

LCD for Application of Bioengineered Skin Substitutes: Ulcers (of Lower Extremities) (L27687)

Contractor Information

Contractor Name

Palmetto GBA

Contractor Number

01202

Contractor Type

MAC - Part B

LCD Information

LCD ID Number

L27687

LCD Title

Application of Bioengineered Skin Substitutes: Ulcers (of Lower Extremities)

Contractor's Determination Number

J1B-08-0009-L

AMA CPT / ADA CDT Copyright Statement

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CMS National Coverage Policy

Title XVIII of the Social Security Act, Section 1862(a)(1)(A) allows coverage and payment for only those services that are considered to be medically reasonable and necessary.

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

Primary Geographic Jurisdiction

American Samoa

Guam

Hawaii

Northern Mariana Islands

Oversight Region

LCD Information

LCD ID Number

Region I

Original Determination Effective Date

For services performed on or after 08/04/2008

Original Determination Ending Date

Revision Effective Date

For services performed on or after 08/04/2008

Revision Ending Date

Indications and Limitations of Coverage and/or Medical Necessity

Application of Bioengineered Skin Substitutes will be covered when the following conditions are met and documented **as appropriate for the individual patient:**

1. Presence of neuropathic diabetic foot ulcers for greater than four (4) weeks duration
2. Presence of venous stasis ulcers of greater than three (3) months duration which have failed to respond to documented conservative measures for greater than two (2) months duration
3. Neuropathic diabetic foot ulcers that have failed to respond to documented conservative measures for greater than one (1) month duration
4. Presence of partial or full-thickness ulcers
5. There **must** be measurements of the initial ulcer size, the size following cessation of conservative management and the size at the beginning of skin substitute treatment.
6. For neuropathic diabetic foot ulcers, appropriate steps to off-load pressure during treatment must be taken.

In addition, the ulcer must be free of infection and underlying osteomyelitis. Following successful treatment of either of these underlying diseases/conditions, documentation must be provided to that effect prior to instituting skin substitute treatment.

Limitations of coverage are as follows:

1. Use of the skin substitute is limited to three (3) separate applications to any given ulcer, or more **only** when utilized with adherence to specific FDA labeling instructions and criteria.

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2. Absent specific medical record documentation of the reasons for more frequent application, there should be no fewer than two (2) weeks between applications for venous stasis ulcers and there should be no fewer than three (3) weeks between applications for neuropathic diabetic foot ulcers, except when more frequent applications are part of the FDA labeling instructions.
3. Treatment of any ulcer will typically last no more than twelve (12) weeks.
4. For venous stasis ulcers, two (2) applications of the skin substitute are indicated, or more only if provided for in the FDA labeling. If after twelve (12) weeks of compression treatment, and the appropriate number of applications of the skin substitute, a 50 percent or greater improvement is noted and documented, then one or more subsequent re-applications of the skin substitute will be considered for Medicare coverage. Otherwise, re-application of the skin substitute is not recommended and will not be reimbursed; and other treatment modalities should be considered.
5. Re-treatment within one (1) year of completion of any given course of skin substitute for venous stasis ulcers is not covered.
6. For neuropathic diabetic foot ulcers, if after nine (9) weeks of treatment, and three (3) applications of the skin substitute, satisfactory healing progress is not noted, then reapplication of the skin substitute is not recommended and other treatment modalities should be considered.
- 7. Providers are urged to note that coverage will not be provided under this LCD for any wound treatment that does not meet the definition of J7340, J7341 or J7342. All other such products, unless they are FDA-labeled for use in the types of ulcers considered in this LCD will be considered to be, at most, "biologic wound dressings" and will be considered to be part of the relevant E/M service provided, and not separately payable. Therefore, the following HCPCS codes are not separately payable: J7343, J7344, J7346, J7347, J7348 and J7349.**

Furthermore, even in those instances where the labeled indications include venous stasis or neuropathic diabetic ulcers, if the product is not biologically active, as noted in the CPT descriptors for J7340, J7341 and J7342, it will still be considered as not covered under the terms of this LCD. As examples of such non-covered "wound dressing" products Biovance™ (Biovance™ is described in its FDA-labeling as "wound covering") and Integra™ are considered wound dressings, not skin substitutes, and are not separately payable by Medicare. Use of these products is included within the appropriate level of E/M service, and to code as "skin substitutes" would be inappropriate coding.

