BlueCross BlueShield of Arizona
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MEDICAL COVERAGE GUIDELINES
SECTION: MEDICINE

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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 Medical Coverage Guideline must be read in its entirety to determine coverage eligibility, if any.

This Medical Coverage Guideline 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.

Medical Coverage Guidelines are subject to change as new information becomes available.

For purposes of this Medical Coverage Guideline, the terms "experimental" and "investigational" are considered to be interchangeable.

BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES (cont.)

Description:

Bio-engineered skin and soft tissue substitutes (artificial skin and soft tissue) may be either acellular or cellular. Acellular products (i.e., cadaveric human dermis with cellular material removed) contain a matrix or scaffold composed of materials such as collagen, hyaluronic acid, and fibronectin. Cellular products contain living cells such as fibroblasts and keratinocytes within a matrix. The cells contained within the matrix may be autologous (from self), allogeneic (from donor) or xenologous (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. Bio-engineered skin substitutes can be used as either temporary or permanent wound coverings. Products derived from human dermis that are minimally processed and not significantly changed in structure from the natural material are classified by the U.S. Food and Drug Administration (FDA) as banked human tissue and do not require FDA approval. Tissue banks must meet the standards of the American Association of Tissue Banks (AATB) and FDA guidelines.

Wound Definitions[1]:

Stage I:
Non-blanchable erythema of intact skin.

Stage II:
Partial thickness skin loss involving epidermis and/or dermis.

Stage III:
Full thickness skin loss involving damage or necrosis of subcutaneous tissues that may extend down to, but not through, underlying fascia.

Stage IV:
Full thickness skin loss with extensive destruction, tissue necrosis or damage to muscle, bone or supporting structures.

Chronic:
A wound or condition present for at least 30 days despite standard medical and surgical management.

BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES (cont.)

Criteria:

For Alloderm®, Allomax™, AlloMend®, DermACELL™, DermaMatrix, FlexHD®, FlexHD® Pliable™, Graftjacket® Regenerative Tissue Matrix (also called Graftjacket Skin Substitute), Graftjacket® Xpress, and Strattice™ used in breast reconstruction surgery, see BCBSAZ Medical Coverage Guideline #O6, *"Breast Reconstruction/Removal and Replacement of Implants"*.

For amniotic membrane or amniotic fluid injections, see BCBSAZ Medical Coverage Guideline #O955, *"Amniotic Membrane and Amniotic Fluid Injections and Transplantation"*.

- The following skin substitutes for all indications other than for use in breast reconstruction surgery following a mastectomy for breast cancer or fibrocystic disease is considered ***experimental and investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives.

  These substitutes include:
  - Alloderm®
  - AlloMend®
  - Cortiva® (AlloMax™)
  - DermACELL™
  - DermaMatrix™
  - FlexHD®
  - FlexHD® Pliable™

- Strattice™ is considered ***medically necessary*** to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes with documentation of **ANY** of the following:

  1. Body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome
  2. Hernia repair

BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES (cont.)

Criteria: (cont.)

- Skin substitutes are considered ***medically necessary*** with documentation of **ALL** of the following:

1. **ONE** of the following substitutes:

   - ACell UBM Hydrated Wound Dressing
   - ACell UBM Lyophilized Wound Dressing
   - Atlas Wound Matrix
   - Avagen Wound Dressing
   - Coreleader Colla-Pad
   - Cytal Matristem® MicroMatrix
   - Endoform Dermal Template™
   - Excellagen®
   - FortaDerm™ PuraPly™
   - Hyalomatrix®
   - Hyalomatrix® PA
   - Integra Flowable Wound Matrix
   - Oasis® Wound Matrix
   - SIS Wound Dressing II
   - SS Matrix™
   - TheraForm™ Standard/Sheet

2. **ONE** of the following conditions:

   - Chronic vascular ulcers
   - Diabetic ulcers
   - Draining wounds
   - Partial or full thickness wounds
   - Pressure ulcers
   - Surgical wounds (e.g., donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)
   - Trauma wounds (e.g., abrasions, lacerations, second-degree burns, skin tears)
   - Tunneled, undermined wounds
   - Venous ulcers

BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES (cont.)

