**Indications:**
Application of a skin substitute graft for lower extremity chronic wounds (diabetic foot ulcer and venous leg ulcer) will be covered when the following conditions are met for the individual patient:

- Presence of a chronic, non-healing wound (i.e. has not responded to standard wound treatment) for at least a 30-day period.
- Presence of neuropathic ulcers and diabetic foot ulcer(s) having failed to respond to documented conservative wound care measures of greater than four weeks, during which the patient is compliant with recommendations, and without evidence of underlying osteomyelitis or nidus of infection.
- Presence of a venous stasis ulcer for at least three months, but unresponsive to appropriate wound care for at least 30-days with documented compliance.
- Presence of a full-thickness, skin loss ulcer that is the result of abscess, injury, or trauma that has failed to respond to appropriate control of infection, foreign body, tumor resection, or other disease process for a period of four weeks or longer.
- Ulcers or wounds with a failed response to standard wound care that are:
  - Partial- or full-thickness ulcers, not involving tendon, muscle, joint capsule, or exhibiting exposed bone or sinus tracts, with a clean granular base unless the CTP package label indicates the CTP is approved for use involving tendon, muscle, joint capsule or exhibiting exposed bone or sinus tracts, with a clean granular base;
  - Skin deficit at least 1.0 cm² in size;
  - Clean and free of necrotic debris or exudate;
  - Have adequate circulation/oxygenation to support tissue growth/wound healing as evidenced by physical examination (e.g. Ankle-Brachial Index (ABI) of no less than 0.60, toe pressure > 30mm Hg);
  - For diabetic foot ulcers, the patient’s medical record reflects a diagnosis of Type 1 or Type 2 Diabetes and also reflects medical management for this condition.
Limitations/Restrictions on Coverage:

- Ideally, patients who have smoked will have ceased smoking or have refrained from systemic tobacco intake for at least four weeks during conservative wound care and prior to planned bioengineered skin replacement therapy.
- In all wound management, the ulcer must be free of infection and underlying osteomyelitis with documentation of the conditions that have been treated and resolved prior to the institution of skin substitute therapy. Appropriate wound management therapy is described in the LCD.
- Partial-thickness loss with the retention of epithelial appendages is not a candidate for grafting or replacement, as epithelium will repopulate the deficit from the appendages, negating the benefit of overgrafting.
- One specific skin substitute graft per wound, per treatment will be allowed for wound care in compliance with FDA guidelines for that specific product, not to exceed ten applications or treatments.
- Treatment of any chronic skin wound will typically last no more than twelve weeks.
- Repeat treatment with the same skin substitute graft 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 four weeks past start of therapy.
- Retreatment of healed ulcers, those showing greater than 75% size reduction and smaller than 0.5 cm².
- Skin substitute grafts are contraindicated and not considered reasonable and necessary in patients with inadequate control of underlying conditions or exacerbating factors (e.g. uncontrolled diabetes, active infection, and active Charcot arthropathy of the ulcer extremity, vasculitis or continued tobacco use, where no documented counseling on the effects of smoking on surgical outcomes and the success of the application of skin grafts is available).
- Skin substitute grafts are contraindicated in patients with known hypersensitivity to any component of the specific skin substitute graft (e.g. allergy to avian, bovine, porcine, or equine products).
- Re-treatment within one year of any given course of skin substitute treatment for a venous stasis ulcer or (diabetic) neuropathic foot ulcer is considered treatment failure and does not meet reasonable and necessary criteria for re-treatment of that ulcer with a skin substitute procedure.
- Medicare coverage for wound care on a continuing basis, for a single wound, in an individual patient is contingent upon evidence documented in the patient’s medical record that the wound is improving in response to the wound care being provided. Since it is neither reasonable nor medically necessary to continue a given type of wound care in the absence of wound improvement, it is expected that the wounds response to treatment will be documented in the medical record at least once every 30 days for each episode of wound treatment and made available to the contractor upon request.

Coding Guidance:

HCPCS codes listed in the LCD are inclusive of known FDA approved bioengineered wound dressings, skin substitutes, matrices or scaffolding for chronic ulcer treatment as of publication and include:

- Q411B - MicroMatrix®, 1 mg
- Q4166 - Cytal® Wound Matrix, per sq cm

Repeat use of surgical preparation services (CPT codes 15002, 15003, 15004, and 15005) in conjunction with skin substitute application codes will be considered not reasonable and necessary. It is expected that each wound will require the use of an appropriate wound preparation code at least once at initiation of care prior to placement of the skin substitute graft.

When billing for skin substitutes, use of the JW modifier to identify unused product from single use packages that are appropriately discarded is required. The discarded amount shall be billed on a separate claim line using the JW modifier. Providers are required to document the discarded product in the patient’s medical record. The medical record must clearly document the amount applied and the amount wasted. The documentation must include the date, time, and the reason for the wastage. In situations where a portion of a single use package must be discarded, payment will be made for the portion discarded along with the amount applied up to the amount of the product on the package label.
