New Skin Substitute Policies

It's important to keep up with these new regulations.

BY JEFFREY LEHRMAN, DPM

On November 14, 2024, all seven Part B Medicare Administrative Contractors released identical coverage policies that will govern the application of skin substitutes (cellular and tissue-based products) applied to diabetic foot ulcers and venous leg ulcers for Medicare Part B beneficiaries. These policies only rigidly apply to skin substitute application performed for diabetic foot ulcers and venous leg ulcers. These policies will be effective February 12, 2025.

Diabetic Foot Ulcers

The policies state the indication for coverage for a diabetic foot ulcer is:

"Non-infected and failed to achieve at least 50% ulcer area reduction with documented standard of care treatment for a minimum of 4 weeks with documented compliance"

The policies state this "standard of care" of a diabetic foot ulcer referenced above must include documentation of:

- Assessment of Type 1 or Type 2 diabetes
- Management history of diabetes
- Assessment for vascular disease
- Assessment for neuropathy
- Assessment for osteomyelitis
- Review of current blood glucose levels
- Hemoglobin A1c (HbA1c)
- Diet
- Nutritional status
- Activity level
- Assessment of skin
- Ulcer exam
- Assessment for vascular perfusion (Vascular assessment)
- Assessment of off-loading devices or use of appropriate footwear.
- Offloading

Venous Leg Ulcers

The policies state the indication for coverage for a venous leg ulcer is:

"Non-infected and failed to respond to documented standard of care treatment for a minimum of 4 weeks with documented compliance"

The policies state this "standard of care" of a venous leg ulcer referenced above must include documentation of:

- History of prior ulcers
- BMI
- History of pulmonary embolism?
- History of superficial/deep venous thrombosis?
- Number of pregnancies
- Physical inactivity
- Exam relative to edema
- Exam relative to skin changes
- Exam for vascular competence
- Evaluation of venous reflux
- Evaluation of perforator incompetence
- Evaluation for venous thrombosis.
- Sustained use of a firm strength compression garment (>20 mmHg) or multi-layered compressive dressing

Documentation Requirements

For both diabetic foot ulcer and venous leg ulcer application, the documentation must include:

- Debridement as appropriate to a clean granular base.
- Infection control with removal of foreign body or focus of infection.
- Management of exudate with maintenance of a moist environment.
- Documentation of smoking history, and counselling on the effect of smoking on wound healing and outcome of counselling
- Treatments attempted and failed
- Medications
- Name of product
- Risks and complications
- Operative note detailing application procedure
- Quantity used and wasted
- Time of application
- Name of product applied and package size
- Manufacturer's serial/lot/batch or other unit identification number of product applied
- Patient name and date of service on every page
- Legible signature of practitioner
- Why ulcer healing has stalled with standard ulcer care treatment of greater than 4 weeks
- Ulcer description pre- and post- treatment
- Plan for skin replacement therapy and the choice of skin substitute grafts/CTP for the 12-to-16-week period

"Non-infected and failed to respond to documented standard of care treatment for a minimum of 4 weeks with documented compliance"

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- Any anticipated repeat applications within the 12-to-16-week period.
- Modifiable risk factors are being addressed to improve likelihood of healing

Measurement Requirements

For each application, the documentation must contain:

- Measurements and stage at initial presentation
- Measurements and stage at prior to initiating standard of care
- Measurements and stage at each week throughout standard of care attempts
- Measurements and stage at end of standard of care attempts
- Measurements and stage at first application
- Measurements and stage at each subsequent application.

Subsequent Applications

When any subsequent application is performed, providers must document:

- Reason(s) for repeat application
- Whether the current treatment plan has resulted in wound healing
- Expectation that the wound will continue to heal with this plan.
- Estimated time for extended treatment
- Number of additional applications anticipated
- Plan of care if healing is not achieved as planned.

Limitations

The maximum number of applications of a skin substitute graft/CTP allowed by these policies is 8 within the 12 to 16 week episode of skin replacement therapy if there is documentation of progression of wound closure under the current treatment plan and medical necessity for additional applications is documented. This "episode of skin replacement therapy" begins with the first application.

The -KX Modifier should be used when more than 4 applications are performed within the episode of skin replacement therapy and the documentation supports the medical necessity of this number of applications. In addition to all the requirements already listed herein, if more than 4 applications are performed within the episode of skin replacement therapy, added documentation requirements include:

- Why extended time/additional applications are medically necessary
- Current treatment plan has resulted in wound healing and expectation that the wound will continue to heal with this plan.
- Estimated time for extended treatment
- Number of additional applications anticipated
- Plan of care if healing is not achieved as planned.
- What modifiable risk factors, such as diabetes optimization, are being approached to improve likelihood of healing.

Usage Guidelines

Additional utilization guidelines listed in the policy include:

- Use the most appropriately sized product available at the time of treatment, based on size of ulcer.
- The graft must be applied in a single layer without overlay
- Skin substitute may only be applied over exposed muscle, tendon, or bone if the product has labeled indication to do so.
- Cannot repeat applications if previous application was "unsuccessful" where increase in size or depth of an ulcer, no measurable change from baseline, and no sign of improvement or indication that improvement is likely to be defined as "unsuccessful treatment."
- Cannot apply if active infection
- Cannot apply if necrosis
- Cannot apply if active Charcot arthropathy of the ulcer extremity
- Cannot apply if active vasculitis
- Cannot apply if ischemia

The new policies state that patients who receive skin substitute application for diabetic foot ulcers or venous leg ulcers "should be under the care of a physician/non-physician practitioner for the treatment of their systemic disease process."

Coding

Under these new policies, for all 7 Part B MACs, when all the skin substitute product is used, the product code should be listed on one line with the -JZ Modifier appended. If there is skin substitute product wasted, the product code should be listed twice, with the number of units used on one line and the number of units wasted on another line with the JW Modifier appended to the wastage line.

Under these new policies, for all 7 Part B MACs, when all the skin substitute product is used, the product code should be listed on one line with the -JZ Modifier appended.

Products

These new policies name 20 brand name products that are "covered for diabetic foot ulcers." These new policies name 5 brand name products that are "covered for venous leg ulcers." All 5 of the products on the venous leg ulcer list are also on the diabetic foot ulcer list.

Conclusion

These new policies, and their guidelines listed herein, are scheduled to take effect February 12, 2025, and will govern skin substitute application to diabetic foot ulcers and venous leg ulcers for all Medicare Part B beneficiaries in the country. PM

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