COALITION OF

Wound Care Manufacturers

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Oral Testimony on FCSO Draft LCD
Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (DL36377)
August 25 2022 Public Meeting

Good Afternoon - My name is Karen Ravitz and I am the Health Care Policy Advisor for the Coalition of Wound Care Manufacturers - I do not have any conflicts of interest other than our members do pay a membership fee to participate in the Coalition. Thank you for the opportunity to once again provide the Coalition's comments on the draft LCD and the accompanying LCA. 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 – and therefore have a vested interested in ensuring that this policy is clinically sound and based on evidence.

The Coalition continues to have major concerns with this proposed LCD. As we have stated previously, unfortunately, clinical evidence continues to be omitted from this policy review and what is still is being utilized is either not the most current evidence available, or is used in such a way that is contradictory to the points First Coast is trying to make. Furthermore, the policy continues to be fraught with clinical inaccuracies that ultimately will be detrimental to patient care. It would have been more advantageous of First Coast to reissue a draft policy which incorporated stakeholder concerns already submitted rather than reissuing virtually the same policy but simply moving the so called evidence recommendations out of the documentation section as well as moving 46 products from the covered group to the non-covered group – which is inappropriate given this policy is still in draft form with little to no detailed evidentiary requirements provided in the policy or any specific reasons for the change.

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

As with Ms. Nusgart– the Coalition also presented oral testimony and a detailed written comment letter outlining our very expansive and substantive concerns with the draft policy during the last open meeting and comment period, so in the interest of time I will not be addressing all of the significant issues that we raised supporting the withdrawal of the LCD and LCA.

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I would like to raise a couple specific concerns from this new draft that we find extremely problematic. As a practical matter – the MAC should not begin to enforce policies that have not yet been finalized. This is a violation of the Administrative Procedures Act. As part of the draft policy, FCSO is requesting manufacturers submit TRG letters for coverage purposes. While TRG letters are now a requirement in order to obtain a new HCPCS code, those 361 products that have been in the marketplace for years have not been required to obtain a TRG letter. So, either these products need to be grandfathered OR be afforded a reasonable amount of time after the policy has been finalized to obtain these letters before any action is taken to provide non-coverage.

Furthermore Moving 46 products from the group 2 covered list from the original draft policy to the non-covered group 3 in the most recent draft list without any explanation as to why these products were moved is extremely disconcerting and lacks in transparency. The Coalition does not support any product being included in the non-covered list until first - the policy is finalized and a reasonable amount of time has been afforded to manufacturers to obtain and submit the necessary information. This date should be in the future - after the policy has been finalized. Please note that If a letter from the TRG is being required we understand it is taking at times over 9 months to obtain. Until this policy is finalized with specific requirements identified - all products should be covered as they are currently.

Second - First Coast should also identify clearly the type of evidence which is being required for coverage. Just simply stating evidence based literature is not specific enough – what type of evidence based literature is FCSO willing to accept in order to be placed and maintained in the group 2 covered list.

Third - FCSO also needs to clearly identify why products have been moved from the covered group to the non-covered group. There is no consistency in products that have been moved and therefore there is no clarity as to why some products were moved to the non-covered list. FCSO needs to be more transparent in their decision making process

And finally, as practical matter - the LCD states that it is recommended that the manufacturers of the particular CTP product obtain the appropriate information and send to the MAC along with evidence-based literature, if available. Once this information has been received by the MAC, the product will be considered for coverage. Doesn't this mean that the information being requested is actually required as a manufacturer will not gain coverage without the submission of this material.

Thank you for the opportunity to speak with you today and again based on all of the significant issues contained in this policy – we urge First Coast to not finalize this LCD and accompanying LCA and work w stakeholders to create a more accurate and balanced policy.