

Centers for Medicare & Medicaid Services

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LCD for Metabolically and Non-Metabolically Active Dermal Skin Substitute Dressings (L13914)

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Please note: This is a Retired LCD.

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Metabolically and Non-Metabolically Active Dermal Skin Substitute Dressings

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03A-0010-L

LCD Information

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Title XVIII of the Social Security Act, §1862 (a)(1)(A) allows coverage and payment for only those services that are considered to be reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Title XVIII of the Social Security Act, §1833 (e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

CMS Manual System, Pub 100-8, Medicare Program Integrity, Transmittal 63, dated January 23, 2004, Change Request 3010

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Metabolically and non-metabolically active dermal skin substitute dressings are bioengineered dermal tissues, which contain the characteristics of dermis, or both dermis and epidermis. These are manufactured under aseptic conditions using human fibroblast, or fibroblast and keratinocytic cells derived from newborn male foreskin tissue. These cells are tested and found free from human and animal viruses. Human dermal and/or epidermal replacements do not contain macrophages, lymphocytes, blood vessels or hair follicles.

Apligraf®

Apligraf® is a living, bilayered, skin construct. The epidermal layer is formed by human keratinocytes and has a well-differentiated stratum corneum. The dermal layer is composed of human fibroblasts in a bovine Type 1 collagen lattice. While matrix proteins and cytokines found in human skin are present in Apligraf®, it does not contain Langerhans cells, or melanocytes.

Apligraf® is covered for the following indications:

- When used with diabetic foot ulcer care for the treatment of non-infected full-thickness neuropathic diabetic foot ulcers that have not adequately responded to conventional diabetic foot ulcer therapy. Coverage for Apligraf® for neuropathic diabetic foot ulcers will be considered when all of the following conditions are met:

-The type 1 or type 2 diabetic is under current medical management

-The neuropathic diabetic foot ulcer has been present for a minimum of four weeks duration

-The neuropathic diabetic foot ulcer has failed to respond to documented conservative measures of at least four weeks duration

-The patient has adequate arterial blood supply to support tissue growth.

- When used with therapeutic compression for the treatment of non-infected partial and full-thickness skin ulcers due to venous insufficiency that have not adequately responded to conventional venous insufficiency ulcer therapy. Coverage for Apligraf® for venous insufficiency ulcers will be considered when all of the following conditions are met:

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- The venous stasis ulcer has been present for a minimum of three months duration
- The venous stasis ulcer has failed to respond to documented conservative measures of at least eight weeks duration. Conservative measures include debridement of necrotic tissue. Debridement can take the form of wet-to-dry dressings, enzymatic debridement and surgical debridement.

Dermagraft®

Dermagraft® is a single layered cryopreserved dermal substitute composed of human fibroblasts, extracellular matrix, and a bioabsorbable scaffold. During the manufacturing process, the human fibroblasts are seeded into a bioabsorbable polyglactin mesh scaffold. The fibroblasts proliferate to fill the interstices of this scaffold and secrete human dermal collagen, matrix proteins, growth factors and cytokines to create a three-dimensional human dermal replacement.

Coverage for Dermagraft® used in the treatment of full thickness diabetic foot ulcers will be considered when all of the following conditions are met:

- The patient has documented type 1 or type 2 diabetes and is currently receiving medical management for this condition
- The full thickness diabetic foot ulcer has been present for a minimum of six weeks duration
- The ulcer has failed to respond to conservative measures; and,
- The ulcer extends through the dermis, but does not involve tendon, muscle, joint capsule, or have bone exposure.

OrCel®

OrCel® is a bilayered cellular matrix in which normal human epidermal keratinocytes and dermal fibroblasts are cultured in two separate layers onto a Type I bovine collagen sponge. The bovine sponge serves as an absorbable biocompatible matrix that provides a favorable environment for host cell migration. When OrCel® is applied to a wound, it serves as a protective wound dressing and provides a favorable environment for the body's cells to grow and secrete various growth factors at the wound site which in turn aid wound healing. As healing at the wound site occurs, it is expected that OrCel® will dissolve and the patients' own skin cells will replace the OrCel® cells, creating a new intact skin surface.

Coverage for OrCel® used in the treatment of clean split thickness donor site wounds in burn patients will be considered when all of the following conditions are met:

- The patient has sustained a thermal injury (2nd or 3rd degree burn)
- The site is clinically free of infection.

