BlueCross BlueShield Arizona

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EVIDENCE-BASED CRITERIA	**ORIGINAL EFFECTIVE DATE: 05/21/24**
SECTION: SURGERY	**LAST REVIEW DATE: 05/21/24**
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BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES

Non-Discrimination Statement and Multi-Language Interpreter Services information are located at the end of this document.

Coverage for services, procedures, medical devices and drugs are dependent upon benefit eligibility as outlined in the member's specific benefit plan. This Evidence-Based Criteria must be read in its entirety to determine coverage eligibility, if any.

This Evidence-Based Criteria provides information related to coverage determinations only and does not imply that a service or treatment is clinically appropriate or inappropriate. The provider and the member are responsible for all decisions regarding the appropriateness of care. Providers should provide BCBSAZ complete medical rationale when requesting any exceptions to these guidelines.

The section identified as "Description" defines or describes a service, procedure, medical device or drug and is in no way intended as a statement of medical necessity and/or coverage.

The section identified as "Criteria" defines criteria to determine whether a service, procedure, medical device or drug is considered medically necessary or experimental or investigational.

State or federal mandates, e.g., FEP program, may dictate that any drug, device or biological product approved by the U.S. Food and Drug Administration (FDA) may not be considered experimental or investigational and thus the drug, device or biological product may be assessed only on the basis of medical necessity.

Evidence-Based Criteria are subject to change as new information becomes available.

For purposes of this Evidence-Based Criteria, the terms "experimental" and "investigational" are considered to be interchangeable.

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BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES

Description:

Amniotic and placental products are not reviewed in this policy.

Bioengineered skin and soft tissue substitutes may be derived from human tissue (autologous or allogeneic), non-human tissue (xenographic), synthetic materials, or a composite of these materials. Bioengineered skin and soft tissue substitutes are being evaluated for a variety of conditions, including breast reconstruction and healing lower-extremity ulcers and severe burns. Acellular dermal matrix (ADM) products are also being evaluated for soft tissue repair.

There is no standard definition of “skin substitute". Products in this review cover products that do not require U.S. Food and Drug Administration (FDA) approval or clearance as well as a number of products cleared through the 510(k) pathway with a variety of FDA product codes. The FDA product codes that include these products are not limited to skin substitute products and may include other indications not related to wounds. The list of products named in this review is not a complete list of all commercially available products.

The Women’s Health and Cancer Rights Act (WHCRA) helps protect many women with breast cancer who choose to have their breasts rebuilt (reconstructed) after a mastectomy. Mastectomy is surgery to remove all or part of the breast. This federal law requires most group insurance plans that cover mastectomies to also cover breast reconstruction. It was signed into law on October 21, 1998. The United States Departments of Labor and Health and Human Services oversee this law.

Bioengineered skin and soft tissue substitutes may be either acellular or cellular. Acellular products (e.g., dermis with cellular material removed) contain a matrix or scaffold composed of materials such as collagen, hyaluronic acid, and fibronectin. Acellular dermal matrix (ADM) products can differ in a number of ways, including by species source (human, bovine, porcine), tissue source (e.g., dermis, pericardium, intestinal mucosa), additives (e.g., antibiotics, surfactants), hydration (wet, freeze-dried), and required preparation (multiple rinses, rehydration).

Cellular products contain living cells such as fibroblasts and keratinocytes within a matrix. The cells contained within the matrix may be autologous, allogeneic, or derived from other species (e.g., bovine, porcine). Skin substitutes may also be composed of dermal cells, epidermal cells, or a combination of dermal and epidermal cells, and may provide growth factors to stimulate healing. Bioengineered skin substitutes can be used as either temporary or permanent wound coverings.

AlloDerm® (LifeCell Corp.) is an acellular dermal matrix (allograft) tissue-replacement product created from native human skin and processed so that the basement membrane and cellular matrix remain intact. Originally, AlloDerm® required refrigeration and rehydration before use. It is currently available in a ready-to-use product stored at room temperature. An injectable micronized form of AlloDerm® (Cymetra) is available.

AlloPatch® (Musculoskeletal Transplant Foundation) is an acellular human dermis allograft derived from the reticular layer of the dermis and marketed for wound care. This product is also marketed as FlexHD® for postmastectomy breast reconstruction.

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Apligraf® (Organogenesis) is a bilayered living cell therapy composed of an epidermal layer of living human keratinocytes and a dermal layer of living human fibroblasts. It was approved by the FDA in 1998 for use in conjunction with compression therapy for the treatment of noninfected, partial- and full-thickness skin ulcers due to venous insufficiency and in 2001 for full-thickness neuropathic diabetic lower-extremity ulcers nonresponsive to standard wound therapy.

Cortiva® (previously marketed as AlloMax™ Surgical Graft and before that NeoForm™) is an acellular non-cross-linked human dermis allograft.

DermACELL™ (LifeNet Health) is an allogeneic ADM processed with proprietary technologies MATRACELL® and PRESERVON®.

Dermagraft® (Organogenesis) is composed of cryopreserved human-derived fibroblasts and collagen derived from newborn human foreskin and cultured on a bioabsorbable polyglactin mesh scaffold. It was approved by the FDA for repair of diabetic foot ulcers.

DermaMatrix™ (Synthes) is a freeze-dried ADM derived from donated human skin tissue. DermaMatrix Acellular Dermis is processed by the Musculoskeletal Transplant Foundation.

