

Corporate Medical Policy

Bioengineered Skin and Tissue

File Name:	bioengineered_skin_and_tissue
Origination:	1/1994
Last CAP Review:	9/2011
Next CAP Review:	9/2012
Last Review:	3/2012

Description of Procedure or Service

Bioengineered skin or graftskin (living skin equivalent) is used to treat chronic wounds, burns and rare skin conditions such as recessive dystrophic epidermolysis bullosa. These products promote the growth of new skin, or serve as a temporary cover until other grafts can be placed.

Bioengineered skin consists of a dermal layer and/or an epidermal layer which is embedded into a cellular matrix forming the skin substitute.

It is thought that bioengineered skin accelerates wound healing by introducing living cells, which are "smart", to reestablish the condition needed for repair.

Skin ulcers are a diverse and complex group of disorders with a variety of apparent causes. They are a source of major disability, morbidity and carry an increased risk of mortality. Skin ulcers can result from venous insufficiency, diabetic neuropathy and/or peripheral arterial disease, pressure sores, acute surgical wounds such as those caused by excision of skin cancer, and/or burn injuries.

Management of skin wounds is designed with attention to each patient's particular set of characteristics and causal factors. Treatment strategies incorporate common principles that apply to the management of all wounds. While there is no universally agreed upon standard of care, there are a number of accepted components of what is considered optimal local care. Principles of good wound care include optimized tissue perfusion, a moist wound environment, antimicrobial therapy where appropriate, aggressive wound debridement, pressure relief and adequate nutrition.

Treatment for each category of ulcers has components that are indication-specific and should be used in addition to the common principles of good wound care. For example, venous ulcers combine good wound care with compression treatment. This decreases the venous pressure and improves the blood return to the heart. Diabetic neuropathic ulcers often require extensive debridement, weight off-loading, and aggressive control of blood glucose. Diabetic ulcers can be particularly difficult to heal and may require additional interventions for healing.

In the absence of complications, most acute wounds tend to heal within 8 weeks or so with standard care. However, a minority of wounds will not heal and become refractory. Refractory skin wounds are characterized by lack of healing, prolonged treatment courses and frequent recurrences. In some cases of prolonged non-healing ulcers, skin grafting can be attempted.

Bioengineered skin has been shown to improve the management and healing in the treatment of severe burns. Bioengineered skin is used when there is limited amount of the patient's own skin to use for grafts or they are too ill to have more wound sites created.

Another use for bioengineered skin is for a condition called epidermolysis bullosa. Epidermolysis bullosa (EB) is a rare disease that is usually inherited. These patients suffer from extremely fragile

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skin with recurrent painful blister formation that can develop into open sores or ulcers. An exacerbation of this disease can be caused by just minor skin friction or trauma.

Alloderm® is an acellular dermal matrix (allograft) derived from donated human skin tissue supplied by US AATB-compliant tissue banks using the standards of the American Association of Tissue Banks (AATB) and U.S. Food and Drug Administration's (FDA) guidelines. Acellular tissue matrix is a tissue-replacement product that is created from native human skin and processed so that the basement membrane and cellular matrix remain intact. The processing removes the cellular components that can lead to rejection and infection. Since AlloDerm® is regarded as minimally processed and not significantly changed in structure from the natural material; the FDA has classified it as banked human tissue.

Apligraf® is a bilayered cell therapy composed of an epidermal layer of living human keratinocytes and a dermal layer of living human fibroblasts. It was FDA approved in 1998 for use in conjunction with compression therapy for the treatment of non-infected, 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.

Biobrane®/Biobrane-L is a biosynthetic wound dressing constructed of a silicon film with a nylon fabric partially imbedded into the film. The fabric creates a complex 3-dimensional structure of tri-filament thread which chemically binds collagen. Blood/sera clot in the nylon matrix, adhering the dressing to the wound until epithelialization occurs. Under FDA PMA approval, Biobrane® is indicated use as a temporary covering for partial thickness burn wounds until autografting is clinically appropriate.

Celaderm® is an allograft that contains active keratinocytes made from epithelial cells of the foreskin. Although metabolically active they are not capable of proliferating. The product has not received FDA approval at this time. Individuals are currently being enrolled in an FDA-approved study to evaluate the safety of Celaderm® in humans and to assess its potential for acceleration of healing of venous leg ulcers.