Criteria: (cont.)

- Skin substitutes are considered ***medically necessary*** with documentation of **ALL** of the following:

  1. **ONE** of the following substitutes:

     - Alphaplex™ with MariGen Omega3™
     - Architect™ Extracellular Matrix
     - Dermadapt™ Wound Dressing
     - Integra™ Bi-layer Matrix Wound Dressing
     - Integra Meshed Bi-layer Wound Matrix
     - Unite® Biomatrix

  2. **ONE** of the following conditions:

     - Chronic vascular ulcers
     - Diabetic ulcers
     - Draining wounds
     - Partial or full thickness wounds
     - Pressure sores/ulcers
     - Surgical wounds (e.g., donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric wounds, and dehisced surgical wounds)
     - Trauma wounds (e.g., abrasions, lacerations, partial thickness burns, and skin tears)
     - Venous ulcers

- Skin substitutes are considered ***medically necessary*** with documentation of **ALL** of the following:

  1. **ONE** of the following substitutes:

     - Collagen Sponge (Innocoll)
     - CollaGUARD
     - Collieva

  2. **ONE** of the following conditions:

     - Diabetic ulcers
     - First and second degree burns
     - Partial **or** full thickness wounds
     - Pressure ulcers
     - Superficial injuries
     - Venous stasis ulcers

BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES (cont.)

Criteria: (cont.)

- Skin substitutes are considered ***medically necessary*** with documentation of **ALL** of the following:

  1. **ONE** of the following substitutes:

     - DressSkin
     - PriMatrix™
     - Primatrix™ Dermal Repair Scaffold

  2. **ONE** of the following conditions:

     - Diabetic ulcers
     - Draining wounds
     - Partial or full thickness wounds
     - Pressure ulcers
     - Second degree burns
     - Surgical wounds (e.g., donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)
     - Trauma wounds (e.g., abrasions, lacerations, skin tears)
     - Tunneled, undermined wounds
     - Venous ulcers

- AlloPatch® for treatment of chronic, non-infected, full-thickness diabetic lower extremity ulcer is considered ***medically necessary***.

- Aongen™ Collagen Matrix is considered ***medically necessary*** with documentation of **ANY** of the following:

  1. Diabetic ulcers
  2. Draining wounds
  3. Oral wounds and sores
  4. Partial **or** full thickness wounds
  5. Pressure ulcers
  6. Second degree burns
  7. Surgical wounds
  8. Trauma wounds
  9. Vascular ulcers
  10. Venous ulcers

BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES (cont.)

Criteria: (cont.)

- Apligraf® is considered ***medically necessary*** with documentation of **ANY** of the following:

  1. Full-thickness neuropathic diabetic foot ulcer of greater than 3 weeks duration

     - As an adjunct to standard diabetic foot ulcer care, **and**
     - Ulcer has not adequately responded to conventional ulcer therapy, **and**
     - Ulcer extends through the dermis but without tendon, muscle, capsule or bone exposure

  2. Non-infected partial or full-thickness skin ulcer of greater than 1 month duration

     - Ulcer is the result of venous insufficiency, **and**
     - Ulcer has not adequately responded to conventional ulcer therapy

- Avaulta Support System is considered ***medically necessary*** for tissue reinforcement and long lasting stabilization of fascial structures of the pelvic floor in vaginal wall prolapse where surgical treatment is intended either as mechanical support or bridging material for the fascial defect.

- Biobrane™ Biosynthetic Dressing is considered ***medically necessary*** for the temporary covering of a superficial partial-thickness burn wound.

- CellerateRX® (CRXa) is available as an over-the-counter medication and is, therefore, considered a ***benefit plan exclusion*** and ***not eligible for coverage***.

- Collagen Wound Dressing (Oasis) is considered ***medically necessary*** with documentation of **ANY** of the following:

  1. Abrasions
  2. Dehisced surgical incisions
  3. Diabetic ulcers
  4. Donor sites and other bleeding surface wounds
  5. Partial **or** full thickness wounds
  6. Pressure ulcers
  7. Second degree burns
  8. Traumatic wounds healing by secondary intention
  9. Ulcers caused by mixed vascular etiologies
  10. Venous ulcers

BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES (cont.)