Epicel® (Genzyme Biosurgery) is an epithelial autograft composed of an individual's own keratinocytes cultured ex vivo and is FDA-approved under a humanitarian device exemption for the treatment of deep dermal or full-thickness burns comprising a total body surface area of 30% or more. It may be used in conjunction with split-thickness autografts or alone in individuals for whom split-thickness autografts may not be an option due to the severity and extent of their burns.

FlexHD® and the newer formulation FlexHD® Pliable™ (Musculoskeletal Transplant Foundation) are acellular hydrated reticular dermis allograft derived from donated human skin.

GraftJacket® Regenerative Tissue Matrix (also called GraftJacket Skin Substitute; KCI) is an acellular regenerative tissue matrix that has been processed from human skin supplied from U.S. tissue banks. The allograft is minimally processed to remove the epidermal and dermal cells while preserving dermal structure. GraftJacket Xpress® is an injectable product.

Integra® Dermal Regeneration Template (also marketed as Omnigraft Dermal Regeneration Matrix; Integra LifeSciences) is a bovine, collagen/glycosaminoglycan dermal replacement covered by a silicone temporary epidermal substitute. It was approved by the FDA for use in the post-excisional treatment of life-threatening full-thickness or deep partial-thickness thermal injury where sufficient autograft is not available at the time of excision or not desirable because of the physiologic condition of the individual, and for certain diabetic foot ulcers. Integra® Matrix Wound Dressing and Integra® Meshed Bilayer Wound Matrix are substantially equivalent skin substitutes and were cleared for marketing by the FDA for other indications. Integra® Bilayer Matrix Wound Dressing (Integra LifeSciences) is designed to be used in conjunction with negative pressure wound therapy. The meshed bilayer provides a flexible wound covering and allows drainage of wound exudate.

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Integra Flowable Wound Matrix is composed of a porous matrix of cross-linked bovine tendon collagen and glycosaminoglycan. It is supplied as a granular product that is mixed with saline.

mVASC® (MicroVascular Tissues, Inc.) is a microvascular tissue structural allograft made of small blood vessels and extracellular matrix, inherent non-viable cells, and associated biological signaling factors harvested from subcutaneous tissue of cadaveric human donors.

Oasis™ Wound Matrix (Cook Biotech) is a collagen scaffold (extracellular matrix) derived from porcine small intestinal submucosa. In 2000, it was cleared by the FDA for the management of partial- and full-thickness wounds, including pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled undermined wounds, surgical wounds, trauma wounds, and draining wounds.

OrCel™ (Forticell Bioscience; formerly Composite Cultured Skin) is an absorbable allogeneic bilayered cellular matrix, made of bovine collagen, in which human dermal cells have been cultured. It was approved by FDA premarket approval for healing donor site wounds in burn victims and under a humanitarian device exemption for use in individuals with recessive dystrophic epidermolysis bullosa undergoing hand reconstruction surgery to close and heal wounds created by the surgery, including those at donor sites.

TheraSkin® (LifeNet Health) is a cryopreserved split-thickness human skin allograft composed of living fibroblasts and keratinocytes and an extracellular matrix in epidermal and dermal layers. TheraSkin® is derived from human skin allograft supplied by tissue banks compliant with the American Association of Tissue Banks and FDA guidelines. It is considered a minimally processed human cell, tissue, and cellular- and tissue-based product by the FDA.

Criteria:

- Breast reconstructive surgery using the following allogeneic acellular dermal matrix products is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. There is insufficient tissue expander or implant coverage by the pectoralis major muscle and additional coverage is required

  2. **ONE** of the following:

     - There is viable but compromised or thin postmastectomy skin flaps that are at risk of dehiscence or necrosis
     - The inframammary fold and lateral mammary folds have been undermined during mastectomy and re-establishment of these landmarks is needed

  3. **ONE** of the following allogenic acellular dermal matrix products:

     - AlloDerm®
     - AlloMend®

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- Cortiva® [AlloMax™]
- DermACELL™
- DermaMatrix™
- FlexHD®
- FlexHD® Pliable™
- GraftJacket®

- Tissue-engineered skin substitutes for the treatment of chronic, full-thickness lower-extremity ulcers is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. Lower extremity ulcers are due to diabetes

  2. Lower extremity ulcers are not infected

  3. **ONE** of the following tissue-engineered skin substitutes:

     - AlloPatch®
     - Apligraf®
     - Dermagraft®
     - Integra® Omnigraft™ Dermal Regeneration Matrix (also known as Omnigraft™)
     - Integra Flowable Wound Matrix
     - mVASC®
     - TheraSkin®

- Tissue-engineered skin substitutes Apligraf® or Oasis™ Wound Matrix for the treatment of chronic, partial- or full-thickness lower-extremity skin ulcers are considered ***medically necessary*** with documentation of **ALL** of the following:

  1. Lower extremity ulcers are due to venous insufficiency

  2. Lower extremity ulcers are not infected

  3. Ulcers have not adequately responded following a 1-month period of conventional ulcer therapy

- Tissue-engineered skin substitute OrCel™ for the treatment of dystrophic epidermolysis bullosa is considered ***medically necessary*** with documentation of **ALL** of the following**:**

  1. Mitten-hand deformity present when standard wound therapy has failed

  2. Treatment is provided in accordance with the humanitarian device exemption (HDE) specifications of the U.S. Food and Drug Administration (FDA)

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- Tissue-engineered skin substitute Epicel® for the treatment of second- and third-degree burns is considered ***medically necessary*** with documentation of **ALL** of the following:

  1. Individual has deep dermal or full-thickness burns comprising a total body surface area ≥30%

  2. Treatment is provided in accordance with the HDE specifications of the FDA

- Tissue-engineered skin substitute Integra® Dermal Regeneration Template for the treatment of second- and third-degree burns is considered ***medically necessary***.