Cymetra®, an injectable micronized particulate form of Alloderm, has been proposed as a minimally invasive tissue graft product. Cymetra is approved by the US Food and Drug Administration (FDA) as a human tissue for transplantation for the repair or replacement of damaged or inadequate integumental tissues. At this time, there are several peer-reviewed published articles addressing the use of this product. All of these studies involve patients with vocal cord paralysis. There are no long-term results showing lasting benefit of injection for voice quality or glottal closure.

C-QUR™ biosynthetic mesh has been proposed for use in abdominal surgical repair procedures. At this time there are no peer-review published studies available describing this product or its use in human patients. C-QUR V-Patch™ Mesh is indicated for use in hernia repair, chest wall reconstruction, traumatic or surgical wounds and other fascial surgical intervention procedures requiring reinforcement with a nonabsorbable supportive material.

Dermagraft® is composed of cryopreserved human-derived fibroblasts and collagen applied to a bioabsorbable mesh. Dermagraft has been approved by the FDA for repair of diabetic foot ulcers and for use in the treatment of wounds related to dystrophic epidermolysis bullosa.

Epicel® is a cultured epithelial autograft and is FDA approved under a humanitarian device exemption (HDE) for the treatment of deep dermal or full-thickness burns comprising a total body surface area of greater than or equal to 30%.

GraftJacket® Regenerative Tissue Matrix is an acellular regenerative tissue matrix that has been processed from screened donated human skin supplied from U.S. tissue banks. The allograft is

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processed minimally to remove the epidermal and dermal cells while preserving dermal structure. It is regulated by the FDA as human tissue for transplantation.

Hyalomatrix PA®, is a bilayer of an esterified hyaluronan scaffold beneath a silicone membrane. The scaffold delivers hyaluronan to the wound bed, and the silicone membrane acts as a temporary epidermal barrier. The matrix is FDA 510(k) approved and is indicated as a staging treatment for burn wounds.

Integra® Dermal Regeneration Template is a bovine, collagen/Glycosaminoglycan dermal replacement covered by a silicone temporary epidermal substitute. It is FDA approved for use in 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 physiological condition of the patient. Integra™ Matrix Wound Dressing and Integra™ Meshed Bilayer Wound Matrix are substantially equivalent skin substitutes that are FDA 510(k) approved for other indications

OASIS®Wound Matrix is a xenographic collagen scaffold derived from porcine small intestinal mucosa. It was cleared by the FDA's 510(k) process in 2000 for the management of partial and full-thickness wounds including pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled undermined wounds, surgical wound, trauma wounds, and draining wounds.

OrCel ®(formally known as composite cultured skin) is an absorbable allogeneic bilayered cellular matrix, made of bovine collagen, in which human dermal cells have been cultures. It was approved by the FDA (PMA) for healing donor site wounds in burn victims and under a humanitarian device exemption (HDE) for use in patients with recessive dystrophic epidermolysis bullosa undergoing hand reconstruction surgery to close and heal wounds created by the surgery, including those at donor sites.

Transcyte® consists of human dermal fibroblasts grown on nylon mesh combined with a synthetic epidermal layer and was approved by the FDA in 1997. TransCyte is intended to be used as a temporary covering over burns until autografting is possible. It can also be used as a temporary covering for some burn wounds that heal without autografting.

TheraSkin® is a recently introduced product designed to promote healing of ulcerated and burn wounds. The manufacturer's website states, "TheraSkin is a biologically active cryopreserved human skin allograft with both epidermis and dermis layers. TheraSkin's cellular and extracellular composition provides a supply of growth factors, cytokines and collagen to promote wound healing." TheraSkin is regulated by the American Association of Tissue banks and the FDA guidelines for banked human tissue.

