COALITION OF

Wound Care Manufacturers

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Oral Testimony
Novitas Draft LCD
Skin Substitutes for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers (DL 35041)
August 26, 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, 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 Novitas is trying to make. Furthermore, the policy continues to be fraught with clinical inaccuracies that ultimately will be detrimental to patient care and to patients access to care.

It would have been more advantageous of Novitas 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 without providing any evidence to support the withdrawal of coverage for these products - which is not only inappropriate it violates the 21 Century Cures Act.

The Coalition once again recommends that Novitas withdraw this draft policy, work with stakeholders and the CAC to craft a more accurate and well balanced policy as the policy as written now will be detrimental to patient care.

5225 Pooks Hill Rd | Suite 627S
Bethesda, MD 20814
T 301.530.7846 | C 301.802.1410
www.woundcaremanufacturers.org

As with previous speakers– 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. Novitas needs to pay paying attention to the significant and substantive stakeholders concerns regarding access – they are real.

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 – given that you are currently in an active notice and comment period.

As part of the draft policy, Novitas 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 are not required to obtain a TRG letter. During the open meeting yesterday, Dr. Schaening stated that CMS required TRG letters to be obtained through provisions in the physician fee schedule regulations issued last year. But, as Dr. Rudolf mentioned that is not correct. The regulations stated that TRG letters are only required for those products obtaining a new HCPCS code. So Novitas cannot remove products from being covered based on whether a TRG letter is being provided the until the LCD is finalized and there is a specific requirement to submit these letters as there is currently no requirement to do so. If Novitas decides to move forward with requiring a TRG letter as requirement for coverage then manufacturers must be afforded a reasonable amount to obtain and provide these letters before any action is taken to move them to the non-covered Group 3 list and only after the policy is finalized and they are given a reasonable amount of time to obtain them.

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. This movement also violates the 21st Century Cures Act as Novitas has placed absolutely no evidence to support the movement of these products in the bibliography. The Coalition does not support any product being included in the non-covered list until

1. 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 going to be 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.
2. Novitas should also identify clearly the type of evidence which is being required for coverage. Just simply stating evidence based literature is recommended is not specific enough – what type of evidence based literature is Novitas willing to accept in order to be placed and maintained in the group 2 covered list. If Novitas

is requiring evidence to be submitted by manufacturers – Novitas needs to clearly identify what evidence they will accept. This is currently not the case and Novitas needs to provide a more transparent process. More information is needed.

3. The provision of evidence is not only a manufacturer issue. If products will be moved from one category to another Novitas is required to provide evidence in the bibliography supporting their decision. This information needs to be clearly identified in the policy. However, no new evidence was placed in the bibliography and the evidence that is in the bibliography currently does not support the movement of these products to the non- covered list. In fact, as Dr. Rudolf stated during the FCSO hearing, the evidence that is currently sited in the policy supports these products being utilized and covered. Novitas 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. The movement of these products seems arbitrary. Novitas needs to be more transparent in their decision making process and provide the evidence it is using to make any changes in coverage.

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?

Finally, Dr. Schaeining also mentioned yesterday that the purpose of the comment period and the open meeting is for manufacturers to submit evidentiary requirements for consideration for coverage. But I state again, this is a draft policy. Novitas cannot require manufacturers to go through the exercise of providing TRG letters or anything else until this policy is finalized nor can they do so until a reasonable amount of time is afforded to obtain the information required.

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 Novitas to withdraw this LCD and accompanying LCA and work with stakeholders to create a more accurate and balanced policy. The stakeholder community needs to know that Novitas will do the right thing and at this point, given the newly released draft without any real significant changes, we are doubtful and concerned.