- Use of all bioengineered skin and soft tissue substitutes listed above for all other indications not previously listed or if above criteria not met is considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:

  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  5. Insufficient evidence to support improvement outside the investigational setting.

- All other skin and soft tissue substitutes not previously listed are considered ***experimental or investigational*** when any **ONE** or more of the following criteria are met:

  1. Lack of final approval from the appropriate governmental regulatory bodies (e.g., Food and Drug Administration); or
  2. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes; or
  3. Insufficient evidence to support improvement of the net health outcome; or
  4. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives; or
  5. Insufficient evidence to support improvement outside the investigational setting.

  These skin and soft tissue substitutes include, *but are not limited to:*

  - ACell® UBM Hydrated/Lyophilized Wound Dressing
  - AlloSkin™
  - AlloSkin™ RT
  - Apis®
  - Aongen™ Collagen Matrix
  - Architect® ECM, PX, FX
  - Artacent® Wound
  - ArthroFlex™ (Flex Graft)
  - AxoGuard® Nerve Protector (AxoGen)

BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES

- Biobrane®/Biobrane-L
- Bio-ConneKt® Wound Matrix
- CollaCare®
- CollaCare® Dental
- Collagen Wound Dressing (Oasis Research)
- CollaGUARD®
- CollaMend™
- CollaWound™
- Coll-e-derm
- Collexa®
- Collieva®
- Conexa™
- Coreleader Colla-Pad
- CorMatrix®
- Cymetra™ (Micronized AlloDerm)™
- Cytal™ (previously MatriStem®)
- DeNovoSkin™
- Dermadapt™ Wound Dressing
- Derma-gide
- DermaPure™
- DermaSpan™
- DressSkin
- Durepair Regeneration Matrix®
- Endoform Dermal Template™
- *ENDURA*Gen™
- Excellagen®
- ExpressGraft™
- E-Z Derm™
- FlowerDerm™
- GammaGraft
- Geistlich Derma-Gide™
- GraftJacket® Xpress, injectable
- Helicoll™
- hMatrix®
- Hyalomatrix®
- Hyalomatrix® PA
- Integra™ Bilayer Wound Matrix
- Integra® Matrix Wound Dressing (previously Avagen)
- InteguPly®
- Keramatrix®
- Kerecis™ Omega3
- Keroxx™
- InnovaMatrix®
- MatriDerm®
- MatriStem

BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES

- Matrix HD™
- MicroMatrix®
- Miroderm®
- Mediskin®
- MemoDerm™
- Microderm® biologic wound matrix
- Microlyte matrix®
- MyOwn skin
- Novosorb™ Biodegradable Temporizing Matrix (BMT)
- Oasis® Burn Matrix
- Oasis® Ultra
- Ologen™ Collagen Matrix
- Omega3 Wound (originally Merigen wound dressing)
- Omeza® Collagen Matrix
- Permacol™
- PermeaDerm® B
- PermeaDerm® C
- PermeaDerm® Glove
- Phoenix™ Wound Matrix
- PriMatrix™
- PriMatrix™ Dermal Repair Scaffold
- Progenamatrix™
- Puracol® and Puracol® Plus Collagen Wound Dressings
- PuraPly™ Wound Matrix (previously FortaDerm™)
- PuraPly™ AM (Antimicrobial Wound Matrix)
- Puros® Dermis
- ReCell®
- RegenePro™
- Repliform®
- Repriza™
- Restrata®
- SkinTE™
- StrataGraft®
- Strattice™
- SUPRA SDRM®
- Suprathel®
- SurgiMend®
- Symphony™
- Talymed®
- TenoGlide™
- TenSIX™ Acellular Dermal Matrix
- TissueMend
- TheraForm™ Standard/Sheet
- TheraGenesis®
- TransCyte™

BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES

- TruSkin™
- Tutomesh™ Fenestrated Bovine Pericardium
- Veritas® Collagen Matrix
- Xcellistem®
- XCM Biologic® Tissue Matrix
- XenMatrix™ AB

Resources:

Literature reviewed 05/21/24. We do not include marketing materials, poster boards and non-published literature in our review.

Resources prior to 05/21/24 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. Armstrong DG, Galiano RD, Orgill DP, et al. Multi-centre prospective randomised controlled clinical trial to evaluate a bioactive split thickness skin allograft vs standard of care in the treatment of diabetic foot ulcers. *Int Wound J*. May 2022;19(4):932-944. doi:10.1111/iwj.13759

2. Baldursson BT, Kjartansson H, Konrádsdóttir F, Gudnason P, Sigurjonsson GF, Lund SH. Healing rate and autoimmune safety of full-thickness wounds treated with fish skin acellular dermal matrix versus porcine small-intestine submucosa: a noninferiority study. *Int J Low Extrem Wounds*. Mar 2015;14(1):37-43. doi:10.1177/1534734615573661

3. Barber FA, Burns JP, Deutsch A, Labbé MR, Litchfield RB. A prospective, randomized evaluation of acellular human dermal matrix augmentation for arthroscopic rotator cuff repair. *Arthroscopy*. Jan 2012;28(1):8-15. doi:10.1016/j.arthro.2011.06.038

