2025 Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers

WHAT CHANGED?

CURRENT LCD

FUTURE EFFECTIVE LCD

Assessments	DFU – Assessment of Type I or II diabetes and management history. Review HbAIC and ABI, diet, nutrition, activity, and physical exam. Ankle-Brachial Index (ABI) of no less than 0.6t toe pressure greater than 30 millimeters of mercury (mmHg)	DFU – Assessment of Type I or II diabetes and management history. Review of HbAIC, diet, nutrition, activity, physical exam that includes assessment of skin, ulcer, and vascular perfusion, and assessment of off-loading devices or use of appropriate footwear.
	VLU – Assessment of clinical history, ABI, duplex scan to confirm CEAP classification.	VLU – Assessment of clinical history, higher body mass index, history of pulmonary embolism or superficial deep vein thrombosis, higher number of pregnancies and physical inactivity. Physical exam must include vascular competence. The documented use of a firm strength compression garment (>20 mmHg) or multi-layered compressive dressings is an essential component of SOC for venous stasis ulcers.
Minimum Size of Ulcer	1 cm ²	No minimum
Smoking Cessation	Ideally, 4 weeks cessation. Smoking cessation counseling.	Smoking history; counseled on effects of smoking on wound healing; outcomes of counseling.
Duration of Ulcer	DFU - 4 weeks VLU - 3 months	4 weeks
Standard of Care	DFU - 4 weeks VLU - 30 days	4 weeks
Treatment Window	12 weeks	12 - 16 weeks. More than 12 weeks will require documentation demonstrating progression of wound closure under current treatment plan.
Allowed Applications	10 applications	8 applications. More than 4 applications must be appended with a -KX modifier.
Switching Products	Allowed	Allowed
Retreatments (new episode of same ulcer)	No retreatment within one year. Retreatment allowed with (defined) medical necessity. Not allowed if > 75% size reduction & smaller than 0.5 cm ² .	The reason(s) for any repeat application should be specifically addressed in the medical record, whether the current treatment plan has resulted in wound healing, and expectation that the wound will continue to heal with this plan. Documentation should include estimated time for extended treatment, number of additional applications anticipated, and plan of care if healing is not achieved as planned.
Wastage	Where multiple sizes of a specific product are available, the size that best fits the wound with the least amount of wastage will be utilized. See LCD for documentation requirements.	Use product in an efficient manner utilizing the most appropriate sized product available at the time of treatment (i.e., if multiple sizes, use size that best fits ulcer to minimize waste). The LCD and Billing & Coding Article has specific guidance around the utilization of the -JW and -JZ modifiers for wastage.
Diagnosis	Addresses DFU/VLU	Addresses DFU/VLU
Diagnosis Lists	No	Included in Billing and Coding Articles.

EPIFIX AND EPICORD REMAIN COVERED