Criteria: (cont.)

- CollaSorb® is considered ***medically necessary*** with documentation of **ANY** of the following:

  1. Abrasions
  2. Dehisced surgical incisions
  3. Diabetic ulcers
  4. Donor and graft sites
  5. Pressure ulcers
  6. Second degree burns
  7. Traumatic wounds healing by secondary intention
  8. Ulcers caused by mixed vascular etiologies
  9. Venous ulcers

- CollaMend™ is considered ***medically necessary*** with documentation to reinforce soft tissue where weakness exists, e.g., for repair of hernia and chest wall defects, and for the surgical repair of damaged or ruptured soft tissue membranes.

- CollaWound™ is considered ***medically necessary*** with documentation of **ANY** of the following:

  1. Chronic vascular ulcers
  2. Diabetic ulcers
  3. Draining wounds
  4. First and second degree burns
  5. Partial **or** full thickness wounds
  6. Pressure ulcers
  7. Surgical wounds
  8. Trauma wounds
  9. Venous ulcers

- Collexa® is considered ***medically necessary*** with documentation of **ANY** of the following:

  1. Abrasions
  2. Dehisced surgical wounds
  3. Diabetic ulcers
  4. Exuding wounds
  5. First and second degree burns
  6. Full **or** partial thickness wounds
  7. Pressure ulcers
  8. Traumatic wounds
  9. Ulcers caused by mixed vascular etiologies
  10. Venous ulcers

BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES (cont.)

Criteria: (cont.)

- Conexa™ is considered ***medically necessary*** with documentation of **ANY** of the following:

  1. Reinforcement of soft tissue repaired by sutures or suture anchors during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps or other tendons
  2. Repair of body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome

- CorMatrix® ECM for Carotid Repair is considered ***medically necessary*** with documentation of vascular reconstruction and repair of the carotid artery, including patch closure following carotid endarterectomy and suture line buttressing.

- CorMatrix ECM for Vascular Repair is considered ***medically necessary*** with documentation for use as patch material for peripheral vasculature repair and reconstruction, including carotid, renal, iliac, femoral, and tibial blood vessels.

- CorMatrix Patch for Cardiac Tissue Repair is considered ***medically necessary*** with documentation for use as an intracardiac patch or pledget for tissue repair [i.e., atrial septal defect (ASD), ventricular septal defect (VSD), etc.] and suture-line buttressing.

- CorMatrix Pericardial Patch is considered ***medically necessary*** with documentation for the reconstruction and repair of the pericardium.

- CorMatrix Protect ECM Envelope is considered ***medically necessary*** with documentation for use to securely hold an implantable electronic device to create a stable environment when implanted; devices that may be used with include pacemaker pulse generators, defibrillators or other cardiac implantable electronic devices.

- Dermagraft® and Graftjacket Regenerative Tissue Matrix (also called Graftjacket Skin Substitute) for the treatment of a full-thickness diabetic foot ulcer are considered ***medically necessary*** with documentation of **ALL** of the following:

  1. Ulcer duration of 6 weeks or greater
  2. As an adjunct to standard diabetic foot ulcer care including a non-weight bearing regimen of the affected extremity
  3. Adequate blood supply to the involved foot
  4. Ulcer extends through the dermis but without tendon, muscle, capsule or bone exposure
  5. Ulcer is free of infection and osteomyelitis
  6. No co-existing autoimmune connective tissue disease, nutritional compromise, or poor medical condition (e.g., disabling cardiovascular, neuromuscular or peripheral vascular conditions)

- Durepair® Regeneration Matrix is considered ***medically necessary*** for the repair of defects in the dura mater.

BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES (cont.)

Criteria: (cont.)

- Epicel for treatment of deep dermal or full-thickness burns comprising a total body surface area of greater than or equal to 30% is considered ***medically necessary***.

