COALITION OF

Wound Care Manufacturers

June 8, 2024

CGS Administrators, LLC
Attn: Medical Review
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Nashville, TN 37214-3685

Novitas Solutions, Inc
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First Coast Service Options, Inc
Medical Affairs
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Palmetto GBA
Part A Policy
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Madison, WI 53701-1787

Noridian Healthcare Solutions, LLC
JE and JF Part B Contractor Medical Director(s)
Attn: Draft LCD Comments
P.O. Box 6781
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Submitted Electronically to *CGS cmd.inquiry@cgsadmin.com; FCSO proposedLCDcomments@FCSO.com; NGS NGSDraftLCDComments@anthem.com; Noridian policydraft@noridian.com; Novitas ProposedLCDComments@novitas-solutions.com; Palmetto A.Policy@PalmettoGBA.com; and WPS policycomments@wpsic.com*

RE: **Skin Substitute Grafts/ Cellular and Tissue-Based Products (CTP) for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers**
CGS (DL39756/DA59618**)**
FCSO (DL36377/DA57680**)**
NGS (DL39828/DA59712**)**
Noridian (DL39760/DA59626 & DL39764/DA59628**)**
Novitas (DL35041/DA54117**)**
Palmetto (DL39806/DA59691**)**
WPS (DL39865/DA59740**)**

Dear Medicare Administrative Contractor Medical Directors:

On behalf of the Coalition of Wound Care Manufacturers ("Coalition"), I am pleased to submit comments on the draft Local Coverage Determination (LCD) for "Skin Substitute Grafts/Cellular

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And Tissue-Based Products (CTP) for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers" and the accompanying Local Coverage Article (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 interest in ensuring that this policy is clinically sound and based on evidence.

CTPs are a medically necessary advanced treatment option for patients with chronic non-healing wounds. There are published scientific studies showing their effectiveness in wound healing, including the reduction of amputation and infection when they have been used.[i],[ii],[iii] The Coalition recognizes that the development of a CTP LCD and LCA has been challenging. Thus, we appreciate the efforts being put forward by the Medicare Administrative Contractors (MACs) in issuing this latest draft LCD and LCA and for incorporating many of the recommendations made by the Coalition from previous draft policies. However, there are additional issues that need to be addressed. The Coalition provides our specific comments and recommendations below as well as areas in which clarification is needed.

EVIDENCE

First and foremost, the Coalition supports the MACs by issuing a coverage policy that is based on evidence. This allows for products with substantiated published evidence supporting the medical necessity to be included in the Group 2 covered products list. The Coalition has been surprised that over the years the MACs have permitted coverage of products without a requirement of providing evidence. However, we have concerns that the draft LCD does not include clear criteria regarding the data/evidence necessary for a product to be covered nor does the vague criteria in the proposed policy seem to be applied consistently or equally. The MACs identified that the GRADE methodology was utilized to evaluate the evidence and yet the protocols that were used are not publicly available. It has been difficult to gain an understanding of the protocols used when reviewing the rationale provided in the Tables provided in the LCD. Protocols that should accompany a GRADE decision-making process are absent and therefore the decisions being made by the MACs appear to be arbitrary. **As such, the Coalition recommends that the MACs provide the GRADE criteria or protocols utilized to evaluate CTP evidence prior to this policy becoming finalized.**

PROCESS

In 2019, CMS modified the LCD process and with that removed coding (i.e., CPT/ICD-10 and HCPCS) from LCDs and placed them into an LCA. The rationale provided by CMS was so that "the codes can be efficiently and promptly maintained when coding changes (revisions, retirement, additions) occur (annually or quarterly for some code sets) without requiring a reconsideration of the LCD." [iv],[v] However, in the issuance of the proposed LCD and LCA for CTPs, the MACs included detailed product-by-product information in the LCD. This has led to concerns that the MACs will require a full reopening of the LCD through the LCD reconsideration process before products can be moved to covered status. The Coalition disagrees that a reconsideration request be required, particularly given the changes in the Program Integrity Manual Chapter 13(PIM) which removes specific codes and products from LCDs into LCAs in order to address coding changes promptly. The MACs will be receiving evidence constantly and therefore there are also serious practical implications of reopening the LCD every time new evidence is reviewed and products placed on the Group 2 covered list. Reopening an LCD is not a quick process. Timelines are prescribed by the PIM and therefore the product codes which maybe added to the Group 2 list cannot be promptly added as was the intent of the creation of the LCA.

Therefore, the Coalition recommends that the MACs remove the product-by-product evaluation from the LCD and instead place in an Appendix or even in the LCA so the entire LCD does not have to be reopened every time new evidence is reviewed.

Furthermore, given the high volume of evidence submissions the MACs will likely receive once the policy is finalized, there is no process established/identified for how to review evidence submissions efficiently and timely without, as stated above, reopening the entire LCD. As such, **the Coalition encourages the MACs to provide an efficient and timely process for manufacturers to submit additional published evidence or other data to support movement of products located within the non-covered Group 3 to the covered Group 2 list.** For example, will reviews take place quarterly? Will reviews of an individual manufacturer be conducted within 30 days of receipt of the evidence? The Coalition **recommends that these evidence reviews be completed within 60 days of submission and that the MACs publicly provide this timeline and process**.