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TransCyte®

TransCyte® is a human fibroblast derived temporary skin substitute. TransCyte® consists of a polymer membrane and newborn human fibroblast cells cultured under aseptic conditions in vitro on a nylon mesh. Prior to cell growth, this nylon mesh is coated with porcine dermal collagen and bonded to a polymer membrane (silicone).

The human fibroblast-derived temporary skin substitute provides a temporary protective barrier. TransCyte® is also indicated for the treatment of mid-dermal to indeterminate depth burn wounds that typically require debridement and that may be expected to heal without auto grafting.

Graft Jacket®

The Graft Jacket® Regenerative Tissue Matrix is processed from donated human skin supplies from U.S. tissue banks utilizing the guidelines of the American Association of Tissue Banks (AATB) and the Food and Drug Administration's (FDA) applicable rules and regulations. The allograft skin is minimally processed to remove epidermal and dermal cells through a patented method while preserving the remaining bioactive components and structure of dermis. The resulting allograft serves as a framework to support cellular repopulation and vascularization.

Integra® Bilayer Matrix Wound Dressing/ Dermal Regeneration Template

Integra® Bilayer Matrix Wound Dressing/ Dermal Regeneration Template consists of a porous matrix of cross-linked bovine tendon collagen and glycosaminoglycan and a semi-permeable silicone layer.

The Dermal Regeneration Template is covered for the following indications:

- Postexcisional 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 physiological condition of the patient.
- The repair of scar contractures when other therapies have failed or when donar sites for repair are not sufficient or desirable due to the physiological condition of the patient. The scars must be documented to be disabling by limiting elasticity and immobilizing the skin.

The Bilateral Matrix Dressing is covered for the management of wounds including: partial and full-thickness wounds, ulcers, surgical wounds, trauma wounds, and draining wounds.

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Coding Information

Bill Type Codes: [back to top](#)

Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.

12x	Hospital–inpatient or home health visits (Part B only)
13x	Hospital–outpatient (HHA–A also) (under OPPS 13X must be used for ASC claims submitted for OPPS payment -- eff. 7/00)
18x	Hospital–swing beds
21x	SNF–inpatient (including Part A)
22x	SNF–inpatient or home health visits (Part B only)
23x	SNF–outpatient (HHA–A also)
71x	Clinic–rural health
73x	Clinic–independent provider based FQHC (eff 10/91)
85x	Special facility or ASC surgery–rural primary care hospital (eff 10/94)

Revenue Codes: [back to top](#)

Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.

036X	Operating room services–general classification
045X	Emergency room–general classification
051X	Clinic–general classification
0636	Drugs requiring specific identification–detailed coding (eff 3/92)
076X	Treatment or observation room–general classification

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15002	Wnd prep, ch/inf, trk/arm/lg
15003	Wnd prep, ch/inf addl 100 cm
15004	Wnd prep ch/inf, f/n/hf/g
15005	Wnd prep, f/n/hf/g, addl cm
15170	Acell graft trunk/arms/legs
15171	Acell graft t/arm/leg add-on
15175	Acellular graft, f/n/hf/g
15176	Acell graft, f/n/hf/g add-on
15340	Apply cult skin substitute
15341	Apply cult skin sub add-on
15360	Apply cult derm sub, t/a/l
15361	Aply cult derm sub t/a/l add
15365	Apply cult derm sub f/n/hf/g
15366	Apply cult derm f/hf/g add
15400	Apply skin xenograft, t/a/l
15401	Apply skn xenogrft t/a/l add
15420	Apply skin xgraft, f/n/hf/g
15421	Apply skn xgrft f/n/hf/g add
15430	Apply acellular xenograft
15431	Apply acellular xgraft add
J7340	Metabolic active D/E tissue
J7341	Non-human, metabolic tissue
J7342	Metabolically active tissue
J7343	Nonmetabolic act d/e tissue
J7344	Nonmetabolic active tissue
J7346	Injectable human tissue

