n05189

Skin Substitutes and Other Advanced Wound Healing Products

Values

Accountability ● Integrity ● Service Excellence ● Innovation ● Collaboration

Abstract Purpose:

Network Health Plan/Network Health Insurance Corporation/Network Health Administrative Services, LLC's (NHP/NHIC/NHAS) utilization management (UM) team, applies review guidelines for determinations involving medical necessity for the use of Skin Substitutes - and other advanced wound healing products. These products are used for complex wounds, burns, and surgical procedures.

Policy Detail:

Refer to the appropriate Certificate of Coverage, Evidence of Coverage, Summary Plan Description, or Individual and Family Plan 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. In the absence of a Medicare LCD/NCD Network Health will use this internal policy criteria for medical necessity determinations for Medicare Advantage membership.

I. Description
   A. Biologic skin substitutes are collagen dermal matrix materials 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:
      1. 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.
      2. 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.
      3. 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.
      4. 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. For individuals meeting coverage indications for skin substitutes, up to two (2) initial applications may be approved. Approval for additional applications of a skin substitute 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 skin substitutes medically necessary when the following criteria for the specific skin substitute requested are met:

1. Breast Reconstruction procedures:
    a. Skin substitute treatment is medically necessary for breast reconstruction procedures for at least one of the following indications:
        i. When there is insufficient tissue expander or implant coverage by the pectoralis major muscle and additional coverage is required, **OR**
        ii. Then there is viable but compromised or thin post-mastectomy skin flaps that are at risk of dehiscence or necrosis, **OR**
        iii. 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:
    a. Skin Substitutes for the use of non-healing surgical, traumatic and/or radiation therapy wounds are medically necessary when all the criteria are met:
        i. Used in conjunction with standard wound care regimens to promote wound healing **AND**
        ii. Ulcer or skin deficit is at least one (1.0) square cm in size and has failed or had no response to documented conventional wound therapies for at least six (6) weeks.
3. Full thickness/Partial Thickness Ulcers and Diabetic Foot Ulcers:
    a. Skin Substitutes for the use of full thickness/partial thickness and/or neuropathic diabetic foot ulcers are medically necessary when **ALL** the criteria are met:
        i. Used in conjunction with standard wound care regimens to promote wound healing **AND**
        ii. Ulcer or skin deficit is at least one (1.0) square cm in size and has failed or had no response to documented conventional wound therapies for at least twelve (12) weeks. **AND**
        iii. An involved foot has adequate blood supply (i.e., ankle-brachial index (ABI) ≥ 0.70 or positive palpable pedal pulse) **AND**
        iv. 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., toe-brachial index (TBI) ≥ 0.50 or positive palpable pedal pulse) **AND**
4. Is following appropriate non-weight bearing or off-loading pressure.

4. Venous Insufficiency/Venous Stasis Ulcers
   a. Network Health considers the use of skin substitutes medically necessary for the treatment of Venous Insufficiency/Venous Stasis Ulcers when **ALL** the following criteria are met:
      i. The venous stasis ulcer has failed or had no response to documented conventional wound therapies for at least twelve (12) weeks **AND**
      ii. If the wound is on the foot, the involved foot has adequate blood supply - (i.e., ankle-brachial index (ABI) ≥ 0.70 or palpable pedal pulse) **AND**
      iii. The venous stasis ulcer history is longer than 4 weeks duration **AND**
      iv. The patient is following appropriate compression therapy with documented diligent use of multilayer dressings, compression hose, or pneumatic compression, **AND**
5. Burns
   a. See table below for coverage based upon each skin substitute used
6. For all wound types being treated with a skin substitute graft, the following apply:
   a. The ulcer must be clean, free of infection and exudate and have undergone debridement to remove necrotic debris **AND**
   b. Any underlying infection (cellulitis, osteomyelitis) must be resolved prior to initiation any skin substitute regimen.
   c. Limited to two (2) initial applications when above criteria are met.
   d. Additional applications may be applied with evidence of improvement (i.e., granulation, reduction in size of ulcer)
   e. Application use beyond 12 weeks is considered not medically necessary no matter the status of the wound.
   f. 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.