Avaulta Plus™, Collamend, Cuffpatch™, E-Z Derm™, Integra™ Matrix Wound Dressing, Mediskin®, Oasis®, OrthADAPT™, Pelvicol®, Pelvisoft®, PriMatrix, Strattice™, Surgimend®, Surgisis®, TissueMend®, Matristem®, Endoform Dermal Template™, CorMatrix® Pericardial Patch, Veritas® Collagen Matrix and Unite™ are xenograft products that have been chemically crosslinked with aldehyde (non-human skin graft) to provide strength and durability. These products are derived from non-human organisms (e.g., cows, pigs, horses, etc.). Xenograft materials have been proposed for many applications including wound management and reconstruction procedures of the breast, pelvic floor, abdominal wall, tendons and other anatomical sites. These products may provide wound coverage or are sewn onto the soft tissues where they are needed to provide support and strengthen the underlying structures.

Note: Please also refer to the following BCBSNC policies:

- Orthopedic Applications of Stem Cell Therapy

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- Meniscal Allograft and Collagen Meniscus Implants
- Plugs for Fistula Repair
- Growth Factors in Wound Healing

*****Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician.**

Policy

BCBSNC will provide coverage for Apligraf® bioengineered skin, Oasis® Wound Matrix and Dermagraft® for the treatment of skin ulcers when it is determined to be medically necessary because the medical criteria and guidelines shown below have been met.

BCBSNC will provide coverage for Alloderm® bioengineered skin for the use in breast reconstruction when it is determined to be medically necessary because the medical criteria and guidelines shown below have been met.

BCBSNC will provide coverage for bioengineered skin for the treatment of burns and rare skin conditions when it is determined to be medically necessary because the medical criteria and guidelines shown below have been met

Benefits Application

This medical policy relates only to the services or supplies described herein. Please refer to the Member's Benefit Booklet for availability of benefits. Member's benefits may vary according to benefit design; therefore member benefit language should be reviewed before applying the terms of this medical policy.

When Bioengineered Skin and Tissue Products are covered

- A. The applications of **Apligraf®** and **Oasis® Wound Matrix** are covered for the treatment of vascular ulcers when **all** of the following criteria are met:
1. When used in conjunction with standard therapy,
 2. The ulcers have not healed by at least 50% after clinically appropriate therapy,
 3. The ulcers intended for treatment are partial or full thickness venous stasis ulcers, and
 4. The patient has adequate arterial blood supply to the involved limb, including restoration by vascular bypass grafting, stenting or other means.
- B. The application of **Apligraf®** is covered for the treatment of chronic neuropathic foot ulcers when **all** of the following criteria are met:
1. When used in conjunction with clinically appropriate foot ulcer care,
 2. The ulcers have persisted for three weeks or longer,
 3. The ulcers have not healed by 50% after 3 weeks of standard treatment,
 4. The patient has adequate arterial blood supply to the involved foot,

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5. The ulcers intended for treatment are full-thickness neuropathic diabetic foot ulcers, but do not go down to the tendon, muscle, capsule, or bone.

***Applications will be limited to no more than 4 applications per wound when the above criteria are met.

- C. The application of **Dermagraft®** is covered for the treatment of full-thickness diabetic foot ulcers when all of the following criteria are met:

1. When used in conjunction with clinically appropriate diabetic foot ulcer care protocols,
2. The ulcers have persisted for six weeks or longer,
3. The ulcers have not healed by 50% after 3 weeks of standard treatment,
4. The ulcers intended for treatment are full-thickness neuropathic diabetic foot ulcers, but do not extend down to the tendon, muscle, joint capsule, or bone,
5. The patients have adequate blood supply to the involved foot

***Applications will be limited to no more than 8 weekly applications per wound when the above criteria are met.

- D. **Alloderm** (an acellular allograft) may be considered medically necessary for use in breast reconstruction surgery.

- E. **Bioengineered skin** may be considered medically necessary in the treatment of burns and rare skin conditions such as recessive dystrophic epidermolysis bullosa when **all** of the following criteria are met:

1. When the product has **full** FDA approval, and
2. When the product is used within the scope of the FDA indications

When Bioengineered Skin and Tissue Products are not covered

- A. The application of **Apligraf®** has not been proven medically effective and is therefore considered investigational for all applications not listed under “When Bioengineered Skin and Tissue Products are covered,” including, but not limited to pressure sores and acute surgical wounds. BCBSNC does not pay for investigational services.