If a specific HCPCS code is assigned to these products and as literature concerning their use sufficiently matures, this A/B MAC will welcome requests for reconsideration of this coverage decision. However, these requests for reconsideration must be submitted as formal reconsideration requests (See www.PalmettoGBA.com/J1 for the reconsideration process.) and must be accompanied by complete copies of relevant peer-reviewed literature that support the recommendation as well as complete copies of FDA labeling for their uses (providers are reminded that abstracts are not acceptable - by Medicare rule - for this purpose).

8. Providers are also reminded that this LCD does not purport to cover use of any skin substitutes or related products in the treatment of burns. This statement is intended to include the list of CPT codes used primarily in burn treatment, which remains outside the purview of this LCD.

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The only reason the burn code treatments and range of burn diagnoses are mentioned in this policy is due to the fact that HCPCS 2007 has included in its description of J7340 the direction, "Use this code for Apligraf, Orcel, TransCyte™." It appears that currently the only labeled use of the TransCyte™ product is in burn wound treatment. Given that, as noted above, the primary thrust of this LCD is toward the use of skin substitute products in ulcers and given that we have not experienced significant mis-use of the TransCyte™ product or similar burn treatment products, this A/B MAC includes the use of TransCyte™ and other similar burn treatments in this LCD only to the extent that we indicate coverage is available when medically reasonable and necessary in the treatment of burns and when used consistent with FDA labeling. This LCD does not cover any other aspect of these burn treatment products, nor are any other criteria for the burn uses of these products subject to this policy. Once again, providers are reminded that requirements for use according to FDA labeling and for medical reasonableness and necessity apply. If circumstances in the future warrant LCD consideration of these products and their uses, this A/B MAC will consider establishing a LCD specific to them.

9. In most instances, consistent with FDA product labeling, which limits the use of these products to clean wounds, CPT code 15002 and 15004 are not appropriate (CPT 15002-15005 are listed below in the "CPT/HCPCS" section of this LCD, primarily for information only). Minimal wound preparation is considered a part of the procedure. Providers are reminded that CPT 2007 language in the introductory comments to the "Skin Replacement Surgery and Skin Substitutes" chapter reconfirms this position in stating, "Identify by size" and the type of graft or skin substitute; **includes simple debridement of granulation tissue or recent avulsion.**" (emphasis this A/B MAC) When more substantial debridement is felt to be warranted, consider use of one of the superficial debridement codes (11040-11042). In either instance, the medical record documentation must clearly support that any amount of debridement was medically reasonable and necessary. Bear in mind that the literature clearly demonstrates that development on as often as a weekly basis of necrosis significant enough to warrant debridement strongly suggests that vascularity is insufficient to allow wound healing, even with the use of skin substitute therapy. Furthermore, this A/B MAC considers the CPT debridement codes to be appropriate for use only by Physicians or NPPs (with the exception of the Physical Therapy debridement codes). Billing for "debridement" performed during routine dressing changes in the course of treatments as contemplated in this LCD is **not** appropriate. Debridement carried out by a Physical Therapist **must** be done within a program of care authorized and closely supervised by the treating Physician.

If at any time procedures are billed and inadvertently paid, providers are reminded that, with special reference to this set of codes and due especially to the program experience of significant misuse of these products:

Compliance with the provisions in this policy is subject to monitoring by active and ongoing post payment data analysis and subsequent medical review.