III. Coverage
   A. The use of skin substitutes is a covered benefit when deemed medically necessary per the criteria listed above.
   B. The use of Porcine (Pig) skin dressing are covered if reasonable and necessary for the individual patient as an occlusive dressing for burns, donor sites of a homograft, and decubiti/other ulcers.
   C. 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 skin substitute 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)
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 with use of skin substitutes, for any chronic skin wound(s) for greater than twelve (12) weeks, is considered not medically necessary.
G. Skin substitutes are allowed for an episode of wound care following FDA guidelines for the specific product. Treatment applications will not exceed eight (8) per wound per episode (per clinical reviewer determination of the wound). In situations where more than one product is used, the expectation is that the total number of applications or treatments will still not exceed eight (8).
H. Network Health will consider a request for a skin substitute submitted using an unlisted code, to be experimental/investigational/unproven.
I. Those identified by codes not listed below will be considered experimental/investigation/unproven.

Regulatory Citations:

UM2

Related Documents:

CPT Codes

The following CPT/HCPCS codes are covered if medical necessity criteria are met for diabetic foot ulcers, breast reconstruction, venous stasis ulcers, and/or surgical wounds*:

Q4101	Apligraf
Q4102	Oasis Wound Matrix, per sq cm
Q4106	Dermagraft
Q4110	Primatrix, per sq cm
Q4116	alloderm, per square cm
Q4121	TheraSkin
Q4122	DermACELL, per sq cm
Q4124	OASIS ultra tri-layer wound matrix, per sq cm
Q4128	FlexHD or AllopatchHD, per sq cm
Q4132	Grafix Core, per sq cm
Q4133	Grafix Prime, per sq cm
Q4151	Aminoband or Guardian
Q4159	Affinity
Q4186	Epifix
Q4187	Epicord, per square centimeter
The below skin substitutes are considered medically necessary for the treatment of burns when the indications for coverage have been met.	

Q4100	Biobrane Biosynthetic	Temporary covering of full thickness (third degree) or superficial partial thickness (second degree) burns prior to autografting.
Q4100	Biobrane L	Full thickness (third degree) or superficial partial thickness (second degree) burns.
Q4182	TransCyte	Full thickness (third degree) and deep partial thickness (second degree) burns prior to autograft
*CPT/HCPCS codes are subject to change as codes are retired or new ones are developed. This list may not be all inclusive.		

References:

A. MCG Ambulatory Care 30th Edition, Skin Substitute, Tissue Engineered (Human Cellular), for Diabetic Foot Ulcer and Venous Ulcer A-0326(AC)
B. U.S. Department of Health and Human Services CMS/Center for Medicare and Medicaid Services National Coverage Determination (NCD) for Porcine Skin and Gradient Pressure Dressing (270.5), publication number 100-3, Version 1.

Disclaimer:

Origination Date: 10/13/2011	**Approval Date:** 02/19/2026	**Next Review Date:** 02/20/2027
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Revision Reason: 10/07/2016 –Transferred to new policy template. 01/19/2017 –Policy update 01/18/2018-Annual review 11/20/2018 –Policy update requested and MPC approved 01/17/2019-Policy updated 10/17/2019-Annual review		

10/15/2020-Annual review, ulcer or skin deficit is 1.0 square cm, ABI changed to TBI, added porcine skin dressings, grammar, formatting & references updated, CPT Codes added
3/23/21 CPT codes Q4195 & Q4196 added
10/21/2021 Annual review, grammar, formatting, and references updated. CPT code Q4151.
03/22/2022 - updated formatting- CONSENT
10/20/2022 – Annual review, grammar, formatting, CPT codes, and references updated, Changed initial applications to 2 from 1, Approved at MPC 10/20/22
11/07/2023 removal of codes not covered under the policy, formatting, grammar, Approved at MPC
12/14/2023-+yearly review
12/12/2024-updates include code updates, grammatical updates, review/updates to references, and approving committee
02/19/2026 Annual review, Grammar, formatting, CPT codes and references updated. Added language surrounding timeline for documented failed conventional wound therapies