Apligraf® is contraindicated for use in the following situations:

1. The wounds are infected
2. The patient has a known allergy to bovine collagen
3. The patient has a known hypersensitivity to components in the product’s agarose shipping medium
4. No more than 4 applications of **Apligraf®** will be approved per wound

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B. **Oasis® Wound Matrix** is contraindicated in the following situations:

1. The patient has a known allergy to porcine collagen
2. For any indications other than those listed above in the "When Covered" section of the policy

C. **Dermagraft®** is contraindicated for use in the following situations:

1. Ulcers that have signs of clinical infection
2. Ulcers that have sinus tracts
3. Patients with known hypersensitivity to bovine products
4. For any indications other than those listed above in the "When Covered" section of the policy

D. **Alloderm®** is considered investigational for all indications except those addressed in the "When Covered" section including but not limited to parotidectomy and recurrent hernia repair or other major abdominal cavity reconstruction.

E. **Bioengineered skin and tissue products** are not covered for any indications other than those listed under "When Bioengineered Skin and Tissue Products are covered." Other Graftskin products have not been proven medically effective and are therefore considered investigational for all other applications. BCBSNC does not pay for investigational services. With the exception of products used within the scope of FDA indications for treatment of burns and rare skin conditions such as recessive dystrophic epidermolysis bullosa, FDA approval for a specific use does not define that product as non-investigational. The following list of products may not be all-inclusive:

AlloPatch HD™ -Regulated by the American Association of Tissue banks and the FDA guidelines for banked human tissue. Indicated for tendon/ligament repair.

AlloMax™ -Regulated by the American Association of Tissue banks and the FDA guidelines for banked human tissue. Indicated for soft tissue repair, including hernia and abdominal wall reconstruction

AlloSkin™ -Regulated by the American Association of Tissue banks and the FDA guidelines for banked human tissue. Indicated for use with partial and full thickness wounds.

ArthroFlex™ (FlexGraft) -Regulated by the American Association of Tissue banks and the FDA guidelines for banked human tissue. Indicated for shoulder reconstruction and Achilles tendon repair.

Avaulta Plus™ -FDA 510(k) approved xenograft indicated for tissue reinforcement and longlasting 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. See information regarding FDA 2011 warning:

<http://www.fda.gov/MedicalDevices/Safety/AlertsandNotices/ucm262435.htm>

Biobrane® -See description section

BioDfence/BioDfactor -Regulated by the American Association of Tissue banks and the FDA guidelines for banked human tissue. Indicated for use as a physical barrier between the dura and soft tissue of the paraspinal muscles to reduce fibroblast infiltration into the epidural space and postoperative scarring.

CellerateRX® -Collagen-based powder or gel FDA approved for all acute and chronic wounds except 3rd degree burns.

Conexa™ -FDA 510(k) approved xenograft indicated for the reinforcement of soft tissue repaired

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by sutures or suture anchors during tendon repair surgery including reinforcement of rotator cuff, patellar, Achilles, biceps, quadriceps, or other tendons.

CorMatrix® -FDA 510(k) approved xenograft indicated for the reconstruction and repair of the pericardium.

CRXa™ -See CellerateRX®

Cymetra® See description section

DermaMatrix Acellular Dermis -Regulated by the American Association of Tissue banks and the FDA guidelines for banked human tissue. Indicated for repair of facial soft tissue defects, eyelid or anophthalmic reconstruction, nasal reconstruction, septal perforation, parotidectomy, cleft palate repair, oral resurfacing, vestibuloplasty, radial forearm free flap repair, breast reconstruction postmastectomy, and abdominal wall repair.

Durepair Regeneration Matrix® -FDA 510(k) approved xenograft indicated for repair of defects in the dura mater.

Endoform Dermal Template™ -FDA 510(k) approved xenograft indicated for partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns) and skin tears) and draining wounds

ENDURAGEN™ -FDA 510(k) approved xenograft indicated for soft tissue repair or reinforcement in plastic and reconstructive surgery of the face and head

Epifix® - Amniotic membrane graft material regulated by the American Association of Tissue banks and the FDA guidelines for banked human tissue. Amniotic membrane transplantation may be considered medically necessary for use in corneal reconstruction. (See CPT code 65778-65780.)

E-Z Derm™ -No FDA approval. Xenograft wound matrix

FlexHD® Acellular Hydrated Dermis -Regulated by the American Association of Tissue banks and the FDA guidelines for banked human tissue. Indicated for the replacement of damaged or inadequate integumental tissue or the repair, reinforcement or supplemental support of soft tissue defects.

