

LCD for Skin Substitutes for Wound Healing (L21785)

Retired

Please note: This is a Retired LCD.

Contractor Information

Retired **Retired**

Contractor Name

[Palmetto GBA](#)

Contractor Number

00884

Contractor Type

Carrier

LCD Information

Retired **Retired**

LCD ID Number

L21785

LCD Title

Skin Substitutes for Wound Healing

Contractor's Determination Number

2005-07LR2.1

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CMS National Coverage Policy

Primary Geographic Jurisdiction

West Virginia

Oversight Region

Region V

Original Determination Effective Date

For services performed on or after 04/01/2006

Original Determination Ending Date

01/01/2009

Revision Effective Date

For services performed on or after 08/01/2007

Revision Ending Date

01/01/2009

Indications and Limitations of Coverage and/or Medical Necessity

This LCD is applicable to all skin substitutes, currently available or available at a future date, used as adjunctive treatment devices to assist in wound healing. Substitutes may be developed from human or non-human origin and contain epidermal and/or dermal tissue, with or without other bioengineered or processed elements and metabolically active elements.

Treatment Device Limitations

To meet the HCPCS code descriptions for HCPCS codes J7340, J7341 and J7342, products must contain biologically active elements. Products without biologically active elements and products labeled with indications for venous stasis or neuropathic diabetic ulcers that do NOT contain biologically active elements will be denied as “wound dressings”. Palmetto GBA considers

services for wound dressings included in the wound care service and will not reimburse at a separate rate.

Provider Type Limitations

Skin substitute treatment is limited to physicians, osteopaths, podiatrists, or non-physician practitioners who are skilled and experienced in the treatment of wounds with human skin equivalents.

Wound Type Limitations

Skin substitutes are limited to the following conditions:

- Wounds with an adequate blood supply
- Wounds free of infection
- Wounds that have failed conventional therapy

J7340-Dermal and epidermal(substitute)tissue of human origin, with or without other bioengineered or processed elements with metabolically active elements.

Examples:

1. **Apligraf®**, a bilayered living skin equivalent composed of a dermal layer of bovine collagen/human fibroblasts and epidermal layer of human keratinocytes, is considered medically reasonable and necessary for the following:

- Treatment of full-thickness, neuropathic, diabetic foot ulcers that have failed conservative measures of at least four weeks duration.
- Treatment of partial and full-thickness skin venous insufficiency ulcers present for a minimum of three months duration and have failed conventional treatment for at least eight weeks.

2. **OrCel**, a cellular bovine collagen matrix with human dermal fibroblast and keratinocyte layers, is considered medically reasonable and necessary for use on fresh, clean, split thickness donor site wounds in burn patients.

J7341 - Dermal(substitute)tissue of nonhuman origin, with or without other bioengineered or processed elements with metabolically active elements.

Examples:

1. **Oasis® Wound Matrix**, an acellular, porcine-derived extracellular matrix (ECM), is considered medically reasonable and necessary for the following:

- Treatment of neuropathic diabetic foot ulcers that have failed conservative measures of at least four weeks duration.
- Treatment of partial and full-thickness skin venous insufficiency ulcers present for a minimum of four weeks duration and have failed conventional treatment for at least two weeks.

- Skin substitute used in conjunction with standard wound care regimen.

J7342-Dermal(substitute)tissue of human origin, with or without other bioengineered or processed elements with metabolically active elements.

Examples:

1. **Dermagraft®**, a living dermal equivalent consisting of human fibroblasts on a bioabsorbable mesh, is considered medically reasonable and necessary when the following conditions are met:

- Full-thickness diabetic foot ulcers of greater than six weeks duration
- Ulcer extends through the dermis, but without tendon, muscle, and joint capsule or bone exposure, and without active Charcot's arthropathy.
- Skin substitute used in conjunction with standard wound care regimen.

Coding Information



Bill Type Codes:

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.

Revenue Codes:

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.

99999

Not Applicable

CPT/HCPCS Codes**CPT Codes**

| | |
|-------|-----------------------------|
| J7340 | Metabolic active D/E tissue |
| J7341 | Non-human, metabolic tissue |
| J7342 | Metabolically active tissue |

ICD-9 Codes that Support Medical Necessity

Indicated code use does not guarantee reimbursement. Medical record documentation must meet the policy coverage criteria.