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- 250.80 – 250.83 DIABETES WITH OTHER SPECIFIED MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED – DIABETES WITH OTHER SPECIFIED MANIFESTATIONS, TYPE I [JUVENILE TYPE], UNCONTROLLED
- 454.0 VARICOSE VEINS OF LOWER EXTREMITIES WITH ULCER
- 454.2 VARICOSE VEINS OF LOWER EXTREMITIES WITH ULCER AND INFLAMMATION
- 707.12 ULCER OF CALF
- 707.13 ULCER OF ANKLE
- 707.14 ULCER OF HEEL AND MIDFOOT
- 707.15 ULCER OF OTHER PART OF FOOT
- 709.2 SCAR CONDITIONS AND FIBROSIS OF SKIN
- 757.39 OTHER SPECIFIED CONGENITAL ANOMALIES OF SKIN
- 941.20 BLISTERS WITH EPIDERMAL LOSS DUE TO BURN (SECOND DEGREE) OF FACE AND HEAD UNSPECIFIED SITE
- 941.21 BLISTERS WITH EPIDERMAL LOSS DUE TO BURN (SECOND DEGREE) OF EAR (ANY PART)
- 941.24 – 941.29 BLISTERS WITH EPIDERMAL LOSS DUE TO BURN (SECOND DEGREE) OF CHIN – BLISTERS WITH EPIDERMAL LOSS DUE TO BURN (SECOND DEGREE) OF MULTIPLE SITES (EXCEPT WITH EYE) OF FACE HEAD AND NECK
- 941.30 FULL-THICKNESS SKIN LOSS DUE TO BURN (THIRD DEGREE NOS) OF UNSPECIFIED SITE OF FACE AND HEAD
- 941.31 FULL-THICKNESS SKIN LOSS DUE TO BURN (THIRD DEGREE NOS) OF EAR (ANY PART)
- 941.34 – 941.39 FULL-THICKNESS SKIN LOSS DUE TO BURN (THIRD DEGREE NOS) OF CHIN – FULL-THICKNESS SKIN LOSS DUE TO BURN (THIRD DEGREE NOS) OF MULTIPLE SITES (EXCEPT WITH EYE) OF FACE HEAD AND NECK
- 941.40 DEEP NECROSIS OF UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE) OF UNSPECIFIED SITE OF FACE AND HEAD WITHOUT LOSS OF BODY PART
- 941.41 DEEP NECROSIS OF UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE) OF EAR (ANY PART) WITHOUT LOSS OF EAR
- 941.44 – 941.49 DEEP NECROSIS OF UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE) OF CHIN WITHOUT LOSS OF CHIN – DEEP NECROSIS OF

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- UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE) OF MULTIPLE SITES (EXCEPT WITH EYE) OF FACE HEAD AND NECK WITHOUT LOSS OF A BODY PART
- 941.50 DEEP NECROSIS OF UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE) OF FACE AND HEAD UNSPECIFIED SITE WITH LOSS OF BODY PART
- 941.51 DEEP NECROSIS OF UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE) OF EAR (ANY PART) WITH LOSS OF EAR
- 941.54 – 941.59 DEEP NECROSIS OF UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE) OF CHIN WITH LOSS OF CHIN – DEEP NECROSIS OF UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE) OF MULTIPLE SITES (EXCEPT EYE) OF FACE HEAD AND NECK WITH LOSS OF A BODY PART
- 942.20 – 942.29 BLISTERS WITH EPIDERMAL LOSS DUE TO BURN (SECOND DEGREE) OF UNSPECIFIED SITE OF TRUNK – BLISTERS WITH EPIDERMAL LOSS DUE TO BURN (SECOND DEGREE) OF OTHER AND MULTIPLE SITES OF TRUNK
- 942.30 – 942.39 FULL-THICKNESS SKIN LOSS DUE TO BURN (THIRD DEGREE NOS) OF UNSPECIFIED SITE OF TRUNK – FULL-THICKNESS SKIN LOSS DUE TO BURN (THIRD DEGREE NOS) OF OTHER AND MULTIPLE SITES OF TRUNK
- 942.40 – 942.49 DEEP NECROSIS OF UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE) OF TRUNK UNSPECIFIED SITE WITHOUT LOSS OF BODY PART – DEEP NECROSIS OF UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE) OF OTHER AND MULTIPLE SITES OF TRUNK WITHOUT LOSS OF BODY PART
- 942.50 – 942.59 DEEP NECROSIS OF UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE) OF UNSPECIFIED SITE OF TRUNK WITH LOSS OF BODY PART – DEEP NECROSIS OF UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE) OF OTHER AND MULTIPLE SITES OF TRUNK WITH LOSS OF A BODY PART
- 943.20 – 943.29 BLISTERS WITH EPIDERMAL LOSS DUE TO BURN (SECOND DEGREE) OF UNSPECIFIED SITE OF UPPER LIMB – BLISTERS WITH EPIDERMAL LOSS DUE TO BURN (SECOND DEGREE) OF MULTIPLE SITES OF UPPER LIMB EXCEPT WRIST AND HAND
- 943.30 – 943.39 FULL-THICKNESS SKIN LOSS DUE TO BURN (THIRD DEGREE NOS) OF UNSPECIFIED SITE OF UPPER LIMB – FULL-THICKNESS SKIN LOSS DUE TO BURN (THIRD DEGREE NOS) OF MULTIPLE SITES OF UPPER LIMB EXCEPT WRIST AND HAND
- 943.40 – 943.49 DEEP NECROSIS OF UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE) OF UNSPECIFIED SITE OF UPPER LIMB WITHOUT LOSS OF A BODY PART – DEEP NECROSIS OF UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE) OF MULTIPLE SITES OF UPPER LIMB EXCEPT WRIST AND HAND WITHOUT LOSS OF UPPER LIMB

