Abstract Purpose:
Network Health Plan/Network Health Insurance Corporation/Network Health Administrative Services, LLC’s (NHP/NHIC/NHAS) care management (CM) department, including utilization management (UM), applies review guidelines for determinations involving medical necessity for the use of Skin Substitutes - Collagen Dermal Matrix materials. These products are used for complex wounds and surgical procedures.

Policy Detail:
Refer to the appropriate Certificate of Coverage, Evidence of Coverage, Summary Plan Description, Individual and Family Plan or State of Wisconsin It's Your Choice Reference Guide to determine eligibility and coverage because Employer Group/Plan Sponsor and government contracts may vary. NHIC follows Medicare’s National/Local (Wisconsin area) Coverage Determinations for its Medicare Advantage membership.

I. Description:
   A. Collagen dermal matrix materials are biologic skin substitute made from human tissue which is processed to remove all potentially allergenic cells or those that may cause rejection. Bioengineered skin substitutes are classified into the following categories:
      a. Acellular matrices: derived from xenogeneic collagen or tissue. The majority of bioengineered skin substitutes falls into this category. These are composed of allogenic or xenogeneic collagen, membrane or cellular remnants which promote healing by creating localized intensification of an array of enzymatic and hormone activity to accelerate wound closure.
      b. Allogenic matrices: derived from human tissues (fibroblasts and membrane) are usually derived from human neonate foreskin tissue. This tissue contains regenerative components primarily used for soft tissue support and at times, full thickness skin loss.
      c. Composite matrices: derived from human keratinocytes, fibroblasts and xenogeneic collagen and are supported by synthetic mesh or xenogeneic collagen. Commonly called “human skin equivalents”, thought to be accelerated due to the active cell components that generate protein and bioactive compounds.
      d. Human skin allografts: derived from donated human skin/cadavers where intact cells are treated and removed to avoid immunologic rejection.
B. The Food and Drug Association (FDA) regulates “Skin Substitute” products and lists them with a HCPCS code Q41XX.

C. Coverage for wound care on a continuing basis is contingent upon evidence documented in the patient’s medical record that the wound is improving in response to the wound care being provided. A wound with no response is defined as having failed to respond to documented appropriate wound-care measures, has increased in size or depth, or has not changed in baseline size or depth, AND shows no signs that improvement is likely (such as granulation, epithelialization or progress towards closing).

II. Medical Indicators/Criteria:

A. NHP/NHIC/NHAS considers the use of collagen dermal materials as medically necessary when the following criteria for the specific skin substitute requested are met:

1. Breast Reconstruction procedures:
   i. Skin substitute treatment is medically necessary for breast reconstruction procedures for at least one of the following indications:
      1. When there is insufficient tissue expander or implant coverage by the pectoralis major muscle and additional coverage is required; OR
      2. Then there is viable but compromised or thin post-mastectomy skin flaps that are at risk of dehiscence or necrosis; OR
      3. The infra-mammary fold and lateral mammary folds have been undermined during mastectomy and re-establishment of these landmarks are needed.

2. Non-healing surgical, traumatic and/or radiation therapy wounds.
   i. Skin Substitutes for the use of non-healing surgical, traumatic and/or radiation therapy wounds are medically necessary when all the criteria are met:
      1. Used in conjunction with standard wound care regimens to promote wound healing AND
      2. Ulcer or skin deficit is at least 1.0 cm in size and has failed or had no response to documented conventional wound therapies.
   ii. Limited to one initial application when above criteria is met.
   iii. Additional applications may be applied with evidence of improvement (i.e. granulation, reduction in size of ulcer)
   iv. Application use beyond 12 weeks is considered not medically necessary no matter the status of the wound.
   v. It is expected all response to treatment will be documented in the patient’s medical record at least once every 30 days for each episode of wound treatment.