GammaGraft -Regulated by the American Association of Tissue banks and the FDA guidelines for banked human tissue. Indicated for the treatment of venous stasis ulcers; diabetic foot ulcers; full-thickness ulcers; Mohs surgery sites; skin graft donor sites; partial thickness wounds; burns; areas of dermabrasion; temporary coverage of exposed abdominal viscera, including small bowel and liver; exposed pericranium and cranium; fasciotomy sites

GraftJacket® Regenerative Tissue Matrix -See description section

GraftJacket® Xpress, injectable -Regulated by the American Association of Tissue banks and the FDA guidelines for banked human tissue. Indicated for deep tunneling chronic wounds

Hyalomatrix® PA - See description section

Integra™ Flowable Wound Matrix -FDA 510(k) approved xenograft indicated for treatment of partial or full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, skin tears) and draining wounds.

Integra Dermal Regeneration Template - See description section

MatriStem® - FDA 510(k) approved xenograft indicated for the management of wounds including: partial and full-thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled/undermined wounds, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second degree burns, skin tears) and draining wounds

Matrix HD™ -Regulated by the American Association of Tissue banks and the FDA guidelines for banked human tissue. Indicated for use in repair of tendon and muscle fascia.

MediHoney® -FDA 510(k) approved wound dressing indicated for the management of light to heavily exuding wounds.

Mediskin® -No FDA approval. Xenograft wound matrix

MemoDerm™ -Regulated by the American Association of Tissue banks and the FDA guidelines

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for banked human tissue. Indicated for use in repair of tendon and ligament repair as well a chronic diabetic foot ulcers.

Oasis® Burn Matrix - FDA 510(k) approved xenograft indicated for the treatment of partial-thickness burns. It is not indicated for treatment of third degree burns.

Oasis® Ultra Tri-Layer Matrix - FDA 510(k) approved xenograft derived from porcine small intestinal mucosa. It is indicated for the management of partial and full-thickness wounds including pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, tunneled undermined wounds, surgical wound, trauma wounds, and draining wounds. This product is similar to Oasis® Wound Matrix but is in triple layer structure.

Permacol™ - FDA 510(k) approved xenograft indicated for soft tissue repair or reinforcement in plastic and reconstructive surgery of the face and head and inguinal hernia repair.

PriMatrix - FDA 510(k) approved xenograft indicated for treatment of partial and full thickness wounds, pressure, diabetic, and venous ulcers, second-degree burns, surgical wounds-donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence, trauma wounds-abrasions, lacerations, and skin tears, tunneled/undermined wounds, draining wounds.

Repriza™- Regulated by the American Association of Tissue banks and the FDA guidelines for banked human tissue. Indicated for use in breast reconstruction, abdominal wall reconstruction, and augmentation of soft tissue irregularities.

Strattice™ - FDA 510(k) approved xenograft indicated for the reinforcement of soft tissues repaired by sutures or suture anchors, during rotator cuff surgery. Indications for use also include the repair of hernias and/or body wall defects which require the use of reinforcing or bridging material to obtain the desired surgical outcome.

SurgiMend®- FDA 510(k) approved xenograft indicated for plastic and reconstructive surgery, muscle flap reinforcement, and hernia repair.

Talymed®- FDA 510(k) approved wound matrix comprised of shortened fibers of poly-Nacetylglucosamine, isolated from microalgae. Indicated for treatment of diabetic ulcers, venous ulcers, pressure wounds, ulcers caused by mixed vascular etiologies, full thickness and partial thickness wounds, second degree burns, surgical wounds-donor sites/grafts, post-mohr's surgery, post-laser surgery, and other bleeding surface wounds, abrasions, lacerations, traumatic wounds healing by secondary intention, chronic vascular ulcers and dehisced surgical wounds.

TenoGlide™ - FDA 510(k) approved matrix of cross-linked collagen and Glycosaminoglycan, indicated for use as tendon protector sheath.

TheraSkin®Unite™- See description section

Veritas® Collagen Matrix- FDA 510(k) approved xenograft indicated for repair of complex abdominal wall reconstruction procedures.