Finally, since all the MACs proposed LCDs and LCAs were issued at the same time and there was substantive collaboration, we assume the MACs plan on making collective decisions on these LCDs and LCAs moving forward. However, this information has again not been addressed and lacks transparency. **The Coalition recommends the MACs provide a single efficient and timely process for manufacturers in which the evidence is reviewed and accepted. This would reduce the administrative burden for manufacturers to submit evidence to each MAC if a collective decision is being made for all of the MAC LCDs.** This will ensure efficiency, consistency, and proper maintenance of coverage for CTPs under these LCDs.

KX Modifier

We support and agree with the use of the KX modifier when a patient is required to utilize more than the number of applications or for a longer duration of time that is permitted under this policy once it is finalized. Several MACs have utilized the KX modifier – including Novitas in its retired skin substitute LCD (L35122). The Coalition would, however, offer alternative language for the MAC consideration related to the KX modifier.

The recommended revised language reads as follows:

Physicians and facilities should append the -KX modifier to the product HCPCS code *and application* CPT code(s) of resource-intensive CTP applications when the provider's covered services are in excess of policy frequency limitation threshold(s) and are documented as medically necessary and reasonable in the medical record. Such services qualify for an automatic claims processing exemption by the MAC or Medicare Advantage plan. "Automatic" refers to the manner in which the claim is processed and does not indicate that the exemption itself is automatic. Supporting documentation must be supplied upon request. Aberrant use of the KX modifier may trigger focused medical review."

IMPLEMENTATION

The Coalition appreciates that the 21st Century Cures has prescribed a process in which the MACs have to abide in terms of implementation of LCDs and their accompanying LCAs. However, the Coalition would like to ensure that patient access is not compromised with the implementation of this CTP policy. As such, we **recommend that patients on a current plan of care protocol when the policy is implemented be grandfathered so they are able to complete the plan of care**

established by their clinician based on current LCD language. In the alternative, this can also be achieved by providing a sufficient "future effective date" for the LCDs.

CLARIFICATIONS

The Coalition requests clarification on a few issues related to evidence. Specifically:

1. There needs to be clarity regarding the evidence criteria required for new products to be placed on the approved list. While the Coalition fully supports and appreciates the MACs commitment to high-quality clinical evidence, manufacturers and researchers must have some degree of certainty when investing in research that the study, subject to actual results, will meet the MACs newly required standard. As such clarification is needed. We would support the following:

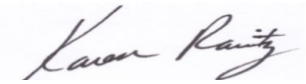
   Preferred Evidence Level: Level 1 Evidence – Prospective Randomized Controlled Study (RCT for DFU **OR** VLU **OR** DFU/VLU (in the same study) compared to standard of care. The study must be statistically powered.
   Minimum Evidence Level – Prospective Study enrolling patients with DFU **OR** VLU wounds refractory to standard of care.
   Adjunctive Evidence- Real World Evidence enrolling patients with DFU **OR** VLU wounds refractory to standard of care may be used as adjunct evidentiary support to RCTs and/or Prospective Studies.

2. The LCD Table 1: Evidence for Covered Products includes a column for "Ulcer Type". The purpose of this column appears to reference the type of wounds addressed by a particular published article. There are some published articles where the "Ulcer Type" column is blank. Although there is no language that limits a particular CTP to either DFU or VLU elsewhere in the LCD or LCA, some stakeholders are concerned that this table may be a limitation of coverage to a particular type of wound. We ask that you **confirm that all covered products identified in the Group 2 covered list are in fact covered for both DFU and VLU indications addressed by this policy.**

CONCLUSION

The Coalition appreciates the opportunity to provide our written comments. Should you have any questions or need additional information, please do not hesitate to contact me.

Sincerely,



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[i] *Skin grafts may help heal diabetic foot ulcers and reduce amputations. Metabolics Hormones and Diabetes 19.04.16 doi: 10.3310/signal-000227*

[ii] *Frykberg RG, Marston WA, Cardinal M.The incidence of lower-extremity amputation and bone resection in diabetic foot ulcer patients treated with a human fibroblast-derived dermal substitute. Adv Skin Wound Care 2015;* ***28*** *(1): 17–20.*

[iii] *Veves A, Falanga V, Armstrong DG, Sabolinski ML, Apligraf Diabetic Foot Ulcer S. Graftskin, a human skin equivalent, is effective in the management of noninfected neuropathic diabetic foot ulcers: a prospective randomized multicenter clinical*
trial. Diabetes Care 2001; ***24*** *(2): 290–5.*

[iv] *Local Coverage Determination (LCD) Process Modernization Qs & As*
https://www.cms.gov/medicare/coverage/determinationprocess/downloads/lcd_qsas.pdf

[v] *https://www.cms.gov/newsroom/fact-sheets/summary-significant-changes-medicare-program-integrity-manual- chapter-13-local-coverage*