3. Full thickness/Partial Thickness Ulcers and Diabetic Foot Ulcers
   i. Skin Substitutes for the use of full-thickness/partial thickness and/or neuropathic diabetic foot ulcers are medically necessary when all of the criteria are met:
      1. Used in conjunction with standard wound care regimens to promote wound healing AND
      2. Ulcer or skin deficit is at least 1.0 cm in size and has failed or had no response to documented conventional wound therapies AND
      3. An involved foot has adequate blood supply (i.e. ankle-
brachial index (ABI) ≥ 0.70 or palpable pedal pulse) AND

4. For diabetic foot ulcers, the patient:
   1. Is diagnosed as a type I or type II diabetic AND
   2. has optimal diabetic management during treatment (i.e. hemoglobin A1c less than 12%) AND
   3. An involved foot has adequate blood supply (i.e. ankle-brachial index (ABI) ≥ 0.70 or palpable pedal pulse) AND
   4. is following appropriate non-weight bearing or off-loading pressure.

   ii. Limited to one initial application when above criteria are met.
   iii. Additional applications may be applied with evidence of improvement (i.e. granulation, reduction in size of ulcer)
   iv. Application use beyond 12 weeks is considered not medically necessary no matter the status of the wound.
   v. It is expected all response to treatment will be documented in the patient’s medical record at least once every 30 days for each episode of wound treatment

4. Venous Insufficiency/Venous Stasis Ulcers
   i. Network Health considers the use of skin substitutes medically necessary for the treatment of Venous Insufficiency/Venous Stasis Ulcers when all of the following criteria are met:
      1. The venous stasis ulcer has failed or had no response to documented conventional wound therapies AND
      2. If the wound is on the foot, the involved foot has adequate blood supply to the (i.e. ankle-brachial index (ABI) ≥ 0.70 or palpable pedal pulse) AND
      3. The venous stasis ulcer history is longer than 4 weeks duration
      4. The patient is following appropriate compression therapy with documented diligent use of multilayer dressings, compression hose, or pneumatic compression.
      5. Limited to one initial application when above criteria are met.

   ii. Additional applications over 12 weeks may be applied with evidence of improvement (i.e. granulation, reduction in size of ulcer)
   iii. Application use beyond 12 weeks is considered not medically necessary no matter the status of the wound.
   iv. It is expected all response to treatment will be documented in the patient’s medical record at least once every 30 days for each episode of wound treatment.

5. For all wound types being treated with a skin substitute graft, the following apply:
   i. The ulcer must be clean, free of infection and exudate and have undergone debridement to remove necrotic debris.
   ii. Any underlying infection (cellulitis, osteomyelitis) must be resolved prior to initiation any skin substitute regimen.

III. Coverage:
   A. The use of collagen dermal matrix materials is a covered benefit deemed medically necessary per the criteria listed above.
B. NHP/NHIC/NHAS follows CMS National Coverage Determinations (NCD) and Wisconsin Local Coverage Determinations (LCD) for application to its Medicare Advantage membership if available.

IV. Limitations/Exclusions:
   A. The use of skin substitutes is not medically necessary for the treatment of pressure ulcers.
   B. The use of collagen dermal matrix materials for all indications other than outlined above will be reviewed under NHP/NHIC/NHAS experimental, investigational and/or unproven process.
   C. Skin substitute grafts are contraindicated and are considered NOT medically necessary in patients with inadequate control of underlying conditions or exacerbating factors (e.g., uncontrolled diabetes, infection, and/or continued tobacco smoking without physician attempt to effect smoking cessation.
   D. Repeat or alternative applications of another skin substitute graft are not considered medically reasonable and necessary when a previous full course of applications was unsuccessful.
   E. Re-treatment with any skin substitute treatment for a diabetic foot ulcer or venous stasis ulcer within one (1) year is considered treatment failure and is therefore considered not medically necessary.
   F. Treatment for any chronic skin wounds should not continue longer than twelve (12) weeks.
   G. Skin substitutes are allowed for an episode of wound care following FDA guidelines for the specific product. Treatment applications will not exceed ten (10). In situations where more than one product is used, the expectation is that the total number of applications or treatments will still not exceed ten (10).
   H. Network Health will consider a request for a skin substitute submitted using an unlisted code, to be experimental/investigational/unproven.

V. References:
   H. Karr, Jeffrey C. Retrospective Comparison of Diabetic Foot Ulcer and Venous Stasis Ulcer Healing Outcome Between a Dermal Repair Scaffold (PriMatrix) and a Bilayered Living Cell Therapy (Apligraf). Adv Skin Wound Care, 24(3): 119-125, 2011.


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**Regulatory Citations:**
UM2

**Related Policies:**
None

**Related Documents:**
None

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**Revision Reason:**
10/07/16 – Transferred to new policy template.
1/19/17 – Policy update
1/18/2018- Annual review
11/20/18 – Policy update requested and MPC approved
1/17/2019- Policy updated