- HA Absorbent Wound Dressing-F an absorbent fibrous fleece is available as an over-the-counter medication for abrasions, lacerations, minor cuts and first degree burns and is, therefore, considered a ***benefit plan exclusion*** and ***not eligible for coverage***.

- HA Absorbent Wound Dressing-F an absorbent fibrous fleece under the supervision of a healthcare provider is considered ***medically necessary*** with documentation of **ANY** of the following:

  1. Diabetic ulcers
  2. Leg ulcers
  3. Pressure ulcers (stages I-IV)
  4. Second degree burns
  5. Surgical wounds (e.g., post-operative, donor sites, dermatological)
  6. Traumatic wounds
  7. Wounds that are prone to bleeding (e.g., surgically or mechanically debrided)

- HA Absorbent Wound Dressing-R an absorbent fibrous rope is considered ***medically necessary*** for the management of deep exuding wounds, sinuses, and fistulae.

- Helicoll™ is considered ***medically necessary*** with documentation of **ANY** of the following:

  1. Chronic vascular ulcers
  2. Diabetic ulcers
  3. Partial or full-thickness wounds
  4. Pressure ulcers
  5. Second degree burns
  6. Surgical wounds (e.g., donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)
  7. Trauma wounds (e.g., abrasions, lacerations, skin tears)
  8. Venous ulcers

BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES (cont.)

Criteria: (cont.)

- Integra® Dermal Regeneration Template (IDRT) is considered ***medically necessary*** with documentation of **ANY** of the following:

  1. For the post-excisional treatment of life-threatening full-thickness or deep partial-thickness thermal injuries where sufficient autograft is not available at the time of excision or not desirable due to the individual's physiological condition
  2. For treatment of partial and full-thickness diabetic foot ulcers that are greater than six weeks duration, with no capsule, tendon or bone exposed, when used in conjunction with standard diabetic ulcer care
  3. For repair of scar contractures with documentation of **ONE** of the following:

     - Donor sites for repair are not desirable due to the individual's physiological condition
     - Donor sites for repair are not sufficient
     - Other therapies have failed

- Integra® Omnigraft Dermal Regeneration Matrix (also known as Omnigraft) is considered ***medically necessary*** with documentation for the treatment of partial and full-thickness diabetic foot ulcers that are greater than six weeks duration, with no capsule, tendon or bone exposed, when used in conjunction with standard diabetic ulcer care.

- Jaloskin® is considered ***medically necessary*** with documentation of **ANY** of the following:

  1. Chronic vascular ulcers
  2. Diabetic ulcers
  3. First and second degree burns
  4. Pressure ulcers
  5. Surgical wounds (e.g., donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence)
  6. Trauma wounds (e.g., abrasions, lacerations, skin tears)
  7. Venous ulcers

- Matrix Collagen Wound Dressing is considered ***medically necessary*** with documentation of **ANY** of the following:

  1. Acute wounds (e.g., trauma and surgical wounds)
  2. Diabetic ulcers
  3. Partial-thickness burns
  4. Pressure ulcers
  5. Venous stasis ulcers

BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES (cont.)

Criteria: (cont.)

- Medihoney® Wound Dressing is considered ***medically necessary*** with documentation of **ANY** of the following:

  1. 1st and 2nd degree partial thickness burns
  2. Diabetic foot ulcers
  3. Donor sites
  4. Leg ulcers (venous stasis ulcers, arterial ulcers and leg ulcers of mixed etiology)
  5. Pressure ulcers/sores (partial and full thickness)
  6. Traumatic and surgical wounds

- OrCel® is considered ***medically necessary*** with documentation of **ANY** of the following:

  1. Mitten hand deformity in an individual with dystrophic epidermolysis bullosa when standard wound therapy has failed
  2. Fresh, clean split thickness donor site wounds in burned individuals

- Permacol™ is considered ***medically necessary*** for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes with documentation of **ANY** of the following:

  1. Hernia repair: abdominal, inguinal, diaphragmatic, femoral, scrotal, umbilical or incisional
  2. Muscle flap reinforcement
  3. Pelvic floor reconstruction
  4. Prolapse: colon, rectal, urethral or vaginal
  5. Sacrocolposuspension
  6. Urethral sling

- Permacol Crosslinked Porcine Dermal Collagen Surgical Mesh is considered ***medically necessary*** for reinforcement of the soft tissues which are repaired by suture or suture anchors limited to the supraspinatus during rotator cuff repair surgery.

- Permacol Surgical Implant is considered ***medically necessary*** for the repair of abdominal wall defects and hernias, including, *but not limited, to* parastomal hernias.

- Permacol Surgical Implant T-piece is considered ***medically necessary*** for rectal intussusception repair.

- Permacol Surgical Implant Rectocele-piece is considered ***medically necessary*** for rectocele repair.

BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES (cont.)

Criteria: (cont.)

- Stimulen™ Collagen is considered ***medically necessary*** with documentation of **ANY** of the following:

  1. Abrasions
  2. Acute wounds
  3. Diabetic ulcers
  4. Donor sites
  5. Other surface wounds
  6. Partial **or** full thickness wounds
  7. Partial thickness burns
  8. Pressure ulcers (stages I-IV)
  9. Traumatic wounds healing by secondary intention
  10. Venous stasis ulcers

- Suprathel® is considered ***medically necessary*** with documentation of **ANY** of the following:

  1. Acute wounds
  2. Cuts and abrasions
  3. Diabetic ulcers
  4. First and second degree burns
  5. Grafted wounds and donor sites
  6. Partial **or** full thickness wounds
  7. Pressure (stage I and IV) and venous ulcers
  8. Superficial wounds
  9. Surgical wounds
  10. Trauma wounds
  11. Ulcers caused by mixed vascular etiologies
  12. Venous stasis ulcers

- SurgiMend® is considered ***medically necessary*** to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes with documentation of **ANY** of the following:

  1. Hernia repair including abdominal, inguinal, diaphragmatic, femoral, scrotal, umbilical and incisional
  2. Muscle flap reinforcement
  3. Reconstructive surgery

BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES (cont.)

Criteria: (cont.)

- Talymed® is considered ***medically necessary*** with documentation of **ANY** of the following:

  1. Abrasions, lacerations
  2. Chronic vascular ulcers
  3. Dehisced surgical wounds
  4. Diabetic ulcers
  5. Partial or full thickness wounds
  6. Pressure wounds
  7. Second degree burns
  8. Surgical wounds (e.g., donor sites/grafts, post-Mohs' surgery, post-laser surgery, and other bleeding surface wounds)
  9. Traumatic wounds healing by secondary intention
  10. Ulcers caused by mixed vascular etiologies
  11. Venous ulcers

- TenoGlide™ Tendon Protector Sheet is considered ***medically necessary*** for the management and protection of tendon injuries in which there has been no substantial loss of tendon tissue.

- TheraSkin® is considered ***medically necessary*** with documentation of **ANY** of the following:

  1. Burns
  2. Dehisced surgical wounds
  3. Diabetic foot ulcers (with or without exposed tendon, muscle or bone)
  4. Pressure ulcers (stage II plus)
  5. Radiation burns
  6. Venous ulcers
  7. Wounds that might otherwise require autografts

- TransCyte® is considered ***medically necessary*** with documentation of **ANY** of the following:

  1. As a temporary wound covering prior to autograft treatment for surgically excised full-thickness and deep partial-thickness thermal burn wounds
  2. As treatment for mid-dermal to indeterminate depth burn wounds that may be expected to heal without autografting

BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES (cont.)

Criteria: (cont.)

- Veritas® Collagen Matrix is considered ***medically necessary*** with documentation of **ANY** of the following:

  1. Abdominal and thoracic wall repair
  2. Buttressing and reinforcing staple lines during lung resection (e.g., wedge resection, blebectomy, lobectomy, bullectomy, bronchial resection, segmentectomy, pneumonectomy/pneumectomy, pneumoreduction) and other incisions and excision of the lung and bronchus
  3. Hernia repair (e.g., diaphragmatic, femoral, incisional, inguinal, lumbar, paracolostomy, scrotal, umbilical)
  4. Muscle flap reinforcement
  5. Pelvic floor reconstruction
  6. Rectal and vaginal prolapse repair
  7. Reinforcement of the gastric staple line during the bariatric surgical procedures of gastric bypass and gastric banding
  8. Urinary incontinence treatment

- XenMatrix™ AB is considered ***medically necessary*** to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes with documentation of **ANY** of the following:

  1. Hernia repair including abdominal, inguinal, diaphragmatic, femoral, scrotal, umbilical and incisional
  2. Muscle flap reinforcement
  3. Reconstructive surgery

BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES (cont.)

