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

WHAT CHANGED?	CURRENT LCD	NEW LCD
	DFU — Assessment of Type I or II diabetes and management history. Review HbA1C and ABI, diet, nutrition, activity, and physical exam. Ankle-Brachial Index (ABI) of no less than 0.60, toe pressure greater than 30 millimeters of mercury (mmHg).	DFU — Assessment of Type I or II diabetes and management history. Review of blood glucose level/HbA1C, 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.
Assessments	VLU — Assessment of clinical history, ABI, duplex scan to confirm CEAP classification.	VLU — Assessment of clinical history (that includes prior ulcers, body mass index, history of pulmonary embolism or superficial/deep venous thrombosis, number of pregnancies, and physical inactivity), physical exam (edema, skin changes and vascular competence), evaluation of venous reflux, perforator incompetence, and venous thrombosis. The use of a firm strength compression garment (>20 mmHg) or multi-layered compressive dressing 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; treatment and outcomes of counseling, if applicable.
Duration of Ulcer	DFU – 4 weeks; VLU – 3 months	4 weeks
Standard of Care	DFU – 4 weeks; VLU – 30 days	4 weeks with less than 50% ulcer area reduction with documented SOC.
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
Reapplication (current episode)	Repeat or alternative applications of skin substitute grafts are not considered medically reasonable and necessary when a previous full course of applications was unsuccessful. Unsuccessful treatment is defined as increase in size or depth of an ulcer or no change in baseline size or depth and no sign of improvement or indication that improvement is likely (such as granulation, epithelialization or progress towards closing) for a period of 4 weeks past start of therapy.	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.
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 LCD does not prohibit retreatment of an ulcer that recurs in the same location after previous successful treatment.
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

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Access your MAC's LCD, Billing & Coding Article, and other important resources: mimedx.info/2025-LCDs