Policy Guidelines

Currently there is insufficient evidence to determine the efficacy for uses of certain bioengineered skin or tissue other than those indicated above as covered.

The use of **Alloderm** in breast reconstruction can be particularly useful in women who have insufficient tissue expander or implant coverage by the pectoralis major muscle and additional coverage is required; or when there are viable but compromised or thin post-mastectomy skin flaps that are at risk of dehiscence or necrosis; or when the infra-mammary fold and lateral mammary folds have been undermined during mastectomy, and re-establishment of these landmarks is needed.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative

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Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable service codes: 15150, 15151, 15152, 15155, 15156, 15157, 15271, 15272, 15273, 15274, 15275, 15276, 15277, 15278, 15777, Q4100, Q4101, Q4102, Q4103, Q4104, Q4105, Q4106, Q4107, Q4108, , Q4110, Q4111, Q4112, Q4113, Q4114, Q4115, Q4116, Q4117, Q4118, Q4119, Q4120, Q4121, Q4122, Q4123, Q4124, Q4125, Q4126, Q4127, Q4128, Q4129, Q4130, C9354, C9358, C9360, C9363, C9364, C9366 , C9367.

BCBSNC may request medical records for determination of medical necessity. When medical records are requested, letters of support and/or explanation are often useful, but are not sufficient documentation unless all specific information needed to make a medical necessity determination is included.

Scientific Background and Reference Sources

Consultant Review - 1/94

Physician Advisory Group - 3/95

BCBSA Medical Policy Reference manual (Growth Factors for Wound Healing S9055)

MPAG Review - 3/99

Specialty Matched Consultant Advisory Panel - 10/2000

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Marston WA, Hanft J, Norwood P, Pollak R, for the Dermagraft Diabetic Foot Ulcer Study Group. The efficacy and safety of Dermagraft in improving the healing of chronic diabetic foot ulcers. *Diabetes Care*. 2003;26:1701-1705.

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Medical Director review 3/2012

Policy Implementation/Update Information

1/94	Original Policy Issued.
3/95	Reviewed: Remains investigational
9/95	Reaffirmed: Remains investigational
10/96	Reaffirmed
3/99	Reaffirmed
8/99	Reformatted, Description of procedure changed, Medical Term Definitions added.
10/00	Specialty Matched Consultant Advisory Panel review. No change recommended in criteria. System coding changes. Medical Policy Advisory Group. No change in criteria. Approve.
10/02	Name changed from Keratinocyte Allografts to Bioengineered Skin for the Treatment of Skin Ulcers. Description section expanded. Changed from investigational to covered for certain indications. Specialty Matched Consultant Advisory Panel review.
4/03	Date of Last Review changed to 10/2002 when review was done by the Specialty Matched Consultant Advisory Panel and policy was updated. Date of Next Review changed to 2 years later - 10/2004.
9/03	Added Dermagraft as a covered product with specific criteria. Sources added. Added