HCPCS code J7340

| | |
|---------------------------------|--|
| 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 |
| 941.20 - 941.59 | BLISTERS WITH EPIDERMAL LOSS DUE TO BURN (SECOND DEGREE) OF FACE AND HEAD UNSPECIFIED SITE - 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 - 942.59 | BLISTERS WITH EPIDERMAL LOSS DUE TO BURN (SECOND DEGREE) OF UNSPECIFIED SITE OF TRUNK - 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 - 943.59 | BLISTERS WITH EPIDERMAL LOSS DUE TO BURN (SECOND DEGREE) OF UNSPECIFIED SITE OF UPPER LIMB - 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 - 944.58](#) BLISTERS WITH EPIDERMAL LOSS DUE TO BURN (SECOND DEGREE) OF UNSPECIFIED SITE 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 - 945.59](#) BLISTERS EPIDERMAL LOSS (SECOND DEGREE) OF UNSPECIFIED SITE OF LOWER LIMB (LEG) - 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
- [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

HCPCS code J7341

- [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
- 459.31 CHRONIC VENOUS HYPERTENSION WITH ULCER
- 459.33 CHRONIC VENOUS HYPERTENSION WITH ULCER AND INFLAMMATION
- [707.00 - 707.09](#) PRESSURE ULCER, UNSPECIFIED SITE - PRESSURE ULCER, OTHER SITE
- [707.12 - 707.15](#) ULCER OF CALF - ULCER OF OTHER PART OF FOOT
- [941.20 - 941.21](#) BLISTERS WITH EPIDERMAL LOSS DUE TO BURN (SECOND DEGREE) OF FACE AND HEAD UNSPECIFIED SITE - 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
- [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

[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

[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)

[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)

946.2 BLISTERS WITH EPIDERMAL LOSS DUE TO BURN (SECOND DEGREE) OF MULTIPLE SPECIFIED SITES

949.2 BLISTERS WITH EPIDERMAL LOSS DUE TO BURN (SECOND DEGREE) UNSPECIFIED SITE

HCPCS code J7342

[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

707.14 ULCER OF HEEL AND MIDFOOT

707.15 ULCER OF OTHER PART OF FOOT

Diagnoses that Support Medical Necessity

ICD-9 Codes that DO NOT Support Medical Necessity

All other ICD-9 codes not listed under "ICD-9 Codes that Support Medical Necessity" will be denied as not medically necessary.

ICD-9 Codes that DO NOT Support Medical Necessity Asterisk Explanation

Diagnoses that DO NOT Support Medical Necessity

General Information



Documentation Requirements

Medical record must indicate medical necessity for each service date submitted.

Documentation must be available to Medicare on request.

Failed conservative treatment documentation must indicate type of unsuccessful wound care such as:

- Enzymatic and/or surgical debridement
- Wet-to-dry dressings
- Infection control
- Non-weight bearing

Failed conservative treatment documentation must indicate type of unsuccessful ulcer healing such as:

- No change
- Increase in size
- Increase in depth
- No healthy granulation
- No signs or progress toward healing.

Appendices

Utilization Guidelines

Services performed for excessive frequency are not medically necessary. Frequency is considered excessive when services are performed more frequently than generally accepted by peers, safety and efficacy established by current literature, and the reason for additional services is not justified by documentation.

- Apligraf® is limited to five (5) applications.
- Dermagraft® is limited to 8 applications per treatment site over a 12 week period.

Repeated applications without signs of improvement or exceeds the recommended frequency per manufacturer's labeling instructions are not medically necessary.

Sources of Information and Basis for Decision

The development and coverage guidelines in this policy were based on a review of pertinent medical literature, policies from other Medicare contractors, and discussions with appropriate specialists.

Brem H et al. Healing of Venous Ulcers of Long Duration with a Bilayered Living Skin Substitute: Results From a General Surgery and Dermatology Department. *Dermatol Surg* 2001; 27(11):915-9.

Brigido SA et al. Effective Management of Major Lower Extremity Wounds Using an Acellular Regenerative Tissue Matrix: a Pilot Study. *Orthopedics* 2004; 27(1 Suppl):s145-9.

Chang DW et al. Can a Tissue-Engineered Skin Graft Improve Healing of Lower Extremity Foot Wounds After Revascularization. *Ann Vasc Surg* 2000;14(1):44-9.

