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 HbA1C and ABI, diet, nutrition, activity, and physical exam.	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	No minimum	No minimum
Smoking Cessation	Patient is a nonsmoker, or has refrained from smoking for at least 6 weeks prior to planned skin replacement surgery, or has received counseling on the effects of smoking on surgical outcomes and treatment for smoking cessation.	Smoking history; counseled on effects of smoking on wound healing; outcomes of counseling.
Duration of Ulcer	DFU - 4 weeks VLU - 4 - 6 weeks	4 weeks
Standard of Care	DFU - 4 weeks VLU - 4 - 6 weeks	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	12 applications	8 applications. More than 4 applications must be appended with a -KX modifier.
Switching Products	Not expected	Allowed
Retreatments (new episode of same ulcer)	Subject to medical review.	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	Only a reasonable amount of wastage is covered. 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