Criteria: (cont.)

- All other skin and soft tissue substitutes not previously addressed or if above criteria not met are considered ***experimental or investigational*** based upon:

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

  Skin substitutes include, *but are not limited to:*

  - AlloSkin™
  - AlloSkin™ AC
  - AlloSkin™ RT
  - ArthroFlex™ (FlexGraft)
  - AxoGuard® Nerve Protector (AxoGen)
  - Cymetra®
  - Dermapure™
  - ENDURAgen®
  - E-Z Derm®
  - FlowerDerm™
  - Graftjacket® Xpress (injectable product)
  - GammaGraft®
  - hMatrix®

BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES (cont.)

Criteria: (cont.)

- All other skin and soft tissue substitutes not previously addressed or if above criteria not met are considered ***experimental or investigational*** based upon: (cont.)

  1. Insufficient scientific evidence to permit conclusions concerning the effect on health outcomes, and
  2. Insufficient evidence to support improvement of the net health outcome, and
  3. Insufficient evidence to support improvement of the net health outcome as much as, or more than, established alternatives, and
  4. Insufficient evidence to support improvement outside the investigational setting.

  Skin substitutes include, *but are not limited to:* (cont.)

  - MatriDerm®
  - Matrix HD™
  - Mediskin®
  - MemoDerm™
  - Microderm® biologic wound matrix
  - Neox® 1k
  - Oasis® Burn Matrix
  - Oasis® Ultra Tri-Layer Matrix
  - Puros® Dermis
  - Repliform®
  - Repriza®
  - StrataGraft®
  - TruSkin™
  - TenSIX™
  - XCM Biologic™ Tissue Matrix

[1] Agency for Health Care Policy and Research (AHCPR)

BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES (cont.)

Resources:

Literature reviewed 07/31/18. We do not include marketing materials, poster boards and non-published literature in our review.

The BCBS Association Medical Policy Reference Manual (MPRM) policy is included in our guideline review. References cited in the MPRM policy are not duplicated on this guideline.

Resources prior to 02/05/13 may be requested from the BCBSAZ Medical Policy and Technology Research Department.

1. 7.01.113 BCBS Association Medical Policy Reference Manual. Bio-Engineered Skin and Soft Tissue Substitutes. Re-issue date 02/08/2018, issue date 12/13/2007.

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3. Cazzell SM, Lange DL, Dickerson JE, Jr., Slade HB. The Management of Diabetic Foot Ulcers with Porcine Small Intestine Submucosa Tri-Layer Matrix: A Randomized Controlled Trial. *Advances in wound care.* Dec 01 2015;4(12):711-718.

4. Choi JS, Kim JD, Yoon HS, Cho YW. Full-thickness skin wound healing using human placenta-derived extracellular matrix containing bioactive molecules. *Tissue Eng Part A.* Feb 2013;19(3-4):329-339.

5. Fetterolf DE, Istwan NB, Stanziano GJ. An evaluation of healing metrics associated with commonly used advanced wound care products for the treatment of chronic diabetic foot ulcers. *Manag Care.* Jul 2014;23(7):31-38.

6. Fetterolf DE, Snyder RJ. Scientific and Clinical Support for the Use of Dehydrated Amniotic Membrane in Wound Management. *Wounds.* 2012:299-307.

7. Forbes J, Fetterolf DE. Dehydrated amniotic membrane allografts for the treatment of chronic wounds: a case series. *J Wound Care.* Jun 2012;21(6):290, 292, 294-296.

BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES (cont.)

Resources: (cont.)

8. Koob TJ, Rennert R, Zabek N, et al. Biological properties of dehydrated human amnion/chorion composite graft: implications for chronic wound healing. *Int Wound J.* Oct 2013;10(5):493-500.