Eaglstein W. A Composite Skin Substitute (Graftskin) for Surgical Wounds. A Clinical Experience. *Dermatol Surg* 1995; 21(10):839-43.

Falanga V et al. A Bilayered Living Skin Construct (APLIGRAF) Accelerates Complete Closure of Hard to Heal Venous Ulcers. *Wound Repair Regen* 1999; 7(4):201-7.

Gentzkow G et al. Use of Dermagraft, a Cultured Human Dermis, to Treat Diabetic Foot Ulcers. *Diabetes Care* 1996; 19(4):350-4.

Gentzkow GD, et al. Improved Healing of Diabetic Foot Ulcers After Grafting with a Living Human Dermal Replacement. *Wounds: A Compendium of Clinical Research and Practice* 1999; 11(3):77-84.

Hanft J et al. Healing of Chronic Foot Ulcers in Diabetic Patients Treated with a Human Fibroblast Derived Dermis. *J Foot Ankle Surg* 2002; 41(5):291-9.

Hodde JP, et al. An investigation of the long-term bioactivity of endogenous growth factor in Oasis Wound Matrix. *J Wound Care* 2005; 14:23-25.

Sabolinski M. Cultured Skin as a 'Smart Material' for Healing Wounds: Experience in Venous Ulcers. *Biomaterials* 1996 Feb; 17(3):311-20.

Advisory Committee Meeting Notes

This policy does not reflect the sole opinion of the contractor or the contractor medical director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which include representatives from podiatry, dermatology and general surgery.

West Virginia Meeting: 04/11/2007

Start Date of Comment Period

04/11/2007

End Date of Comment Period

05/26/2007

Start Date of Notice Period

06/15/2007

Revision History Number

2005-07LR2.1

Revision History Explanation

Revision Policy Number: 2005-07LR2.1 (08/2007 Medicare Advisory)

Revision Effective Date: Services performed on or after effective date of revised policy.

Revision Made: Changes made to the DRAFT policy include addition of HCPCS code J7341 with ICD-9 codes as supporting medical necessity 250.80 – 250.83, 454.0, 454.2, 459.31, 459.33, 707.00-707.09, 707.12-707.15, 941.20-941.21, 941.24-941.29, 942.20-942.29, 943.20-943.29, 944.20-944.28, 945.20-945.29, 946.2 and 949.2.

Revision Policy Number: 2005-07LR2 (05/2007 Medicare Advisory)

Revision Effective Date: Services performed on or after effective date of revised policy.

Revision Made: Language added to *Indications and Limitations* section indicating non-coverage for any wound treatment that does not meet the definition of either HCPCS code J7340 or J7342.

Revised policy taken back to CAC for comment & notice 04/11/2007.

Revision Policy Number: 2005-07LR1 (04/2006 Medicare Advisory)

Revision Effective Date: Services performed on or after 04/01/2006

Revision Made: Consolidate policy with SC to provide consistency across all jurisdictions; removal of ICD-9 codes 947.0 - 947.9 under HCPCS code J7340.

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

Original Policy - CAC Meeting: 12/07/2005

Revised Policy - CAC Meeting: 04/11/2007

Original Policy Effective Date: 04/01/2006

Revised Policy Effective Date: 08/01/2007

Rev. 04/06, 05/07, 08/07

08/10/2008 - This policy was updated by the ICD-9 2008-2009 Annual Update.

Revision Policy Number: 2005-07LR2.1 (January 2009 Medicare Advisory)

Revision Effective Date: 01/01/2009

Revision Made: Retired due to deletion of HCPCS codes J7340, J7341, and J7342 per 2009 Annual CPT Update.

Reason for Change

Last Reviewed On Date

08/01/2007

Related Documents

Article(s)

[A44201 - Skin Substitutes for Wound Healing](#)

LCD Attachments

There are no attachments for this LCD.

All Versions



Updated on 01/01/2009 with effective dates 08/01/2007 - 01/01/2009

[Updated on 09/13/2007 with effective dates 08/01/2007 - N/A](#)

[Updated on 08/06/2007 with effective dates 08/01/2007 - N/A](#)

[Updated on 04/06/2006 with effective dates 04/01/2006 - N/A](#)