4. Bellows CF, Shadduck P, Helton WS, Martindale R, Stouch BC, Fitzgibbons R. Early report of a randomized comparative clinical trial of Strattice™ reconstructive tissue matrix to lightweight synthetic mesh in the repair of inguinal hernias. *Hernia*. Apr 2014;18(2):221-30. doi:10.1007/s10029-013-1076-9

5. Bellows CF, Smith A, Malsbury J, Helton WS. Repair of incisional hernias with biological prosthesis: a systematic review of current evidence. *Am J Surg*. Jan 2013;205(1):85-101. doi:10.1016/j.amjsurg.2012.02.019

6. Bochicchio GV, De Castro GP, Bochicchio KM, Weeks J, Rodriguez E, Scalea TM. Comparison study of acellular dermal matrices in complicated hernia surgery. *J Am Coll Surg*. Oct 2013;217(4):606-13. doi:10.1016/j.jamcollsurg.2013.04.041

7. Branski LK, Herndon DN, Pereira C, et al. Longitudinal assessment of Integra in primary burn management: a randomized pediatric clinical trial. *Crit Care Med*. Nov 2007;35(11):2615-23. doi:10.1097/01.Ccm.0000285991.36698.E2

8. Brigido SA. The use of an acellular dermal regenerative tissue matrix in the treatment of lower extremity wounds: a prospective 16-week pilot study. *Int Wound J*. Sep 2006;3(3):181-7. doi:10.1111/j.1742-481X.2006.00209.x

9. Brigido SA, Boc SF, Lopez RC. Effective management of major lower extremity wounds using an acellular regenerative tissue matrix: a pilot study. *Orthopedics*. Jan 2004;27(1 Suppl):s145-9. doi:10.3928/0147-7447-20040102-14

10. Brown-Etris M, Milne CT, Hodde JP. An extracellular matrix graft (Oasis(®) wound matrix) for treating full-thickness pressure ulcers: A randomized clinical trial. *J Tissue Viability*. Feb 2019;28(1):21-26. doi:10.1016/j.jtv.2018.11.001

11. Campitiello F, Mancone M, Della Corte A, Guerniero R, Canonico S. To evaluate the efficacy of an acellular Flowable matrix in comparison with a wet dressing for the treatment of patients with diabetic foot ulcers: a randomized clinical trial. *Updates Surg*. Dec 2017;69(4):523-529. doi:10.1007/s13304-017-0461-9

12. Carsin H, Ainaud P, Le Bever H, et al. Cultured epithelial autografts in extensive burn coverage of severely traumatized patients: a five year single-center experience with 30 patients. *Burns*. Jun 2000;26(4):379-87. doi:10.1016/s0305-4179(99)00143-6

13. Cazzell S. A Randomized Controlled Trial Comparing a Human Acellular Dermal Matrix Versus Conventional Care for the Treatment of Venous Leg Ulcers. *Wounds*. Mar 2019;31(3):68-74.

14. Cazzell S, Vayser D, Pham H, et al. A randomized clinical trial of a human acellular dermal matrix demonstrated superior healing rates for chronic diabetic foot ulcers over conventional care and an active acellular dermal matrix comparator. *Wound Repair Regen*. May 2017;25(3):483-497. doi:10.1111/wrr.12551

15. Centers for Medicare & Medicaid Services (CMS). National Coverage Determination (NCD) for Porcine Skin and Gradient Pressure Dressings (270.5). Accessed November 13, 2023. https://www.cms.gov/medicare-coverage-database/view/ncd.aspx?NCDId=139&ncdver=1&bc=AgAAQAAAAAAA&

16. Centers for Medicare & Medicaid Services (CMS). Fact Sheet: CMS finalizes Medicare Hospital Outpatient Prospective Payment System and Ambulatory Surgical Center Payment System changes for 2019. Accessed November 13, 2023. https://www.cms.gov/newsroom/fact-sheets/cms-finalizes-medicare-hospital-outpatient-prospective-payment-system-and-ambulatory-surgical-center

17. Centers for Medicare & Medicaid Services (CMS). Fact Sheet. Calendar Year (CY) 2023 Medicare Physician Fee Schedule Final Rule. 2022. Accessed November 13, 2023. https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2023-medicare-physician-fee-schedule-final-rule

18. Davila AA, Seth AK, Wang E, et al. Human Acellular Dermis versus Submuscular Tissue Expander Breast Reconstruction: A Multivariate Analysis of Short-Term Complications. *Arch Plast Surg*. Jan 2013;40(1):19-27. doi:10.5999/aps.2013.40.1.19

19. DiDomenico L, Landsman AR, Emch KJ, Landsman A. A prospective comparison of diabetic foot ulcers treated with either a cryopreserved skin allograft or a bioengineered skin substitute. *Wounds*. Jul 2011;23(7):184-9.

20. Dikmans RE, Negenborn VL, Bouman MB, et al. Two-stage implant-based breast reconstruction compared with immediate one-stage implant-based breast reconstruction augmented with an acellular dermal matrix: an open-label, phase 4, multicentre, randomised, controlled trial. *Lancet Oncol*. Feb 2017;18(2):251-258. doi:10.1016/s1470-2045(16)30668-4

21. Driver VR, Lavery LA, Reyzelman AM, et al. A clinical trial of Integra Template for diabetic foot ulcer treatment. *Wound Repair Regen*. Nov-Dec 2015;23(6):891-900. doi:10.1111/wrr.12357

22. Espinosa-de-los-Monteros A, de la Torre JI, Marrero I, Andrades P, Davis MR, Vásconez LO. Utilization of human cadaveric acellular dermis for abdominal hernia reconstruction. *Ann Plast Surg*. Mar 2007;58(3):264-7. doi:10.1097/01.sap.0000254410.91132.a8

23. Falanga V, Margolis D, Alvarez O, et al. Rapid healing of venous ulcers and lack of clinical rejection with an allogeneic cultured human skin equivalent. Human Skin Equivalent Investigators Group. *Arch Dermatol*. Mar 1998;134(3):293-300. doi:10.1001/archderm.134.3.293

24. Fivenson DP, Scherschun L, Cohen LV. Apligraf in the treatment of severe mitten deformity associated with recessive dystrophic epidermolysis bullosa. *Plast Reconstr Surg*. Aug 2003;112(2):584-8. doi:10.1097/01.Prs.0000070730.95956.01

25. Fleshman JW, Beck DE, Hyman N, Wexner SD, Bauer J, George V. A prospective, multicenter, randomized, controlled study of non-cross-linked porcine acellular dermal matrix fascial sublay for parastomal reinforcement in patients undergoing surgery for permanent abdominal wall ostomies. *Dis Colon Rectum*. May 2014;57(5):623-31. doi:10.1097/dcr.0000000000000106

26. Frykberg RG, Cazzell SM, Arroyo-Rivera J, et al. Evaluation of tissue engineering products for the management of neuropathic diabetic foot ulcers: an interim analysis. *J Wound Care*. Jul 1 2016;25(Sup7):S18-s25. doi:10.12968/jowc.2016.25.Sup7.S18

27. Frykberg RG, Marston WA, Cardinal M. The incidence of lower-extremity amputation and bone resection in diabetic foot ulcer patients treated with a human fibroblast-derived dermal substitute. *Adv Skin Wound Care*. Jan 2015;28(1):17-20. doi:10.1097/01.ASW.0000456630.12766.e9

28. Gonzalez SR, Wolter KG, Yuen JC. Infectious Complications Associated with the Use of Integra: A Systematic Review of the Literature. *Plast Reconstr Surg Glob Open*. Jul 2020;8(7):e2869. doi:10.1097/gox.0000000000002869

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29. Gould LJ, Orgill DP, Armstrong DG, et al. Improved healing of chronic diabetic foot wounds in a prospective randomised controlled multi-centre clinical trial with a microvascular tissue allograft. *Int Wound J*. May 2022;19(4):811-825. doi:10.1111/iwj.13679

30. Graftskin for the treatment of skin ulcers TEC Assessments. Vol. 16:Tab 12. Located at: Blue Cross Blue Shield Association Technology Evaluation Center (TEC), Chicago, USA; 2001.

31. Gupta A, Zahriya K, Mullens PL, Salmassi S, Keshishian A. Ventral herniorrhaphy: experience with two different biosynthetic mesh materials, Surgisis and Alloderm. *Hernia*. Oct 2006;10(5):419-25. doi:10.1007/s10029-006-0130-2

32. Gurtner GC, Garcia AD, Bakewell K, Alarcon JB. A retrospective matched-cohort study of 3994 lower extremity wounds of multiple etiologies across 644 institutions comparing a bioactive human skin allograft, TheraSkin, plus standard of care, to standard of care alone. *Int Wound J*. Feb 2020;17(1):55-64. doi:10.1111/iwj.13231

33. Harding K, Sumner M, Cardinal M. A prospective, multicentre, randomised controlled study of human fibroblast-derived dermal substitute (Dermagraft) in patients with venous leg ulcers. *Int Wound J*. Apr 2013;10(2):132-7. doi:10.1111/iwj.12053

34. Heimbach DM, Warden GD, Luterman A, et al. Multicenter postapproval clinical trial of Integra dermal regeneration template for burn treatment. *J Burn Care Rehabil*. Jan-Feb 2003;24(1):42-8. doi:10.1097/00004630-200301000-00009

35. Hicks KE, Huynh MN, Jeschke M, Malic C. Dermal regenerative matrix use in burn patients: A systematic review. *J Plast Reconstr Aesthet Surg*. Nov 2019;72(11):1741-1751. doi:10.1016/j.bjps.2019.07.021

36. Hinchcliff KM, Orbay H, Busse BK, Charvet H, Kaur M, Sahar DE. Comparison of two cadaveric acellular dermal matrices for immediate breast reconstruction: A prospective randomized trial. *J Plast Reconstr Aesthet Surg*. May 2017;70(5):568-576. doi:10.1016/j.bjps.2017.02.024

37. Holmes Iv JH, Molnar JA, Carter JE, et al. A Comparative Study of the ReCell® Device and Autologous Spit-Thickness Meshed Skin Graft in the Treatment of Acute Burn Injuries. *J Burn Care Res*. Aug 17 2018;39(5):694-702. doi:10.1093/jbcr/iry029

38. Holmes JHt, Molnar JA, Shupp JW, et al. Demonstration of the safety and effectiveness of the RECELL(®) System combined with split-thickness meshed autografts for the reduction of donor skin to treat mixed-depth burn injuries. *Burns*. Jun 2019;45(4):772-782. doi:10.1016/j.burns.2018.11.002

39. Kalaiselvan R, Carlson GL, Hayes S, Lees NP, Anderson ID, Slade DAJ. Recurrent intestinal fistulation after porcine acellular dermal matrix reinforcement in enteric fistula takedown and simultaneous abdominal wall reconstruction. *Hernia*. Jun 2020;24(3):537-543. doi:10.1007/s10029-019-02097-2

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40. Lagus H, Sarlomo-Rikala M, Böhling T, Vuola J. Prospective study on burns treated with Integra®, a cellulose sponge and split thickness skin graft: comparative clinical and histological study--randomized controlled trial. *Burns*. Dec 2013;39(8):1577-87. doi:10.1016/j.burns.2013.04.023

41. Lantis Ii JC, Lullove EJ, Liden B, et al. Final efficacy and cost analysis of a fish skin graft vs standard of care in the management of chronic diabetic foot ulcers: a prospective, multicenter, randomized controlled clinical trial. *Wounds*. Apr 2023;35(4):71-79. doi:10.25270/wnds/22094

42. Lantis JC, Snyder R, Reyzelman AM, et al. Fetal bovine acellular dermal matrix for the closure of diabetic foot ulcers: a prospective randomised controlled trial. *J Wound Care*. Jul 1 2021;30(Sup7):S18-s27. doi:10.12968/jowc.2021.30.Sup7.S18

43. Lazic T, Falanga V. Bioengineered skin constructs and their use in wound healing. *Plast Reconstr Surg*. Jan 2011;127 Suppl 1:75s-90s. doi:10.1097/PRS.0b013e3182009d9f

44. Lee KT, Mun GH. Updated Evidence of Acellular Dermal Matrix Use for Implant-Based Breast Reconstruction: A Meta-analysis. *Ann Surg Oncol*. Feb 2016;23(2):600-10. doi:10.1245/s10434-015-4873-9

45. Lullove EJ, Liden B, McEneaney P, et al. Evaluating the effect of omega-3-rich fish skin in the treatment of chronic, nonresponsive diabetic foot ulcers: penultimate analysis of a multicenter, prospective, randomized controlled trial. *Wounds*. Apr 2022;34(4):E34-e36. doi:10.25270/wnds/2022.e34e36

46. Lullove EJ, Liden B, Winters C, McEneaney P, Raphael A, Lantis Ii JC. A Multicenter, Blinded, Randomized Controlled Clinical Trial Evaluating the Effect of Omega-3-Rich Fish Skin in the Treatment of Chronic, Nonresponsive Diabetic Foot Ulcers. *Wounds*. Jul 2021;33(7):169-177. doi:10.25270/wnds/2021.169177

47. Luze H, Nischwitz SP, Smolle C, Zrim R, Kamolz LP. The Use of Acellular Fish Skin Grafts in Burn Wound Management-A Systematic Review. *Medicina (Kaunas)*. Jul 9 2022;58(7)doi:10.3390/medicina58070912

48. Marston WA, Hanft J, Norwood P, Pollak R. The efficacy and safety of Dermagraft in improving the healing of chronic diabetic foot ulcers: results of a prospective randomized trial. *Diabetes Care*. Jun 2003;26(6):1701-5. doi:10.2337/diacare.26.6.1701

49. McCarthy CM, Lee CN, Halvorson EG, et al. The use of acellular dermal matrices in two-stage expander/implant reconstruction: a multicenter, blinded, randomized controlled trial. *Plast Reconstr Surg*. Nov 2012;130(5 Suppl 2):57s-66s. doi:10.1097/PRS.0b013e31825f05b4

50. Mendenhall SD, Anderson LA, Ying J, Boucher KM, Neumayer LA, Agarwal JP. The BREASTrial Stage II: ADM Breast Reconstruction Outcomes from Definitive Reconstruction to 3 Months Postoperative. *Plast Reconstr Surg Glob Open*. Jan 2017;5(1):e1209. doi:10.1097/gox.0000000000001209

51. Mendenhall SD, Moss WD, Graham EM, Carter G, Agarwal JP. The BREASTrial Stage III: Acellular Dermal Matrix Breast Reconstruction Outcomes from 3 Months to 2 Years Postoperatively. *Plast Reconstr Surg*. Jan 1 2023;151(1):17-24. doi:10.1097/prs.0000000000009768

52. Mostow EN, Haraway GD, Dalsing M, Hodde JP, King D. Effectiveness of an extracellular matrix graft (OASIS Wound Matrix) in the treatment of chronic leg ulcers: a randomized clinical trial. *J Vasc Surg*. May 2005;41(5):837-43. doi:10.1016/j.jvs.2005.01.042

53. National Institute for Health and Care Excellence (NICE). Diabetic Foot Problems: Prevention and Management [NG19]. 2023. Accessed November 13, 2023. https://www.nice.org.uk/guidance/ng19

54. Niezgoda JA, Van Gils CC, Frykberg RG, Hodde JP. Randomized clinical trial comparing OASIS Wound Matrix to Regranex Gel for diabetic ulcers. *Adv Skin Wound Care*. Jun 2005;18(5 Pt 1):258-66. doi:10.1097/00129334-200506000-00012

55. O'Meara S, Cullum N, Nelson EA, Dumville JC. Compression for venous leg ulcers. *Cochrane Database Syst Rev*. Nov 14 2012;11(11):Cd000265. doi:10.1002/14651858.CD000265.pub3

56. Peirce SC, Carolan-Rees G. ReCell(®) Spray-On Skin System for Treating Skin Loss, Scarring and Depigmentation after Burn Injury: A NICE Medical Technology Guidance. *Appl Health Econ Health Policy*. Apr 2019;17(2):131-141. doi:10.1007/s40258-018-00457-0

57. Rashid MS, Smith RDJ, Nagra N, et al. Rotator cuff repair with biological graft augmentation causes adverse tissue outcomes. *Acta Orthop*. Dec 2020;91(6):782-788. doi:10.1080/17453674.2020.1793613

58. Reyzelman A, Crews RT, Moore JC, et al. Clinical effectiveness of an acellular dermal regenerative tissue matrix compared to standard wound management in healing diabetic foot ulcers: a prospective, randomised, multicentre study. *Int Wound J*. Jun 2009;6(3):196-208. doi:10.1111/j.1742-481X.2009.00585.x

59. Reyzelman AM, Bazarov I. Human acellular dermal wound matrix for treatment of DFU: literature review and analysis. *J Wound Care*. Mar 2015;24(3):128; 129-34. doi:10.12968/jowc.2015.24.3.128

60. Romanelli M, Dini V, Bertone M, Barbanera S, Brilli C. OASIS wound matrix versus Hyaloskin in the treatment of difficult-to-heal wounds of mixed arterial/venous aetiology. *Int Wound J*. Mar 2007;4(1):3-7. doi:10.1111/j.1742-481X.2007.00300.x

61. Romanelli M, Dini V, Bertone MS. Randomized comparison of OASIS wound matrix versus moist wound dressing in the treatment of difficult-to-heal wounds of mixed arterial/venous etiology. *Adv Skin Wound Care*. Jan 2010;23(1):34-8. doi:10.1097/01.Asw.0000363485.17224.26

62. Roth JS, Zachem A, Plymale MA, Davenport DL. Complex Ventral Hernia Repair with Acellular Dermal Matrices: Clinical and Quality of Life Outcomes. *Am Surg*. Feb 1 2017;83(2):141-147.

63. Saffle JR. Closure of the excised burn wound: temporary skin substitutes. *Clin Plast Surg*. Oct 2009;36(4):627-41. doi:10.1016/j.cps.2009.05.005

64. Sanders L, Landsman AS, Landsman A, et al. A prospective, multicenter, randomized, controlled clinical trial comparing a bioengineered skin substitute to a human skin allograft. *Ostomy Wound Manage*. Sep 2014;60(9):26-38.

65. Santema TB, Poyck PP, Ubbink DT. Skin grafting and tissue replacement for treating foot ulcers in people with diabetes. *Cochrane Database Syst Rev*. Feb 11 2016;2(2):Cd011255. doi:10.1002/14651858.CD011255.pub2

66. Snyder D, Sullivan N, Margolis D, Schoelles K. Skin substitutes for treating chronic wounds. Technology Assessment Program Project ID No. WNDT0818. (Prepared by the ECRI Institute-Penn Medicine Evidence-based Practice Center under Contract No. HHSA 290-2015-00005-I) Rockville, MD: Agency for Healthcare Research and Quality. February, 2020. Accessed November 13, 2023. https://effectivehealthcare.ahrq.gov/sites/default/files/pdf/skin-substitute_0.pdf

67. Still J, Glat P, Silverstein P, Griswold J, Mozingo D. The use of a collagen sponge/living cell composite material to treat donor sites in burn patients. *Burns*. Dec 2003;29(8):837-41. doi:10.1016/s0305-4179(03)00164-5

68. U.S. Food and Drug Administration. Regulatory Considerations for Human Cells, Tissues, and Cellular and Tissue-Based Products: Minimal Manipulation and Homologous Use. December, 2017. Accessed November 13, 2023. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/regulatory-considerations-human-cells-tissues-and-cellular-and-tissue-based-products-minimal

69. U.S. Food and Drug Administration. Executive Summary Breast Implant Special Topics. March, 2019. Accessed November 13, 2023. https://wayback.archive-it.org/7993/20201226003814/https://www.fda.gov/media/122956/download

70. U.S. Food and Drug Administration. Acellular Dermal Matrix (ADM) Products Used in Implant-Based Breast Reconstruction Differ in Complication Rates: FDA Safety Communication. March, 2021. Accessed November 13, 2023. https://www.fda.gov/medical-devices/safety-communications/acellular-dermal-matrix-adm-products-used-implant-based-breast-reconstruction-differ-complication

71. Uccioli L, Giurato L, Ruotolo V, et al. Two-step autologous grafting using HYAFF scaffolds in treating difficult diabetic foot ulcers: results of a multicenter, randomized controlled clinical trial with long-term follow-up. *Int J Low Extrem Wounds*. Jun 2011;10(2):80-5. doi:10.1177/1534734611409371

72. Veves A, Falanga V, Armstrong DG, Sabolinski ML. Graftskin, a human skin equivalent, is effective in the management of noninfected neuropathic diabetic foot ulcers: a prospective randomized multicenter clinical trial. *Diabetes Care*. Feb 2001;24(2):290-5. doi:10.2337/diacare.24.2.290

73. Walters J, Cazzell S, Pham H, Vayser D, Reyzelman A. Healing Rates in a Multicenter Assessment of a Sterile, Room Temperature, Acellular Dermal Matrix Versus Conventional Care Wound Management and an Active Comparator in the Treatment of Full-Thickness Diabetic Foot Ulcers. *Eplasty*. 2016;16:e10.

