

Key Updates to Future Effective Local Coverage Determinations (LCDs) for Skin Substitutes effective January 1, 2026

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| Covered products and Indications for Use | Q4133 GRAFIX [®] , GRAFIX PL [®] and STRAVIX [®] Q4102 OASIS [®] Wound Matrix | Chronic, non-infected DFU having failed to achieve at least 50% ulcer area reduction with documented standard of care (SOC) treatment for a minimum of 4 weeks with documented patient compliance |
| | Q4102 OASIS Wound Matrix | Chronic, non-infected VLU having failed to respond to documented SOC treatment for a minimum of 4 weeks with documented patient compliance |
| Treatment guidelines | Current LCD | Future effective LCD |
| Duration of Ulcer | DFU 4 weeks, VLU 3 mos | DFU and VLU 4 weeks |
| Minimum wound size | 1 sq cm | No minimum |
| Treatment period | 12 weeks | 12-16 weeks; Any treatment beyond 12 weeks requires documentation of progression toward wound closure |
| Retreatment | No retreatment within one year | Retreatment is allowed of a previously treated and healed wound, following an additional 4 weeks of SOC |
| Number of applications | 10 applications | Maximum of 8, for more than 4 applications, attach the KX modifier to the HCPCS code |
| Product change | Allowed | Allowed, the total number of applications or treatments must not exceed 8 |
| Prior authorization | Not required | Not required |
| Approved diagnosis codes | No specific diagnosis codes | Diagnosis must include an ICD-10 code from the approved Group 1 or Group 2 list, as well as a diagnosis code to identify the site and severity of the ulcer Use QR code below to refer to Diagnosis Lists in Billing and Coding Articles |
| Treatment of wound with exposed structure | No | Yes, GRAFIX is labeled for use over exposed tendon, muscle or bone |
| KX Modifier documentation requirements | Current LCD | Future effective LCD |
| | Not Applicable | KX modifier is not a limitation but serves as an attestation from the provider showing that the medical necessity requirements have been met. Supporting documentation should include: <ul style="list-style-type: none"> - Explanation of why extended time or additional applications is medically necessary - Current treatment plan has resulted in wound healing and expectation that wound will continue to heal with this plan - Include estimated time for extended treatment, number of additional applications anticipated, and plan of care if healing is not achieved as planned - Modifiable risk factors are being addressed to improve likelihood of healing - For venous leg ulcers, it is expected that appropriate consultation and management be obtained for diagnosis and stabilization of any venous related disease |

Reimbursement support email: AWMreimbursement@smith-nephew.com

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For further information on your
MAC's LCD, Billing & Coding
Articles, and other resources:

