

Key Updates to Future Effective Local Coverage Determinations (LCDs) for Skin Substitutes effective April 13, 2025

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	Subject to medical review	Retreatment is allowed of a previously treated and healed wound, following an additional 4 weeks of SOC
Number of applications	12 applications	Maximum of 8, for more than 4 applications, attach the KX modifier to the HCPCS code
Product change	Not Expected	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	Not Specified	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

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