74. Zelen CM, Orgill DP, Serena T, et al. A prospective, randomised, controlled, multicentre clinical trial examining healing rates, safety and cost to closure of an acellular reticular allogenic human dermis versus standard of care in the treatment of chronic diabetic foot ulcers. *Int Wound J*. Apr 2017;14(2):307-315. doi:10.1111/iwj.12600

75. Zelen CM, Orgill DP, Serena TE, et al. An aseptically processed, acellular, reticular, allogenic human dermis improves healing in diabetic foot ulcers: A prospective, randomised, controlled, multicentre follow-up trial. *Int Wound J*. Oct 2018;15(5):731-739. doi:10.1111/iwj.12920

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EVIDENCE-BASED CRITERIA
SECTION: SURGERY

NEXT ANNUAL REVIEW DATE: 2ND QTR 2025

ORIGINAL EFFECTIVE DATE: 05/21/24
LAST REVIEW DATE: 05/21/24
CURRENT EFFECTIVE DATE: 10/07/24
LAST CRITERIA REVISION DATE: 05/21/24
ARCHIVE DATE:

BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES

History:	Date:	Activity:
Medical Policy Panel	05/21/24	Approved guideline
Medical Director (Dr. Sutanto)	04/16/24	Review with revisions

Policy Revisions:

10/07/24	Added:	HCPCS codes: A2027, A2028, A2029
06/17/24	Added:	CPT codes: A2026, Q4305, Q4306, Q4307, Q4308, Q4309, Q4310

EVIDENCE-BASED CRITERIA	**ORIGINAL EFFECTIVE DATE: 05/21/24**
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BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES

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Blue Cross Blue Shield of Arizona (BCBSAZ) complies with applicable Federal civil rights laws and does not discriminate on the basis of race, color, national origin, age, disability or sex. BCBSAZ provides appropriate free aids and services, such as qualified interpreters and written information in other formats, to people with disabilities to communicate effectively with us. BCBSAZ also provides free language services to people whose primary language is not English, such as qualified interpreters and information written in other languages. If you need these services, call (602) 864-4884 for Spanish and (877) 475-4799 for all other languages and other aids and services.

If you believe that BCBSAZ has failed to provide these services or discriminated in another way on the basis of race, color, national origin, age, disability or sex, you can file a grievance with: BCBSAZ's Civil Rights Coordinator, Attn: Civil Rights Coordinator, Blue Cross Blue Shield of Arizona, P.O. Box 13466, Phoenix, AZ 85002-3466, (602) 864-2288, TTY/TDD (602) 864-4823, crc@azblue.com. You can file a grievance in person or by mail or email. If you need help filing a grievance BCBSAZ's Civil Rights Coordinator is available to help you. You can also file a civil rights complaint with the U.S. Department of Health and Human Services, Office for Civil Rights electronically through the Office for Civil Rights Complaint Portal, available at https://ocrportal.hhs.gov/ocr/portal/lobby.jsf, or by mail or phone at: U.S. Department of Health and Human Services, 200 Independence Avenue SW., Room 509F, HHH Building, Washington, DC 20201, 1–800–368–1019, 800–537–7697 (TDD). Complaint forms are available at http://www.hhs.gov/ocr/office/file/index.html

Multi-Language Interpreter Services:

Spanish: Si usted, o alguien a quien usted está ayudando, tiene preguntas acerca de Blue Cross Blue Shield of Arizona, tiene derecho a obtener ayuda e información en su idioma sin costo alguno. Para hablar con un intérprete, llame al 602-864-4884.

Navajo: Díí kwe'é atah nílínigíí Blue Cross Blue Shield of Arizona haada yit'éego bína'ídíłkidgo éí doodago Háida bíjá anilyeedígíí t'áadoo le'é yína'ídíłkidgo beehaz'áanii hóló díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo bąąh íłínígóó. Ata' halne'ígíí kojį' bich'į' hodíilnih 877-475-4799.

Chinese: 如果您，或是您正在協助的對象，有關於插入項目的名稱 Blue Cross Blue Shield of Arizona 方面的問題，您有權利免費以您的母語得到幫助和訊息。洽詢一位翻譯員，請撥電話 在此插入數字 877-475-4799。

Vietnamese: Nếu quý vị, hay người mà quý vị đang giúp đỡ, có câu hỏi về Blue Cross Blue Shield of Arizona quý vị sẽ có quyền được giúp và có thêm thông tin bằng ngôn ngữ của mình miễn phí. Để nói chuyện với một thông dịch viên, xin gọi 877-475-4799.

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إن كان لديك أو لدى شخص تساعده أسئلة بخصوص Blue Cross Blue Shield of Arizona، فلديك الحق في الحصول على المساعدة والمعلومات الضرورية بلغتك من دون اية تكلفة. للتحدث مع مترجم اتصل ب 877-475-4799.

BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES

<u>Multi-Language Interpreter Services</u>:

Tagalog: Kung ikaw, o ang iyong tinutulangan, ay may mga katanungan tungkol sa Blue Cross Blue Shield of Arizona, may karapatan ka na makakuha ng tulong at impormasyon sa iyong wika ng walang gastos. Upang makausap ang isang tagasalin, tumawag sa 877-475-4799.

Korean: 만약 귀하 또는 귀하가 돕고 있는 어떤 사람이 Blue Cross Blue Shield of Arizona 에 관해서 질문이 있다면 귀하는 그러한 도움과 정보를 귀하의 언어로 비용 부담없이 얻을 수 있는 권리가 있습니다. 그렇게 통역사와 얘기하기 위해서는 877-475-4799 로 전화하십시오.

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