MEDICAL MUTUAL®

Medical Policy

Policy: **200233**

SUBJECT: **Skin and Tissue Substitutes**

Effective Date: **03/09/2024**

Annual Review Date: **04/05/2024**

Last Revised Date: **04/05/2024**

Some or all procedure codes listed in this Corporate Medical Policy may be considered experimental/investigational.

Definition: Skin and tissue substitutes are utilized to for a wide variety of conditions and procedures including breast reconstruction, treatment of acute and chronic nonhealing wounds, ocular defects, surgical wounds and severe burns. They provide wound coverage and aid wound closure and are intended to reduce healing time, pain intensity, and postoperative contracture, thereby obviating the need for more extensive interventions. Skin and tissue substitutes comprise a heterogeneous group of acellular and cellular products. Acellular skin and tissue substitutes consist of a matrix containing collagen and/or other materials but do not contain living cells or cellular material. Cellular skin and tissue substitutes contain living cells, such as fibroblasts and keratinocytes, within a scaffold of natural or synthetic matrices. These matrices provide mechanical stability and a three-dimensional framework for tissue infiltration and growth, which can promote wound healing. The cells within the matrices may be autologous (derived from the individual's own body or body products), allogeneic (derived from humans other than the individual), or xenographic (derived from non-human organisms).

Medical Necessity:

I. The Company considers skin and tissue substitutes for **breast reconstruction surgery** medically necessary and eligible for reimbursement providing that all of the following medical criteria are met:

- Used for breast reconstruction after mastectomy for breast cancer; and
- Skin or tissue substitute used includes one of the following:
    - Cortiva
    - Alloderm Regenerative Tissue Matrix
    - Allomax Surgical Graft
    - DermACELL
    - FlexHD

II. The Company considers skin and tissue substitutes for **diabetic foot ulcers** medically necessary and eligible for reimbursement providing that all of the following medical criteria are met:

- Full thickness skin loss; and
- Treated foot has adequate blood supply (e.g., Ankle-Brachial Index (ABI) of no less than 0.60, toe pressure > 30mm Hg) ; and
- Conventional ulcer therapy has been ineffective for at least six weeks prior to Grafix or three weeks prior to other skin and tissue substitutes listed below; and
- Skin and tissue substitute used includes one of the following:
    - Amnioband
    - Apligraf
    - Oasis Wound Matrix
    - Dermagraft
    - Graftjacket
    - Theraskin
    - Epifix
    - Grafix
    - Integra Bilayer Matric Wound Dressing
    - Integra Dermal Regeneration Template
    - Integra Meshed Bilayer Wound Matrix

III. The Company considers skin and tissue substitutes for **venous leg ulcers** medically necessary and eligible for reimbursement providing that all of the following medical criteria are met:

- Treatment area has adequate blood supply (e.g., Ankle-Brachial Index (ABI) of no less than 0.60, toe pressure > 30mm Hg); and
- At least one month of conventional ulcer therapy has been ineffective; and
- Skin and tissue substitute used includes one of the following:
    - Apligraf
    - Oasis Wound Matrix
    - Theraskin
    - Oasis Ultra Tri-Layer
    - Epifix

IV. The Company considers skin and tissue substitutes for **burn wounds** medically necessary and eligible for reimbursement providing that all of the following medical criteria are met:

- Full thickness autologous graft is not feasible; and
- Skin and tissue substitute used includes one of the following:
    - Biobrane
    - Epicel
    - OrCel

- Integra Bilayer Matric Wound Dressing
- Integra Dermal Regeneration Template
- Integra Meshed Bilayer Wound Matrix
- TransCyte

V. The Company considers skin and tissue substitutes for **epidermolysis bullosa** medically necessary and eligible for reimbursement providing that all of the following medical criteria are met:

- Used during reconstructive hand surgery for individuals with recessive dystrophic epidermolysis bullosa; and
- Skin and tissue substitute used includes one of the following:
  - OrCel

NOTES:

- Based upon our findings, the Company has determined that the products not listed in the medical necessity criteria above have not demonstrated equivalence or superiority to currently accepted standard means of treatment. This includes all other skin and tissue substitute products for wound and dura mater repair. **The Company considers all other skin and tissue substitute products investigational and not eligible for reimbursement.**
- The Company reserves the right to review criteria for coverage of skin and tissue substitutes on a case by case basis as needed.