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- 943.50 – 943.59 DEEP NECROSIS OF UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE) OF UNSPECIFIED SITE OF UPPER LIMB WITH LOSS OF A BODY PART – DEEP NECROSIS OF UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE) OF MULTIPLE SITES OF UPPER LIMB EXCEPT WRIST AND HAND WITH LOSS OF UPPER LIMB
- 944.20 – 944.28 BLISTERS WITH EPIDERMAL LOSS DUE TO BURN (SECOND DEGREE) OF UNSPECIFIED SITE OF HAND – BLISTERS WITH EPIDERMAL LOSS DUE TO BURN (SECOND DEGREE) OF MULTIPLE SITES OF WRIST(S) AND HAND(S)
- 944.30 – 944.38 FULL-THICKNESS SKIN LOSS DUE TO BURN (THIRD DEGREE NOS) OF UNSPECIFIED SITE OF HAND – FULL-THICKNESS SKIN LOSS DUE TO BURN (THIRD DEGREE NOS) OF MULTIPLE SITES OF WRIST(S) AND HAND(S)
- 944.40 – 944.48 DEEP NECROSIS OF UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE) OF UNSPECIFIED SITE OF HAND WITHOUT LOSS OF HAND – DEEP NECROSIS OF UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE) OF MULTIPLE SITES OF WRIST(S) AND HAND(S) WITHOUT LOSS OF A BODY PART
- 944.50 – 944.58 DEEP NECROSIS OF UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE) OF UNSPECIFIED SITE OF HAND WITH LOSS OF HAND – DEEP NECROSIS OF UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE) OF MULTIPLE SITES OF WRIST(S) AND HAND(S) WITH LOSS OF A BODY PART
- 945.20 – 945.29 BLISTERS EPIDERMAL LOSS (SECOND DEGREE) OF UNSPECIFIED SITE OF LOWER LIMB (LEG) – BLISTERS WITH EPIDERMAL LOSS DUE TO BURN (SECOND DEGREE) OF MULTIPLE SITES OF LOWER LIMB(S)
- 945.30 – 945.39 FULL-THICKNESS SKIN LOSS DUE TO BURN (THIRD DEGREE NOS) OF UNSPECIFIED SITE OF LOWER LIMB – FULL-THICKNESS SKIN LOSS DUE TO BURN (THIRD DEGREE NOS) OF MULTIPLE SITES OF LOWER LIMB(S)
- 945.40 – 945.49 DEEP NECROSIS OF UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE) OF UNSPECIFIED SITE OF LOWER LIMB (LEG) WITHOUT LOSS OF A BODY PART – DEEP NECROSIS OF UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE) OF MULTIPLE SITES OF LOWER LIMB(S) WITHOUT LOSS OF A BODY PART
- 945.50 – 945.59 DEEP NECROSIS OF UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE) OF UNSPECIFIED SITE LOWER LIMB (LEG) WITH LOSS OF A BODY PART – DEEP NECROSIS OF UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE) OF MULTIPLE SITES OF LOWER LIMB(S) WITH LOSS OF A BODY PART
- 946.0 – 946.5 BURNS OF MULTIPLE SPECIFIED SITES UNSPECIFIED DEGREE – DEEP NECROSIS OF UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE) OF MULTIPLE SPECIFIED SITES WITH LOSS OF A BODY PART

