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. Collagen dermal matrix materials are biologic skin substitutes made from human cadaver skin which is processed to remove all potentially allergenic cells or those that may cause rejection. 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 cadaver skin which is processed to remove all potentially allergenic cells or those that may cause rejection.
   B. Types of collagen dermal matrix materials addressed in this policy:
      a. Alloderm: derived from human cadaver skin
      b. Apligraft: a culture derived human skin equivalent (HSE)
      c. Dermagraft: cryopreserved skin substitute derived from human allogeneic fibroblasts
      d. Epifix: Amniotic membrane allograft
      e. Grafix: cryopreserved placental membrane comprised of an extracellular matrix (ECM) rich in collagen, growth factors, fibroblasts and epithelial cells native to the tissue.

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. Alloderm 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. Diabetic Foot Ulcers
   i. Apligraft, Dermagraft, Epifix and Grafix for the use of full-
      thickness neuropathic diabetic foot ulcers is 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 has failed or had no response to conventional
         wound therapies AND
      3. The involved foot has adequate blood supply to the (i.e.
         ankle-brachial index (ABI) ≥ 0.70 or palpable pedal
         pulse) AND
      4. The patient has optimal diabetic management during
         treatment (i.e. hemoglobin A1c less than 12%) AND
      5. The diabetic foot ulcer presence is longer than
         1. 3 weeks duration for Apligraft use
         2. 4 weeks duration for Epifix and Grafix use
         3. 6 weeks duration for Dermagraft use
   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)
        1. Up to 5 applications over 12 weeks for Apligraft, Epifix
           and Grafix use; OR
        2. Up to 8 applications over 12 weeks for Dermagraft use
   iv. Application use beyond 12 weeks is considered not medically
       necessary no matter the status of the wound.

3. Venous Insufficiency/Venous Stasis Ulcers
   i. Network Health considers the use of Apligraft and Epifix
      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
         conventional wound therapies AND
      2. 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
   ii. Limited to one initial application when above criteria is met.
   iii. Additional applications up to 5 applications over 12 weeks 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.
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 Local Coverage Determinations (LCD) for application to its Medicare Advantage membership if available.

IV. Limitations/Exclusions:
   A. 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.

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 (Apligraft). Adv Skin Wound Care, 24(3): 119-125, 2011.
   L. Dr. Brian Kiesnowski, Board Certified American Board of Plastic Surgery and American Board of Surgery

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