Surgical Wound Care
ASSOCIATES

Date: 09/15/2025

Attention: United Healthcare Medicare Replacement Advantage PPO

RE: James Lester

Policy # 946494622

Group # 90810

Case # 00159260

Primary diagnosis: L97.222, I89.332

Dear Utilization Review Manager:

On behalf of my patient, James Lester, this letter serves as a pre-authorization request and provides clinical information on this patient's condition. It also serves as a formal request for coverage by United Healthcare for the medically necessary health care services captioned above. This letter and its supporting documents will provide you with a better depiction of this patient's clinical history and this patient's need for the ARTACENT WOUND® SKIN SUBSTITUTE GRAFT PROCEDURE. It is my sincere hope that this additional information will inform your decision to approve this surgery.

Description of Procedure:

Skin Substitute Description: Artacent Wound® is a dual-layer dehydrated amniotic membrane allograft. Human amniotic membrane is a thin collagenous membrane derived from the submucosa of the placenta. Human amniotic membrane consists of multiple layers including epithelial cells, a basement membrane, and a stromal matrix. This skin graft substitute may be used as a wound covering in various surgical procedures.

Utilizing a proprietary process, Allograft tissues are processed in a controlled environment using methods designed to prevent contamination and cross contamination. Allograft tissue is sterilized using gamma irradiation in accordance with ISO 11137 guidelines.

Artacent Wound® is regulated by the U.S. Food and Drug Administration (FDA) as a human skin tissue under its Human Cells, Tissues, and Tissue-Based Products (HCT/P) guidelines, subject to Section 361 of the Public Health Service Act and 21 CFR 1271.

Patient's Clinical Need for the Artacent Wound® Skin Substitute Graft Procedure:

Patient Name: James Lester

Age: 61, Male

Mr. Lester was referred to Surgical Wound Care Associates secondary to full thickness recalcitrant ulcer to left medial lower leg that started in August 2024 after puncture wound from mesquite tree/thorn. He has a complex medical history with rheumatoid arthritis (now holding DMARDS), ankylosing spondylitis, epidermolysis bullosa, chronic septic arthritis and was diagnosed with pulmonary cocci and left lower extremity deep vein thrombosis in August 2024. He continues to take fluconazole daily, doxycycline twice daily and prednisone daily per rheumatologist and infectious disease recommendations.

Since beginning care with surgical wound care associates on 01/16/2026, we have been doing weekly sharp debridement. He also underwent surgical debridement inpatient with Dr. Kraemer, MD on 3/11/2025. He completed varithena procedure to the left GSV with Jennifer Clarke, PA. We have done several different dressing changes including hydrogel, collagen matrix, iodoflex, and wet to dry dressings without much improvement. He just recently completed another round of oral antibiotics secondary to recurrent infections with MRSA and pseudomonas bacteria. They have due to immunocompromised status he is high risk for recurrent infections to chronic recalcitrant wound.

The use of the Artacent Wound® skin substitute is medically necessary for this patient due to the presence of a chronic, non-healing diabetic foot ulcer that has not responded to standard wound care, including regular debridement, offloading, moist wound therapy, and infection control.

Biologic skin substitutes like Artacent Wound® are indicated for wounds that demonstrate delayed healing beyond 30 days, placing the patient at increased risk for infection, hospitalization, amputation, and other serious complications. Artacent Wound® contains dehydrated amnion and chorion membrane, which has been shown to support wound healing through anti-inflammatory, anti-fibrotic, and pro-angiogenic properties.

Given the failure of conservative measures and the high risk of morbidity associated with untreated diabetic foot ulcers, the application of a biologic graft is clinically appropriate and evidence-based to promote closure, prevent further deterioration, and reduce overall

healthcare costs by avoiding escalation of care. Furthermore, his primary insurance Medicare has approved 80% of cost but still patient is unable to afford the 20% remaining co-insurance cost.

In a discussion with the patient following an exam, a decision was made to move forward with a skin substitute graft procedure. The unique design of Artacent Wound® allows for easy manipulation and repositioning, making it a flexible, dependable skin substitute for my patient.

I have attached the package insert for ARTACENT WOUND® SKIN SUBSTITUTE GRAFT. Should you have further questions or concerns, please do not hesitate to call me at 520-497-5080. Thank you for your immediate attention and anticipated authorization of these services for your insured.

Sincerely,

Jennifer Carlile FNP-C

Surgical Wound Care Associates

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