Skin Substitutes for Venous Ulcers and Diabetic Foot Ulcers

Policy Number:	**M20211221065**
Effective Date:	**3/1/2022**
Sponsoring Department:	**Health Care Services**
Impacted Department(s):	**Health Care Services**

Type of Policy: ☒ Internal ☒ External

Data Classification: ☐Confidential ☐Restricted ☒Public

Applies to (Line of Business):

☐ Corporate (All)
☒ State Products, if yes which plan(s): ☒MediSource; ☒MediSource Connect; ☒Child Health Plus; ☒Essential Plan
☒ Medicare, if yes, which plan(s): ☒MAPD; ☐PDP; ☒ISNP; ☒CSNP
☒ Commercial, if yes, which type: ☒Large Group; ☒Small Group; ☒Individual
☒ Self-Funded Services *(Refer to specific Summary Plan Descriptions (SPDs) to determine any pre-authorization or pre-certification requirements and coverage limitations. In the event of any conflict between this policy and the SPD of a Self-Funded Plan, the SPD shall supersede the policy.)*

Excluded Products within the Selected Lines of Business (LOB)

N/A

Applicable to Vendors? Yes ☐ No☒

Purpose and Applicability:

To set forth Independent Health's medical necessity criteria for the use of **skin substitutes** for **diabetic foot ulcers** and **venous stasis ulcers**.

Policy:

Commercial, Self-Funded and Medicare Advantage:

Based upon Independent Health's criteria and assessment of the peer-reviewed literature, each of the following bioengineered tissue products has been proven to be medically effective and, therefore, is considered medically appropriate for the listed indications, when criteria are met.

Diabetic foot ulcers:

- Covered skin substitutes:
  - Allopatch HD
  - Apligraf
  - Amnioband Membrance
  - Dermagraft
  - Epicord
  - Epifix
  - Grafix CORE
  - Grafix PL Core
  - Grafix PRIME
  - Grafix PL Prime
  - Integra
  - Integra Dermal Regeneration Matrix (Omnigraft)
  - Oasis Wound Matrix

- Criteria (all apply):
  - Photographic documentation is submitted of wound(s) prior to treatment;
  - The patient has adequate arterial blood supply as evidenced by ankle-brachial index (ABI) of 0.65 or greater in the limb being treated;
  - The patient is competent and/or has support system required to participate in follow-up care associated with treatment with a bioengineered tissue product;
  - Ulcers are full thickness, extend through the dermis but without tendon, muscle, capsule or bone exposure, and
  - Documentation that ulcer has failed to demonstrate **measurable signs of healing** with at least 4 weeks of standard wound care which includes all of the following:
    - Application of dressings to maintain a moist wound environment
    - Debridement of necrotic tissue if present
    - Offloading
  - Patient has adequate treatment of underlying disease process(es) contributing to the ulcer;
  - Ulcers are located on foot or toes and are free of infection, redness, drainage, underlying osteomyelitis, surrounding cellulitis, tunnels and tracts, eschar, or any necrotic material that would interfere with adherence of a bioengineered tissue product and wound healing; and
  - Patient's current HbA1C does not exceed 12% within the last 60 days.
  - Photographic documentation of wound to be obtained with each skin substitute application and retained by the provider and may be subject to retrospective review.

Venous Ulcers

- Covered skin substitutes
  - Apligraf
  - Oasis Wound Matrix

- Criteria
  - Photographic documentation is submitted of wound(s) prior to treatment;
  - The patient has adequate arterial blood supply as evidenced by ankle-brachial index (ABI) of 0.65 or greater in the limb being treated;
  - The patient is competent and/or has support system required to participate in follow-up care associated with treatment with a bioengineered tissue product;
  - Ulcers are partial or full thickness and have failed to demonstrate **measurable signs of healing** of at least one month duration including:
    - regular dressing changes,
    - debridement of necrotic tissue,
    - and standard therapeutic compression.
  - Patient has adequate treatment of the underlying disease process(es) contributing to the ulcer; and
  - Ulcers are free of infection, redness, drainage, underlying osteomyelitis, surrounding cellulitis, tunnels and tracts, eschar or any necrotic material that would interfere with adherence of a bioengineered tissue product and wound healing;
  - Photographic documentation to be obtained with each skin substitute application and retained by the provider and may be subject to retrospective review.

Note: It is the expected that a specific skin substitute product will be used for the episode of each documented wound, and in compliance with FDA assessments and submitted guidelines for the specific product. Greater than 10 applications for the treatment of a single wound within a 12-week period of time will be considered Not Reasonable and Necessary and will be subject to review.

All other bioengineered tissue products not listed above , have not been medically proven to be effective and, therefore, are considered investigational or unproven for diabetic foot ulcers or venous stasis ulcers.

MediSource, MediSource Connect, Child Health Plus and Essential Plan:
MediSource, MediSource Connect, Essential Plan, and CHP cover skin substitutes for venous stasis ulcers and diabetic foot ulcers utilizing the Commercial criteria above.

Background
The skin's purpose is to regulate body temperature and store water, fat, and vitamin D. Wounds are disruptions of the skin's structural and functional integrity. Chronic wounds have failed to pass through the normal healing process in an orderly and timely manner. Patients with chronic wounds deal with loss of function, wound recurrence, and significant morbidity. Chronic wounds include, among others, diabetic foot ulcers, and venous leg ulcers. Chronic wounds may need specific interventions to restart the healing process which is evidenced by reepithelization of epidermis and repair of the dermis. Successful healing of chronic wounds depends on critical factors, such as proper blood flow and nutrition to ensure tissue growth, infection control, maintenance of a moist environment, and removal of dead tissue to allow space for new cells and tissue to fill in the wound void

Care for chronic wounds involves removing necrotic tissue, applying dressings that maintain a moist wound environment, treating wound infections, and restoring blood flow to the wound site. If these procedures fail to restore the healing process, additional therapies may be considered.