9. Lavery LA, Fulmer J, Shebetka KA, et al. The efficacy and safety of Grafix((R)) for the treatment of chronic diabetic foot ulcers: results of a multi-centre, controlled, randomised, blinded, clinical trial. *Int Wound J.* Oct 2014;11(5):554-560.

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11. Mamede AC, Carvalho MJ, Abrantes AM, Laranjo M, Maia CJ, Botelho MF. Amniotic membrane: from structure and functions to clinical applications. *Cell Tissue Res.* Aug 2012;349(2):447-458.

12. Mrugala A, Sui A, Plummer M, et al. Amniotic membrane is a potential regenerative option for chronic non-healing wounds: a report of five cases receiving dehydrated human amnion/chorion membrane allograft. *Int Wound J.* Aug 2016;13(4):485-492.

13. Mulder G, Tenenhaus M, D'Souza GF. Reduction of diabetic foot ulcer healing times through use of advanced treatment modalities. *Int J Low Extrem Wounds.* Dec 2014;13(4):335-346.

14. Patel VR, Samavedi S, Bates AS, et al. Dehydrated Human Amnion/Chorion Membrane Allograft Nerve Wrap Around the Prostatic Neurovascular Bundle Accelerates Early Return to Continence and Potency Following Robot-assisted Radical Prostatectomy: Propensity Score-matched Analysis. *European urology.* Jun 2015;67(6):977-980.

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BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES (cont.)

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BIO-ENGINEERED SKIN AND SOFT TISSUE SUBSTITUTES (cont.)

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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 hólǫ díí t'áá hazaadk'ehjí háká a'doowołgo bee haz'ą doo bąąh ílínígóó. 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.

Arabic:
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 (cont.)

Multi-Language Interpreter Services: (cont.)

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.

French: Si vous, ou quelqu'un que vous êtes en train d'aider, a des questions à propos de Blue Cross Blue Shield of Arizona, vous avez le droit d'obtenir de l'aide et l'information dans votre langue à aucun coût. Pour parler à un interprète, appelez 877-475-4799.

German: Falls Sie oder jemand, dem Sie helfen, Fragen zum Blue Cross Blue Shield of Arizona haben, haben Sie das Recht, kostenlose Hilfe und Informationen in Ihrer Sprache zu erhalten. Um mit einem Dolmetscher zu sprechen, rufen Sie bitte die Nummer 877-475-4799 an.

Russian: Если у вас или лица, которому вы помогаете, имеются вопросы по поводу Blue Cross Blue Shield of Arizona, то вы имеете право на бесплатное получение помощи и информации на вашем языке. Для разговора с переводчиком позвоните по телефону 877-475-4799.

Japanese: ご本人様、またはお客様の身の回りの方でも、Blue Cross Blue Shield of Arizona についてご質問がございましたら、ご希望の言語でサポートを受けたり、情報を入手したりすることができます。料金はかかりません。通訳とお話される場合、877-475-4799 までお電話ください。

Farsi:
اگر شما، یا کسی که شما به او کمک میکنید ، سوال در مورد Blue Cross Blue Shield of Arizona ، داشته باشید حق این را دارید که کمک و اطلاعات به زبان خود را به طور رایگان دریافت نمایید 877-475-4799
[تماس حاصل نمایید.

Assyrian:
[illegible] Blue Cross Blue Shield of Arizona [illegible]
[illegible] 877-475-4799.

Serbo-Croatian: Ukoliko Vi ili neko kome Vi pomažete ima pitanje o Blue Cross Blue Shield of Arizona, imate pravo da besplatno dobijete pomoć i informacije na Vašem jeziku. Da biste razgovarali sa prevodiocem, nazovite 877-475-4799.

Thai: หากคณ หรอคนทคณกาลงชวยเหลอมคาถามเกยวกบ Blue Cross Blue Shield of Arizona คณมสทธทจะไดรบความชวยเหลอและขอมลในภาษา ของคณไดโดยไมมคาใชจาย พดคยกบลาม โทร 877-475-4799