surgical dressing is a covering and considered a supply. It 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 without exerting any direct effect in the wound bed. Often a surgical dressing is chosen based on whether it helps with exudate or mechanical protection, shearing or friction. As such, it is completely inappropriate to refer to CTPs as surgical supplies and as such this language should be stripped from the policy.

Finally, we are concerned that this policy is not based on evidence as is required under the 21st Century Cures law. We recognize that there are studies and literature cited in this policy that are supposed to substantiate the Novitas’ positions. However, under review of this literature, it is clear that the evidence cited does not substantiate the significant changes that Novitas is attempting to make. As such, the Coalition requests that Novitas work with the CAC and stakeholders to ensure that the policy language is based on evidence and will not negatively impact patient care.

Thank you.