Documentation Requirements:

The Company reserves the right to request additional documentation as part of its coverage determination process. The Company may deny reimbursement when it has determined that the services performed were not medically necessary, investigational or experimental, not within the scope of benefits afforded to the member, and/or a pattern of billing or other practice has been found to be either inappropriate or excessive. Additional documentation supporting medical necessity for the services provided must be made available upon request to the Company. Documentation requested may include patient records, test results, and/or credentials of the provider ordering or performing a service. The Company also reserves the right to modify, revise, change, apply, and interpret this policy at its sole discretion, and the exercise of this discretion shall be final and binding.

Sources of Information:

- Agency for Healthcare Research and Quality (AHRQ). (2020, February 02). Technology Assessment: Skin substitutes for treating chronic wounds. Retrieved from https://www.ahrq.gov/sites/default/files/wysiwyg/research/findings/ta/comments/skin-substitutes-disposition-of-comments.pdf
- American Diabetes Association. (2022, December). Standards of Medical Care in Diabetes—2023. *Diabetes Care*. Retrieved from https://diabetesjournals.org/care/issue/46/Supplement_1
- Centers for Medicare & Medicaid Services. Local coverage determination for Wound Application of Cellular and/or Tissue Based Products (CTPs), Lower Extremities (L36690). CGS Administrators. Revision effective date September 1, 2022.
- Hayes, Inc., Lansdale, PA: Author
    - *Skin Substitutes for Venous Leg Ulcers in Adults*. (2023, July 11).
    - *Acellular Skin Substitutes for Chronic Foot Ulcers in Adults with Diabetes Mellitus*. (2023, May 10).
    - *Cellular Skin Substitutes for Chronic Foot Ulcers in Adults with Diabetes Mellitus.* (2023, April 25).
- Límová M. Active wound coverings: bioengineered skin and dermal substitutes. *Surg Clin North Am.* 2010;90(6):1237-1255.
- Mansbridge JN. Tissue-engineered skin substitutes in regenerative medicine. *Curr Opin Biotechnol*. 2009;20(5):563-567.
- Maurice SM, Skeete DA. Use of human acellular dermal matrix for abdominal wall reconstructions. *Am J Surg*. 2009;197(1):35-42.
- National Institute for Health and Care Excellence (NICE). *Diabetic Foot Problems: Prevention and Management*. London, UK: National Institute for Health and Care Excellence (NICE); 2019. NICE Clinical Guideline No. 19. Retrieved from https://www.nice.org.uk/guidance/ng19/resources/diabetic-foot-problems-prevention-and-management-pdf-1837279828933.
- Zelen CM, Gould L, Serena TE, Carter MJ, Keller J, Li WW. A prospective, randomised, controlled, multi-centre comparative effectiveness study of healing using dehydrated human amnion/chorion membrane allograft, bioengineered skin substitute or standard of care for treatment of chronic lower extremity diabetic ulcers. *Int Wound J*. 2015;12(6):724-732.

