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Alliance of Wound Care Stakeholders' Oral Testimony on FCSO/Novitas Draft LCD/LCA
Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers
August 25-26 2022 Public Meetings

My name is Marcia Nusgart and I am the CEO for the Alliance of Wound Care Stakeholders. Thank you for the opportunity to provide the Alliance's 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, clinical and patient 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.

The Alliance continues to be concerned with this draft policy. We identified many issues and recommendations not only in our public comments given on April 28 but also in our May 27, 2022 comment letter.

We took writing our comments very seriously and spent considerable time on them due to the negative impact that these LCD/LCA make on our members and the patients that they treat. Our comment letter was very unique in that we framed our concerns and recommendations in a chart to make them easier to understand and we also provided a red lined copy of the LCD and LCA and identified our recommendations in red.

Therefore, it is both baffling and disconcerting that First Coast and Novitas have reissued the same draft policy – with not taking into consideration ANY of our comments offered. If First Coast and Novitas were interested in further comments, then releasing a draft policy taking into consideration our already provided comments would have been a more useful exercise.

That said– all of our previous comments still stand – including but not limited to:

- 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 First Coast/Novitas has not only omitted known published evidence,

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but old evidence was cited and often the evidence cited contradicts statements in the policy that the evidence was used to support.
- 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 First Coast/Novitas.
- 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 significant procedural issues with the release of the previous draft LCD and we have continued concerns with the release of this draft.

In terms of the limited changes that First Coast/Novitas did address in this new draft policy, let me be clear--the Alliance does not support the movement of any products into the Group 3 non-covered list during an active comment period nor does the Alliance support the placement of products into the non-covered list when the MAC has not and continues to not be transparent in the evidentiary requirements. If the MAC is moving products into the non-covered category, MAC needs to clearly identify the reason for the movement. If the MAC simply has not yet received a TRG letter from the manufacturer – this is not a good reason to move the product as the TRG letters take time to receive. We understand that even CMS will be allowing companies up to 2024 to obtain these letters.

Furthermore, as a procedural matter, this is a proposed policy – it has not been finalized. As such, the requirement of obtaining a TRG should not be the determining factor as to whether a product is in the covered vs non covered list. Once the policy becomes finalized and the requirement is final – the MAC should provide a date by which these TRG letters are required to be provided in order to stay in the covered grouping. If there are other reasons the MAC moved products in this active comment period to the non-covered list, the MAC is required to identify the rationale for moving these products. It is not clear and is disruptive to patient care.

Finally, the Alliance is concerned with First Coast/Novitas using the term "skin substitutes." We recognize that both MACs used this term along with cellular and/or tissue based products for skin wounds (CTPs) but we would recommend that only the term CTP be used. We would also encourage First Coast and Novitas to place CTP in the title of the LCD/LCA insteadof skin substitutes.

Our rationale for not using the term "skin substitutes" is that it 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 FCSO 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.

As we have stated in the past, the Alliance is happy to serve as a resource for the FCSO medical directors in that we:

- Serve as unbiased multidisciplinary knowledgeable clinical resource for information and as a collaborator and can address any wound care related subject matters
- Our members consist of physicians, surgeons (general, vascular and foot/ankle), podiatrists, physical therapists, nurses, dieticians and can help you 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.