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- codes J7342 and J7350. Removed code 15350.
- 12/03 Billing/Coding section updated for consistency.
- 9/9/04 Policy name changed from Bioengineered Skin for the Treatment of Skin Ulcers to Bioengineered Skin. Specialty Matched Consultant Advisory Panel review 7/14/2004. Added information in Description of Procedure or Service section to include burns. Added statement in Policy section indicating "BCBSNC will provide coverage for bioengineered skin for the treatment of burns when it is determined to be medically necessary because the medical criteria and guidelines shown below have been met." In section regarding When Bioengineered Skin is Covered, added "C. Bioengineered skin may be considered medically necessary in the treatment of burns when all of the following criteria are met. 1. When the product has full FDA approval. and 2. When the product is used within the scope of the FDA indications." Removed reference to Biobrane in that it is a biosynthetic wound dressing for burns and does not apply to this policy. Added HCPCS code Q0183. References added. Notification given 9/9/2004. Effective date 11/11/2004.
- 1/6/05 First quarter 2005 HCPCS codes J7343, J7344 added to Billing/Coding section of policy.
- 1/5/06 Added new 2006 CPT codes 15150, 15151, 15152, 15155, 15156, 15157, 15170, 15171, 15175, 15176, 15300, 15301, 15320, 15321, 15330, 15331, 15335, 15336, 15340 15341, 15360, 15361, 15365, 15366, 15420, 15421, 15430, 15431, and HCPCS code J7341 to "Billing/Coding" section. Deleted CPT codes 15342 and 15343.
- 7/24/06 Specialty Matched Consultant Advisory Panel review 6/20/2006. Updated "Description of Procedure or Service" section to include information regarding specific products. Added "rare skin conditions" to the "Policy" statement. The following changes were made to the "When Bioengineered Skin is Covered" section. Removed the statement "The ulcers are not infected". Changed the wording regarding "standard wound care" to "clinically appropriate therapy". Under B. changed statement from indicating 4 applications to "Applications will be limited to no more than 6 pieces per wound when the above criteria are met." Added additional indication under C. "rare skin conditions such as recessive dystrophic epidermolysis bullosa". Added the following product names under "When Bioengineered Skin is Not Covered"; "EZ Derm®, Mediskin®, Alloderm®, Oasis®, Surgis®, Acticoat®, and GraftJacket. Removed deleted HCPCS code Q0183. References added.
- 1/17/07 Added the following new 2007 HCPCS codes, J7345 and J7346 to "Billing/Coding" section. Deleted HCPCS code, J7350.
- 4/23/07 Added CPT codes 15400 and 15401 to "Billing/Coding" section.
- 01/14/08 Added information to the "Description" section regarding "Primatrix™ (formerly known as DressSkin) and TissueMend®". "Primatrix, DressSkin, and TissueMend" added to "Key Words". Added new 2008 HCPCS codes; "J7347, J7348, and J7349" to "Billing/Coding" section. Removed HCPCS code J7345.
- 7/28/08 Specialty Matched Consultant Advisory Panel review 6/23/08. Added "Celaderm® is an allograft that contains active keratinocytes made from epithelial cells of the foreskin. Although metabolically active they are not capable of proliferating. The product has not received FDA approval at this time." to the "Description section. Added to "Alloderm" under the "When Not Covered" section "is considered investigational for all indications including but not limited to breast reconstruction and recurrent hernia repair." and added "Celladerm®" to the list. Updated the rationale in the "Policy

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- Guidelines" section. References added.
- 1/5/09 Added new HCPCS codes: Q4100, Q4101, Q4102, Q4103, Q4104, Q4105, Q4106, Q4107, Q4108, Q4109, Q4110, Q4111, Q4112, Q4113, and Q4114 to the "Billing/Coding" section. Removed deleted HCPCS codes: J7340, J7341, J7342, J7343, J7344, J7346, J7347, J7348, and J734.
- 2/2/09 Reviewed with Senior Medical Director 1/20/09. The investigational status of Alloderm for the use in breast reconstruction has changed and now may be medically necessary when specific criteria is met. "Policy" statement updated. Added the following statement to the "Description" section; "Alloderm has been researched as a support mechanism for breast reconstruction, difficult hernia repairs and after parotidectomy to avoid Frey's syndrome." Added the following indications to the "When Covered" section: "C. Alloderm (an acellular allograft) may be considered medically necessary for use in breast reconstruction surgery." Reference to breast reconstruction with Allograft was removed in the "When Not Covered" section and reworded to indicate; "E. Alloderm® is considered investigational for all indications except those addressed in the "When Covered" section including but not limited to parotidectomy and recurrent hernia repair or other major abdominal cavity reconstruction." Revised "Policy Guidelines" section and added the following statement; "The use of Alloderm in breast reconstruction can be particularly useful in women who have insufficient tissue expander or implant coverage by the pectoralis major muscle and additional coverage is require, or when there is viable but compromised or thin post-mastectomy skin flaps that are at risk of dehiscence or necrosis or when the infra-mammary fold and lateral mammary folds have been undermined during mastectomy and re-establishment of these landmarks are needed.". References added.
- 8/3/09 Added new HCPCS codes Q4115 and Q4116 to "Billing/Coding" section. (btw)
- 10/26/09 Added the following statement to the "Description" section; "***Note: This Medical Policy is complex and technical. For questions concerning the technical language and/or specific clinical indications for its use, please consult your physician. Changed the wording in the "When Covered" section under B. Dermagraft from "Applications will be limited to no more than 6 pieces per wound when the above criteria are met." to "Applications will be limited to no more than 8 weekly applications per wound when the above criteria are met." Reviewed with Senior Medical Director 9/16/09. References added. (btw)
- 6/22/10 Policy Number(s) removed. (amw)
- 10/26/10 Added new product information to "Description" section for Cymetra®, C-Qur™, Avaulta Plus™, Collamend, Cuffpatch™, DermaMatrix Acellular Dermis, E-Z Derm™, Integra™ Matrix Wound Dressing, Mediskin®, Oasis™, OrthADAPT™, Pelvicol®, Pelvisoft®, PriMatrix, Strattice™, Surgimend®, Surgisis®, Unite™. These products have been added to the "What is not Covered" section. Updated references. Specialty Matched Consultant Advisory Panel review 9/2010. Added HCPCS codes C9358, C9360, C9363 and C9364 to Billing/Coding section. (mco)
- 1/4/11 Added new product information for Matristem®, Hyalomatrix®, Endoform Dermal Template™, and Theraskin®. Added the following codes to reflect the 2011 HCPCS coding updates: C9367, G0440, G0411, Q4117, Q4118, Q4119, Q4120, and Q4121. Deleted code Q4109(mco)
- 1/18/11 Senior Medical Director review 1/2011. Changed title of policy from "Bioengineered Skin" to "Bioengineered Skin and Tissue." Added new product information to "Description" section for CorMatrix® pericardial patch and Veritas® Collagen Matrix. The products were also

