



**Final CTP/Skin Substitute LCDs Reflect Stakeholder Input, Provide Treatment Flexibility,
but Lack Clarity on Timely Process for Future Evidence Submissions for Coverage**

Statement from the Alliance of Wound Care Stakeholders

The Alliance of Wound Care Stakeholders is pleased that CMS' Medicare Administrative Contractors (MACs) carefully considered stakeholder recommendations and made substantive changes following input from the wound care community in the recently released final Local Coverage Determination (LCDs) and accompanying Coding and Billing Articles, "[Skin Substitute Grafts/Cellular and Tissue-Based Products \(CTPs\) for the Treatment of Diabetic Foot Ulcers & Venous Leg Ulcers](#)." With the Nov. 14th, 2024, publication of the final policy by each MAC, the wound care community now has clearer understanding of Medicare coverage for the application of CTP/skin substitute products in treating diabetic foot ulcers (DFU) and venous leg ulcers (VLU).

The Alliance and the larger wound care clinical community mobilized together, illustrating the power of tenacious advocacy and a unified voice to positively influence policies so that they reflect quality wound care practice. In a noted change that was in direct alignment with Alliance recommendations, the MACs increased the covered application limit from 4 to 8 in the final policy, now consistent with the supportive clinical evidence, treatment guidelines and current standard of care to promote wound healing. Similarly, the "episode of care" treatment duration increased from 12 to 16 weeks. The Alliance believes these are considerable improvements to the concerning limitations that had been included in the proposed policies issued for comment this past April. Following a great deal of advocacy efforts across a great number of aligned stakeholders, the final LCDs enable providers to have application flexibility (supported by documentation) needed for wound healing and Medicare beneficiaries with hard-to-heal DFUs/VLUs to benefit from improved outcomes.

The Alliance appreciates that the MACs reviewed several new studies submitted over the comment period and thus added three products to the final "covered" lists, which now includes a total of 18 HCPCS codes – 13 codes (covering 20 products) for DFU only ("[Group 2](#)") and 5 codes (covering 6 products) for both DFU/VLU ("[Group 3](#)"). Approximately 204 products were deemed by the MACs to either not have any evidence or lacked sufficient efficacy evidence and placed on the non-covered list ("[Group 4](#)"). As a result, wound care providers across all sites of service will now need to quickly adjust their selection, prescribing, ordering patterns, formularies, and documentation requirements for their Medicare Part A and Part B patients. Fortunately, the MACs took into account Alliance requests for an extended implementation date to allow for this transition and avoid abrupt interruption of patient treatment plans. The implementation date of February 12, 2025, is 90 days from the date of issuance, rather than the 45 days that is standard for MAC policies.

While we are pleased with many of the changes incorporated in the final policies following stakeholder input, the Alliance intends to seek clarity and provide additional recommendations for improvements. We recognize that the next steps for many manufacturers of products on the noncovered list will likely be investing in studies to support the MACs' new evidence standards for coverage. However, we are concerned that the policy fails to provide sufficient clarity regarding the process by which new data can be submitted and reviewed for coverage consideration and that the timelines included in the LCD are not sufficiently frequent or transparent. The LCDs' concluding section states only that "the intent is this policy will be reviewed every 12 months with updates to products/coverage as indicated." A clearer process is needed to establish a predictable pathway and timeline for coverage consideration following submission of new evidence supporting existing products on the non-covered list, as well as for new products to be considered for coverage. Advocacy continues and the Alliance will be working on behalf of our membership to seek additional clarification from the MACs on these issues.

The Alliance serves as the unified advocacy voice for the wound care community to ensure access to quality care for all patients with chronic wounds. Learn more at www.woundcarestakeholders.org

Resources:

Upcoming MAC Listening Session

- The MACs will be hosting an [online Town Hall](#) meeting on Dec. 10, 2024, 3:00PM-5:00PM EST.
- The Alliance and many of our members will share feedback/recommendations and we encourage other stakeholders to also share perspectives at this MAC listening session.
- [Register](#) to attend and submit request to speak to: J15MRPolicy@cgsadmin.com

Final LCDs, Billing & Coding Articles, and Responses to Comment

- CGS Administrators: [Final LCD L39756](#); [Coding & Billing Article A59618](#); [Response to Comments Article A59941](#)
- First Coast Service Options: [Final LCD L36377](#); [Coding & Billing Article A57680](#); [Response to Comments Article A59824](#)
- National Government Services: [Final LCD L39828](#); [Coding & Billing Article A59712](#); [Response to Comments Article A59953](#)
- Noridian J-E: [Final LCD L39760](#); [Coding & Billing Article A59626](#); [Response to Comments Article A59950](#)
- Noridian J-F: [Final LCD L39764](#); [Coding & Billing Article A59628](#); [Response to Comments Article A59952](#)
- Novitas: [Final LCD L35041](#); [Coding & Billing Article A54117](#); [Response to Comments Article A59823](#)
- Palmetto: [Final LCD L39806](#); [Coding & Billing Article A59691](#); [Response to Comments Article A59945](#)
- WPS: [Final LCD L39865](#); [Coding & Billing Article A59740](#); [Response to Comments Article A59954](#)

Covered Products: DFU

There are 13 codes (20 products) that are available for coverage under the final policy that are specific to DFUs. These products are listed in the “Group 2” covered product list and include the following:

- A2019 Kerecis Omega 3 Marigen Shield
- Q4105 Integra Dermal Regeneration Template or Integra Omnigraft Dermal Regeneration Matrix
- Q4107 GraftJacket
- Q4110 Primatrix
- Q4121 Theraskin
- Q4122 Dermacell, Dermacell AWM or Dermacell AWM Porous
- Q4128 Flex HD or Allopatch HD
- Q4133 Grafix Prime, GrafixPL Prime, Stravix and StravixPL
- Q4158 Kerecis Omega 3
- Q4159 Affinity
- Q4160 Nushield
- Q4187 Epicord
- Q4203 Derma-Gide

Covered Products: DFU and VLU

There are 5 codes (6 products) that are available for coverage under the policy that are indicated for both DFU and VLUs. These products are listed in the “Group 3” covered product list and include:

- Q4101 Apligraf
- Q4102 Oasis Wound Matrix
- Q4106 Dermagraft
- Q4151 Amnioband or Guardian
- Q4186 Epifix

Non-Covered Products

- 204 products are not covered under this policy as the MACs determined there was either no evidence to support the product or the evidence was not sufficient for coverage. See the “Group 4” list in the final Billing and Coding Articles (links above) to review this list.