COALITION OF

Wound
Care
Manufacturers

Coalition of Wound Care Manufacturers Comments on CGS Draft LCD Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (DL36690) and LCA (DA56696) October 25 and 26, 2022 Public Meeting – Oral Testimony

Good afternoon and thank you for the opportunity to provide comments on the draft LCD and accompanying LCA on Skin Substitutes for the Treatment of diabetic foot ulcers or DFUs and venous leg ulcers or VLUs. 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. including cellular and or tissue based products for skin wounds (CTPs) – also referred to as skin substitutes - that are the subject of this draft policy. Our members have a vested interested in ensuring that this policy is clinically sound and based on evidence.

The Coalition has major concerns with the proposed LCD and LCA. To begin, CGS has created an LCD and LCA that is virtually verbatim to what was issued by Novitas and First Coast.

With all due respect, the Coalition would have hoped that in mirroring other MAC draft policies, CGS would have done its own due diligence to ensure that the language contained in their draft would be based on the evidence cited and on sound clinical practice.

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Unfortunately, as with the Novitas and First Coast drafts, the evidence that has been utilized in the draft CGS LCD is either not the most currently available, or is used in such a way that is contradictory to the provisions of the LCD. Furthermore, the policy is fraught with clinical inaccuracies that ultimately will be detrimental to patient care. In fact, Novitas and First Coast notified us that based on our feedback as well as others, they are making substantive changes to their policy and article. So, the provisions in the CGS draft will no longer mirror the policy that this draft sought to emulate.

The Coalition recommends that CGS pull this draft, work with stakeholders and the CAC to craft a more accurate and well balanced policy that is based on the most currently available evidence.

The Coalition has significant concerns with the many provisions contained within the LCD and LCA including those raised by Dr. McInnes in his presentation as well as the previous speaker, but I will highlight just a few other issues today that we believe CGS could have benefitted from CAC and stakeholder involvement. These include but are certainly not limited to the following:

First –CGS allows only 4 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 four 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 or the published scientific studies conducted by the manufacturer for their specific product.

Furthermore, it appears that the number of applications is based on the retrospective study of one product yet there are over 150 products in the marketplace, many of which support more than 4 applications.

Again, the number of applications is arbitrary. The Coalition understands that CGS needs some guidance on what to cover. We believe that since the studies support the use of these products based either on clinical evidence OR on a specific products' label, the number of applications varies based on what product is being utilized. So, perhaps CGS would consider not placing a limitation on the number of applications but rather language in the LCD which supports medical necessity based on the clinicians observation of the wound and the all the patients' co morbid conditions when a CTP is being considered and applied. If the wound shows signs of progression towards closure, the CTP should continue to be applied based on the labeling instructions. This progression can be documented in the patient medical records. On the other hand, if there is no progression then the CTP should either be switched to another product OR it should be discontinued. Again, this information should be documented in the patient medical records. The Coalition believes that CGS should work with the CAC and clinical stakeholders to establish the language but the current application limitation should be eliminated as it is not supported by the evidence for all CTPs.

Second, CGS 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". 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. As such it is completely inappropriate to refer to CTPs as surgical supplies -
there is no other supply that requires the same level of documentation or that has specific Joint Commission recommendations or tissue tracking requirements. This language should be stripped from the policy.

Third – it is concerning that CGS does not identify in the LCA or in the LCD the specific evidence that they are requiring of manufacturers in order for their products to be placed in the Group 2 covered product listing. Merely stating that a CTP needs to provide evidence of regulatory compliance is not good enough. Without specifically identifying this

information in the LCD Or LCA there is no transparency being afforded to manufacturers. There is no rhyme or reason as to why a product is listed in the Group 3 non-covered list and as such the Coalition recommends that CGS identify this information in their policy to ensure that what is being required is clearly identified.

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 CGS positions. However, under review of this literature, it is clear that the evidence cited does not substantiate the significant changes that CGS is attempting to make. As such, the Coalition requests that CGS 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 for the opportunity to provide our feedback today. The Coalition will be providing significant written comments on all of these issues and many more.

Thank you again.