10. Providers are reminded that the use of otherwise payable codes must be consistent with State licensure and scope of practice limitations.

For J7340:

For any product used in ulcer treatment and appropriately billed under this code, the FDA labeling instructions - including at least the criteria, frequency and acceptable duration of treatment - must be followed and documentation of same must be included in the medical record.

For J7341 (Oasis®):

LCD Information

LCD ID Number

Circumstances involving Oasis® have changed since the previous publication of this LCD. The FDA labeling has removed the phrase “wound dressing” from the product description. In addition, clinical experience and emerging clinical literature have combined to convince this A/B MAC that this product can be of significant benefit in the comprehensive treatment of ulcers as contemplated by this policy. Therefore, so long as the product is used according to FDA labeling instructions and good medical practice, it will be covered. Providers should note, however, that the product has been valued according to a 90-day global period under the Physician Fee Schedule. Therefore, the application code will be paid no more frequently than at 90-day intervals. It will be incorrect coding and subject to post-pay review if multiple claims for this code are billed within a 90-day period with such modifiers as -58, suggesting a staged procedure. The product, however, will be reimbursed at a frequency appropriate to the clinical considerations.

Furthermore, since Oasis® application is considered a physician service, it must be applied by either a physician or a non-physician provider (NPP), and **NOT** by non-advance practice nurses, therapists or medical assistants.

In addition, due to marked propensity for mis-use of the entire range of “Skin Substitute” products, after the effective date of this policy update, this A/B MAC will pay **only** when the medical record clearly documents that these products have been used in a comprehensive, organized wound management program, either office- or clinic-based.

Note: CPT codes 15430 and 15431 are to be used under the terms of this LCD **only** with HCPCS code J7341.

For J7342:

Assuming this product re-enters the marketplace following the re-publication of this LCD in 2007, it will be covered for the treatment of full-thickness diabetic foot ulcers greater than six weeks duration which extend through the dermis, but without tendon, muscle, joint capsule or bone exposure. This product **must** be used in conjunction with standard wound care regimens and in patients who have adequate blood supply to the involved foot.

This A/B MAC will cover a maximum of 8 applications of J7342 for the treatment of any given lesion. In addition, the medical record must clearly document that conservative pre-treatment wound management has been tried and failed to induce healing. Also, when used for billing of Dermagraft®, the record must document that the **twenty-four (24) steps** involved in the correct use of this product, as described in the clinical trials leading to FDA approval and included in the manufacturer's "Directions for Use" have been followed. The provider must take notice of these specific instructions for use. They will **not** be listed in this policy.

For J7346:

This describes injectable dermal tissue, **not** considered under this LCD to be a "skin substitute," thus not a part of this policy. Though it appears the J-code could be considered payable, based on information received, this A/B MAC has not been able to determine that there is an appropriate CPT code to acknowledge the work involved in injecting this material. We have determined that it will be considered part of the E/M service.

NOTE: CPT codes 15002, 15003, 15004, 15005, 15170, 15171, 15175, 15176, and HCPCS codes J7343, J7344, J7346, J7347, J7348, J7349 are not covered under the terms of this LCD. They are listed below for information only.

Compliance with the provisions in this policy is subject to monitoring by post payment data analysis and subsequent medical review.

LCD Information

LCD ID Number

Coverage Topic

Supplies
Surgical Services

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.

999x Not Applicable

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

Note: CPT codes 15430 and 15431 are to be used under the terms of this LCD only with HCPCS code J7341.

15002

SURGICAL PREPARATION OR CREATION OF RECIPIENT SITE BY EXCISION OF OPEN WOUNDS, BURN ESCHAR, OR SCAR (INCLUDING SUBCUTANEOUS TISSUES), OR INCISIONAL RELEASE OF SCAR CONTRACTURE, TRUNK, ARMS, LEGS; FIRST 100 SQ CM OR 1% OF BODY AREA OF INFANTS AND CHILDREN

15003

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.