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added to the “When not Covered” section. References updated. Reformatted the “When not Covered” section. (mco)

5/24/11 Medical Director review 5/2011. Under “When Covered” section A-1, replaced the word “venous” with “vascular” and in section A-1-d, added “including restoration by vascular bypass grafting, stenting or other means.” In section 2, deleted the words “diabetic” from the criteria for neuropathic foot ulcers. (mco)

7/01/11 Added new code to “Billing/Coding” section: C9365. Added new product to “Not Covered” section: Oasis Ultra Tri-Layer Matrix. (mco)

11/8/11 Specialty Matched Consultant Advisory Panel review 9/2011. Updated “Description” section. “When Covered” section re-formatted. Added new products to the “When not Covered” section and alphabetized product list. FDA indications provided for all products listed in policy. Added C9354 to “Billing/Coding” section. References updated. (mco)

12/30/11 Deleted the following codes from “Billing/Coding” section: 15170, 15171, 15175, 15176, 15330, 15331, 15335, 15336, , 15340, 15341, 15360, 15361, 15365, 15366, 15400, 15401, 15420, 15421, 15430, 15431, C9365, G0440, G0441. Added the following codes to “Billing/Coding” section: 15271, 15272, 15273, 15274, 15275, 15276, 15277, 15278, 15777, C9366, Q4122, Q4123, Q4124, Q4125, Q4126, Q4127, Q4128, Q4129, Q4130. New codes will be effective 1/1/2012. Added new product “Epifix®” to “When not Covered” section. (mco)

3/20/12 New policy criteria as follows: “BCBSNC will provide coverage for Apligraf® bioengineered skin, **Oasis® Wound Matrix** and Dermagraft® for the treatment of skin ulcers when it is determined to be medically necessary because the medical criteria and guidelines shown below have been met.” “When Covered” section revised to state, “A.The applications of Apligraf® and ~~Dermagraft®~~ **Oasis Wound Matrix®** are covered for the treatment of vascular ulcers when all of the following criteria are met: 1.When used in conjunction with standard therapy, 2. The ulcers have not healed by at least 50% after clinically appropriate therapy, 3.The ulcers intended for treatment are partial or full thickness venous stasis ulcers, and 4.The patient has adequate arterial blood supply to the involved limb, including restoration by vascular bypass grafting, stenting or other means.” “When not Covered” section updated to include the following statements: “B.Oasis® Wound Matrix is contraindicated in the following situations: 1.The patient has a known allergy to porcine collagen 2.For any indications other than those listed above in the “When Covered” section of the policy.” Added the following statement to the “When not Covered” section: “With the exception of products used within the scope of FDA indications for treatment of burns and rare skin conditions such as recessive dystrophic epidermolysis bullosa, FDA approval for a specific use does not define that product as non-investigational.” References updated. Medical Director review 3/2012. (mco)

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