Skin substitutes are indicated for use as an adjunct to standard wound care for uninfected wounds. The wound bed must be prepared prior to their application, generally with sharp debridement and

cleansing. Skin substitutes are heterogeneous and can generally be classified into 2 main types, cellular (comprised of living cells) and acellular (composed of synthetic materials or tissue from which living cells have been removed).

An evaluation of the peer-reviewed scientific literature, including but not limited to subscription materials, has provided Independent Health the basis for its medical necessity coverage outlined above.

Pre-Authorization Required? Yes ☒ No ☐

Preauthorization is required for this service for diabetic foot ulcers and venous stasis ulcers with diagnosis editing.

Definitions

Diabetic foot ulcer is an open break of the skin of the foot associated with neuropathy and/or peripheral arterial disease of the lower limb in a patient with diabetes.

Measurable signs of healing is defined as wound is diminishing in size (either surface or depth) and there is decreased amount of exudate and necrotic tissue.

Skin substitutes are a group of biologic, synthetic, or biosynthetic materials that can provide temporary or permanent coverage of open skin wounds, replicating the properties of the normal skin. Skin substitutes may be used to cover defects following burns or other injuries, or for reconstruction, such as for release of extensive severe post-burn contractures.

Venous stasis ulcer is an open break of the skin in an area in which circulation is sluggish and the venous return is poor, commonly in the ankle.

References

Related Policies, Processes and Other Documents
N/A

Non-Regulatory references
Agency for Healthcare and Research and Quality (AHRQ) [web site]. Technology Assessment Program Skin Substitutes for Treating Chronic wounds. February 2, 2020. Available at: https://www.cms.gov/Medicare/Coverage/DeterminationProcess/downloads/id109TA.pdf Accessed September 6, 2023.

Alexiadou K, Doupis J. Management of diabetic foot ulcers. Diabetes Ther. 2012 Nov;3(1):4.

Álvaro-Afonso FJ, García-Álvarez Y, Lázaro-Martínez JL, Kakagia D, Papanas N. Advances in Dermoepidermal Skin Substitutes for Diabetic Foot Ulcers. Curr Vasc Pharmacol. 2020;18(2):182-192.

Davison-Kotler E, Sharma V, Kang NV, et al . A Universal Classification System of Skin Substitutes Inspired by Factorial Design. Tissue Eng Part B Rev. 2018 Aug;24(4):279-288.

Gould L, Stuntz M, Giovannelli M, et al. Wound Healing Society 2015 update on guidelines for pressure ulcers. Wound Repair Regen. 2016 Jan-Feb;24(1):145-62.

Hayes, Inc. Comparative Effectiveness Review Acellular Skin Substitutes for Chronic Foot Ulcers in Adults with Diabetes Mellitus. Lansdale PA; May 2020.

Hayes, Inc. Comparative Effectiveness Review Cellular Skin Substitutes for Chronic Foot Ulcers in Adults with Diabetes Mellitus. Lansdale PA; March 2020.

Hayes, Inc. Comparative Effectiveness Review Skin Substitutes for Venous Leg Ulcers in Adults. Lansdale PA; July 2020.

Hayes, Inc. Health Technology Assessment Amniotic Allografts for Tendon and Ligament Injuries. Lansdale PA; September 2020.

Hayes, Inc. Health Technology Assessment Skin Substitutes for Venous Leg Ulcers. Lansdale PA; July 2023.

Hayes, Inc. Health Technology Assessment. Grafix Cryopreserved Placental Membrane (Osiris Technologies Inc.) for Treatment of Chronic Foot Ulcers in Patients with Diabetes Mellitus. Lansdale PA; September 3, 2019.

Kabnick LA, Scovell S. Overview of lower extremity chronic venous disease. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on September 6, 2023)

Nussbaum SR, Carter MJ, Fife CE, DaVanzo J, Haught R, Nusgart M, Cartwright D. An Economic Evaluation of the Impact, Cost, and Medicare Policy Implications of Chronic Nonhealing Wounds. Value Health. 2018 Jan;21(1):27-32.

Santema TB, Poyck PP, Ubbink DT. Skin grafting and tissue replacement for treating foot ulcers in people with diabetes. Cochrane Database Syst Rev. 2016 Feb 11;2(2):CD011255.

Shahrokhi S. Skin Substitutes. In: UpToDate, Post TW (Ed), UpToDate, Waltham, MA. (Accessed on September 6, 2023)

White-Chu EF, Conner-Kerr TA. Overview of guidelines for the prevention and treatment of venous leg ulcers: a US perspective. J Multidiscip Healthc. 2014 Feb 11;7:111-7.

Regulatory References

New York State Department of Health, Division of Managed Care Response to Coverage Question (CovQuest). Email response July 20, 2021.

New York State Department of Health [web site]. New York State Medicaid Program Physician Procedure Codes. Section 2 – Medicine, Drugs, and Drug Administration. Version 2021-2. Available at: https://www.emedny.org/providermanuals/physician/PDFS/Physician_Procedure_Codes_Sect2.pdf . Accessed: September 6, 2023.

This policy contains medical necessity criteria that apply for this service. Please note that payment for covered services is subject to eligibility criteria, contract exclusions and the limitations noted in the member's contract at the time the services are rendered.

Version Control

Signature / Approval on File? Yes ☒ No☐

Revision Date	Owner	Notes
1/1/2024	Health Care Services	Revised
11/1/2023	Health Care Services	Reviewed
11/1/2022	Health Care Services	Revised
9/1/2022	Health Care Services	Revised
5/1/2022	Health Care Services	Revised
3/1/2022	Health Care Services	Revised