Applicable Code(s):	
CPT:	**15150, 15151, 15152, 15155, 15156, 15157, 15271, 15272, 15273, 15274, 15275, 15276, 15277, 15278, 15777, C9352, C9353, C9354, C9355, C9356, C9358, C9359, C9360, C9361, C9362, C9363, C9364**
HCPCS:	**A2011, A2012, A2013, A2014, A2015, A2016, A2017, A2018, A2109, A2022, A2023, A2024, A2025, A4100, Q4100, Q4101, Q4102, Q4103, Q4104, Q4105, Q4106, Q4107, Q4108, Q4110, Q4111, Q4112, Q4113, Q4114, Q4115, Q4116, Q4117, Q4118, Q4121, Q4122, Q4123, Q4124. Q4125, Q4126, Q4127, Q4130, Q4132, Q4133, Q4134, Q4135, Q4136, Q4137, Q4138, Q4139, Q4140, Q4142, Q4143, Q4145, Q4146, Q4147, Q4148, Q4149, Q4150, Q4151, Q4152, Q4153, Q4154, Q4155, Q4156, Q4157, Q4158, Q4159, Q4160, Q4161, Q4162, Q4163, Q4164, Q4165, Q4166, Q4167, Q4168. Q4169, Q4170. Q4171, Q4173, Q4174, Q4175, Q4176, Q4177, Q4178, Q4179, Q4180, Q4181, Q4182, Q4183, Q4184, Q4185, Q4186, Q4187, Q4188, Q4189, Q4190, Q4191, Q4192, Q4193, Q4194, Q4195, Q4196, Q4197, Q4199, Q4201, Q4203, Q4224, Q4225, Q4256, Q4257, Q4258, Q4259, Q4260, Q4261, Q4262, Q4263, Q4264, Q4265, Q4266, Q4267, Q4268, Q4269, Q4270, Q4271, Q4272, Q4273, Q4274, Q4275, Q4276, Q4277, Q4278, Q4279, Q4280, Q4281, Q4282, Q4283, Q4284, Q4285, Q4286, Q4287, Q4288, Q4289, Q4290, Q4291, Q4292, Q4293, Q4294, Q4295, Q4296, Q4297, Q4298, Q4299, Q4300, Q4301, Q4302, Q4303, Q4304, Q4305, Q4306, Q4307, Q4308, Q4309, Q4310**
ICD10 Procedure Codes:	**N/A**

HCPCS Codes A2011, A2012, A2013, A2014, A2015, A2016, A2017, A2018, A2019, A2022, A2023, A2024, A2025, Q4103, Q4108, Q4110, Q4111, Q4112, Q4113, Q4114, Q4115, Q4117, Q4118, Q4123, Q4125, Q4126, Q4127, Q4130, Q4134, Q4135, Q4136, Q4137, Q4138, Q4139, Q4140, Q4142, Q4143, Q4145, Q4146, Q4147, Q4148, Q4149, Q4150, Q4152, Q4153, Q4154, Q4155, Q4156, Q4157, Q4158, Q4159, Q4160, Q4161, Q4162, Q4163, Q4164, Q4165, Q4166, Q4167, Q4169, Q4170, Q4171, Q4173, Q4174, Q4175, Q4176, Q4177, Q4178, Q4179, Q4180, Q4181, Q4183, Q4184, Q4185, Q4187, Q4188, Q4189, Q4190, Q4191, Q4192, Q4193, Q4194, Q4195, Q4196, Q4197, Q4199, Q4201, Q4203, Q4224, Q4225, Q4256, Q4257, Q4258, Q4259, Q4260, Q4261, Q4262, Q4263, Q4264, Q4265, Q4266, Q4267, Q4268, Q4269, Q4270, Q4271, Q4272, Q4273, Q4274, Q4275, Q4276, Q4277, Q4278, Q4279, Q4280, Q4281, Q4282, Q4283, Q4284, Q4285, Q4286, Q4287, Q4288, Q4289, Q4290, Q4291, Q4292, Q4293, Q4294, Q4295, Q4296, Q4297, Q4298, Q4299, Q4300, Q4301, Q4302, Q4303, Q4304, Q4305, Q4306, Q4307, Q4308, Q4309, Q4310 are considered investigational and not eligible for reimbursement.

HCPCS Codes, C9352, C9353, C9354, C9355, C9356, C9358, C9359, C9360, C9361, C9362, C9363, and C9364 are temporary codes established by the Centers for Medicare & Medicaid Services. These codes are valid for hospital outpatient services and procedures ONLY and should be submitted on a facility/institutional claim.