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- 948.00 – 948.99 BURN (ANY DEGREE) INVOLVING LESS THAN 10 PERCENT OF BODY SURFACE WITH THIRD DEGREE BURN OF LESS THAN 10 PERCENT OR UNSPECIFIED AMOUNT – BURN (ANY DEGREE) INVOLVING 90 PERCENT OR MORE OF BODY SURFACE WITH THIRD DEGREE BURN OF 90% OR MORE OF BODY SURFACE
- 949.2 – 949.5 BLISTERS WITH EPIDERMAL LOSS DUE TO BURN (SECOND DEGREE) UNSPECIFIED SITE – DEEP NECROSIS OF UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE UNSPECIFIED SITE WITH LOSS OF A BODY PART

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N/A

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N/A

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N/A

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Documentation supporting the medical necessity should be legible, maintained in the patient's medical record, and must be made available to the Intermediary upon request.

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N/A

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Utilization Guidelines [back to top](#)

The safety and effectiveness of Apligraf® have not been established for patients receiving more than five device applications.

The use of Dermagraft® is limited to no more than 8 applications per treatment site over a 12 week period.

The use of OrCel® is limited to a single, one time application per donor site.

Sources of Information and Basis for Decision [back to top](#)

Falanga V. Care of venous leg ulcers. *Ostomy/Wound Management*. 1999; 45(suppl 1A): 33S-43S.

Falanga V & Sabolinski M. A bilayered living skin construct (APLIGRAF®) accelerates complete closure of hard to heal venous ulcers. *Wound Repair and Regeneration*. 1999; 7:201-207.

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Hanft JR, & Surprenant MS. Healing of chronic foot ulcers in diabetic patients treated with a human fibroblast-derived dermis. *Journal of Foot and Ankle Surgery*. 2002; 41(5): 291-299.

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Pennoyer JW, Susser WS, and Chapman MS. Ulcers associated with polyarteritis nodosa treated with bioengineered skin equivalent (Apligraf). *J Am Acad Dermatol*. 2002 Jan; 46(1):145.

Pollak RA, Edington H, Jensen J, Kroeker RO, Gentzkow GD. Human dermal replacement for the treatment of diabetic foot ulcers. *Wounds*. 1997; 9(6): 175-183.

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Santilli JD & Santilli SM. Chronic critical limb ischemia: Diagnosis, treatment and prognosis. *American Family Physician*. 1999; 59(7):1899–1908.

Dermagraft® human fibroblast–derived dermal substitute; directions for use. [Brochure]. Largo, FL. Smith & Nephew, Inc. Wound Management Division. 2001.

Townsend CM. ed. *Sabiston Textbook of Surgery*. 16th ed. St. Louis, MO. W.B. Sanders; 2001:355–356.

Advisory Committee Meeting Notes [back to top](#)

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the Intermediary, this policy was developed in cooperation with advisory groups, which include representatives from the affected provider community. Advisory Committee Meeting date: 08/04/2003.

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Revision #7, 01/01/2007

Revision #6, 09/13/2006

Revision #5, 01/01/2006

Revision #4, 11/23/2005

Revision #3, 03/01/2005

Revision #2, 11/22/2004

Revision #1, 10/01/2004

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Revision #7, 01/01/2007

Under AMA/CPT & ADA/CDT Copyright Statement changed the copyright date from 2005 to 2006. Under Indications and Limitations of Coverage and/or Medical Necessity, Apligraf deleted verbiage from the third paragraph. Under CPT/HCPCS Codes deleted CPT/HCPCS codes 15000, 15001, C9221, J7350, and added CPT/HCPCS codes 15002, 15003, 15004, 15005, J7345 and J7346. The verbiage was changed for the following CPT codes 15170,15171,15175, 15176, 15360, 15361, 15365, 15366, 15400, 15401, 15420, 15421, 15430, and 15431. This revision becomes effective 01/01/2007.

Revision #6, 09/13/2006

Under CMS National Coverage Policy deleted Change Request 4057. Under Indications and Limitations of Coverage and/or Medical Necessity verbiage revised throughout entire section. Deleted the verbiage on Xenograft. Added information on Integra ® Bilayer Matrix Wound Dressing/ Dermal Regeneration Template. Under Bill Type Codes deleted 75X bill type. Under ICD-9 Codes That Support Medical Necessity added ICD-9 code 709.2. Under Sources of Information and Basis for Decision placed the references in the AMA citation format. Under Advisory Committee Meeting Notes changed "affected providers" to now read "the affected provider community." This revision becomes effective 09/13/2006.

Revision #5, 01/01/2006

Under CMS National Coverage Policy section Change Request 4057 has been added. Under Indications and Limitations of Coverage and/or Medical Necessity section xenograph was added. Under CPT/HCPCS Codes section CPT codes 15170, 15171, 15175, 15176, 15340, 15341, 15360, 15365, 15366, 15400, 15401, 15420, 15421, 15430, 15431, J7341, J7343, J7344, and J7350 were added. These CPT codes were deleted 15342, 15343, C1305, C9123, C9200, and C9201. These changes become effective on 01/01/2006.

Revision #4, 11/23/2005

The name of the policy has been changed from Metabolically Active Dermal Skin Substitute Dressings to Metabolically and Non-Metabolically Active Dermal Skin Substitute Dressings. Under AMA/CPT & ADA/CDT Copyright Statement section the copyright date was changed from 2004 to 2005. Under CMS National Coverage Policy the following citation were deleted as the change request had expired:

Program Memorandum No. A-00-36, Change Request 1229, June 2000, details Hospital Outpatient Prospective Payment System (OPPS) implementation instructions.

Program Memorandum No. B-01-07, Change Request 1521, February 2001, provides billing instructions for Apligraf

Program Memorandum No. B-00-03, Change Request 1196, June 2000, clarifies billing instructions carrier contractors for culture skin graft products, including Apligraf.

Under the Indications and Limitations of Coverage and/or Medical Necessity section of the policy the first sentence was changed to read, "Metabolically and non-metabolically active skin substitute dressings are bioengineered dermal tissues, which contain the characteristics of dermis, or both dermis and epidermis." Description of TransCyte™ and GRAFT JACKET™ was added. Bill types 71x and 73x were added under Bill Type Codes section of the policy. Under

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CPT/HCPCS Codes section of the policy these codes were added: C9123, C9221, J7343, J7344 and J7350. Under ICD-9 Codes That Support Medical Necessity section of the policy, the categories of coverage were removed and the ICD-9 codes were combined to make one set of codes to be applicable with any of the HCPCS/CPT codes billed. Under Sources of Information and Basis for Decision section of the policy the following citation were deleted:

American Diabetes Association – Foot care in patients with diabetes mellitus.

<http://www.aafp.org/afp/990401ap/1899.html>.

University of Pennsylvania School of Medicine. (2000) Venous leg ulcer guideline.

These changes become effective on 11/23/2005.

Revision #3, 02/16/2005

Converted the Local Medical Review Policy (LMRP) to a Local Coverage Determination (LCD). This revision becomes effective 02/17/2005.

Under CMS National Coverage Policy section of the policy added Change Request 3010. Under CPT/HCPCS Codes changed the verbiage for C1305, C9200, and C9201. These changes become effective 03/01/2005.

Revision #2, 11/22/2004

Under AMA/CPT Copyright Statement section of this policy, deleted the reference to CDT-4 copyright language, as this policy does not contain CDT-4 codes or descriptions. This revision becomes effective 11/22/2004.

Revision #1, 10/01/2004

Under AMA/CPT Copyright Statement added the American Dental Association copyright statement. Under CMS National Coverage Policy changed citation for Program Memorandum # B-00-30 from May to June and added Change Request # 1229 and 1196 to previously cited program memorandum. These changes become effective 10/01/2004.

01/29/2005 – The description for CPT/HCPCS code C1305 was changed in group 1

01/29/2005 – The description for CPT/HCPCS code C9200 was changed in group 1

01/29/2005 – The description for CPT/HCPCS code C9201 was changed in group 1

This LCD was converted from an LMRP on 2/16/2005

11/26/2005 – The description for CPT/HCPCS code 15000 was changed in group 1

11/26/2005 – The description for CPT/HCPCS code 15001 was changed in group 1

11/26/2005 – The description for CPT/HCPCS code J7340 was changed in group 1

11/26/2005 – The description for CPT/HCPCS code J7342 was changed in group 1

11/26/2005 – The description for CPT/HCPCS code J7344 was changed in group 1

11/26/2005 – The description for CPT/HCPCS code J7350 was changed in group 1

11/26/2005 – CPT/HCPCS code 15342 was deleted from group 1

General Information

11/26/2005 - CPT/HCPCS code 15343 was deleted from group 1
11/26/2005 - CPT/HCPCS code C1305 was deleted from group 1
11/26/2005 - CPT/HCPCS code C9123 was deleted from group 1
11/26/2005 - CPT/HCPCS code C9200 was deleted from group 1
11/26/2005 - CPT/HCPCS code C9201 was deleted from group 1

11/18/2006 - The description for CPT/HCPCS code 15170 was changed in group 1
11/18/2006 - The description for CPT/HCPCS code 15171 was changed in group 1
11/18/2006 - The description for CPT/HCPCS code 15175 was changed in group 1
11/18/2006 - The description for CPT/HCPCS code 15176 was changed in group 1
11/18/2006 - The description for CPT/HCPCS code 15360 was changed in group 1
11/18/2006 - The description for CPT/HCPCS code 15361 was changed in group 1
11/18/2006 - The description for CPT/HCPCS code 15365 was changed in group 1
11/18/2006 - The description for CPT/HCPCS code 15366 was changed in group 1
11/18/2006 - The description for CPT/HCPCS code 15400 was changed in group 1
11/18/2006 - The description for CPT/HCPCS code 15401 was changed in group 1
11/18/2006 - The description for CPT/HCPCS code 15420 was changed in group 1
11/18/2006 - The description for CPT/HCPCS code 15421 was changed in group 1
11/18/2006 - The description for CPT/HCPCS code 15430 was changed in group 1
11/18/2006 - The description for CPT/HCPCS code 15431 was changed in group 1

11/18/2006 - CPT/HCPCS code 15000 was deleted from group 1
11/18/2006 - CPT/HCPCS code 15001 was deleted from group 1
11/18/2006 - CPT/HCPCS code C9221 was deleted from group 1
11/18/2006 - CPT/HCPCS code J7350 was deleted from group 1

11/10/2007 - CPT/HCPCS code J7345 was deleted from group 1

Reason for Change [back to top](#)

CMS Requirement
HCPCS Addition/Deletion

Last Reviewed On Date [back to top](#)

Related Documents [back to top](#)

This LCD has no Related Documents.

LCD Attachments [back to top](#)

There are no attachments for this LCD.

All Versions [back to top](#)

Retired StampRetired Stamp

Updated on 01/04/2008 with effective dates 12/20/2007 - 01/04/2008

Updated on 12/13/2007 with effective dates 12/20/2007 - N/A

Updated on 12/22/2006 with effective dates 01/01/2007 - 12/19/2007

Updated on 09/08/2006 with effective dates 09/13/2006 - 12/31/2006

Updated on 12/13/2005 with effective dates 01/01/2006 - 09/12/2006

Updated on 12/06/2005 with effective dates 01/01/2006 - N/A

Updated on 10/18/2005 with effective dates 11/23/2005 - 12/31/2005

Updated on 02/16/2005 with effective dates 03/01/2005 - 11/22/2005

Updated on 02/16/2005 with effective dates 02/17/2005 - 02/28/2005

Updated on 02/16/2005 with effective dates 11/22/2004 - 02/16/2005

Updated on 11/22/2004 with effective dates 11/22/2004 - N/A

Updated on 11/17/2004 with effective dates 10/01/2004 - 11/21/2004

Updated on 08/26/2004 with effective dates 10/01/2004 - N/A

Updated on 10/22/2003 with effective dates 09/29/2003 - 09/30/2004

Updated on 09/29/2003 with effective dates 09/29/2003 - N/A

Updated on 09/29/2003 with effective dates 09/29/2003 - N/A

Updated on 09/29/2003 with effective dates 11/12/2003 - N/A

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