	SURGICAL PREPARATION OR CREATION OF RECIPIENT SITE BY EXCISION OF OPEN WOUNDS, BURN ESCHAR, OR SCAR (INCLUDING SUBCUTANEOUS TISSUES), OR INCISIONAL RELEASE OF SCAR CONTRACTURE, TRUNK, ARMS, LEGS; EACH ADDITIONAL 100 SQ CM OR EACH ADDITIONAL 1% OF BODY AREA OF INFANTS AND CHILDREN (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
15004	SURGICAL PREPARATION OR CREATION OF RECIPIENT SITE BY EXCISION OF OPEN WOUNDS, BURN ESCHAR, OR SCAR (INCLUDING SUBCUTANEOUS TISSUES), OR INCISIONAL RELEASE OF SCAR CONTRACTURE, FACE, SCALP, EYELIDS, MOUTH, NECK, EARS, ORBITS, GENITALIA, HANDS, FEET AND/OR MULTIPLE DIGITS; FIRST 100 SQ CM OR 1% OF BODY AREA OF INFANTS AND CHILDREN
15005	SURGICAL PREPARATION OR CREATION OF RECIPIENT SITE BY EXCISION OF OPEN WOUNDS, BURN ESCHAR, OR SCAR (INCLUDING SUBCUTANEOUS TISSUES), OR INCISIONAL RELEASE OF SCAR CONTRACTURE, FACE, SCALP, EYELIDS, MOUTH, NECK, EARS, ORBITS, GENITALIA, HANDS, FEET AND/OR MULTIPLE DIGITS; EACH ADDITIONAL 100 SQ CM OR EACH ADDITIONAL 1% OF BODY AREA OF INFANTS AND CHILDREN (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
15170	ACELLULAR DERMAL REPLACEMENT, TRUNK, ARMS, LEGS; FIRST 100 SQ CM OR LESS, OR 1% OF BODY AREA OF INFANTS AND CHILDREN
15171	ACELLULAR DERMAL REPLACEMENT, TRUNK, ARMS, LEGS; EACH ADDITIONAL 100 SQ CM, OR EACH ADDITIONAL 1% OF BODY AREA OF INFANTS AND CHILDREN, OR PART THEREOF (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
15175	

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.

	ACELLULAR DERMAL REPLACEMENT, FACE, SCALP, EYELIDS, MOUTH, NECK, EARS, ORBITS, GENITALIA, HANDS, FEET, AND/OR MULTIPLE DIGITS; FIRST 100 SQ CM OR LESS, OR 1% OF BODY AREA OF INFANTS AND CHILDREN
15176	ACELLULAR DERMAL REPLACEMENT, FACE, SCALP, EYELIDS, MOUTH, NECK, EARS, ORBITS, GENITALIA, HANDS, FEET, AND/OR MULTIPLE DIGITS; EACH ADDITIONAL 100 SQ CM, OR EACH ADDITIONAL 1% OF BODY AREA OF INFANTS AND CHILDREN, OR PART THEREOF (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
15340	TISSUE CULTURED ALLOGENEIC SKIN SUBSTITUTE; FIRST 25 SQ CM OR LESS
15341	TISSUE CULTURED ALLOGENEIC SKIN SUBSTITUTE; EACH ADDITIONAL 25 SQ CM
15360	TISSUE CULTURED ALLOGENEIC DERMAL SUBSTITUTE, TRUNK, ARMS, LEGS; FIRST 100 SQ CM OR LESS, OR 1% OF BODY AREA OF INFANTS AND CHILDREN
15361	TISSUE CULTURED ALLOGENEIC DERMAL SUBSTITUTE, TRUNK, ARMS, LEGS; EACH ADDITIONAL 100 SQ CM, OR EACH ADDITIONAL 1% OF BODY AREA OF INFANTS AND CHILDREN, OR PART THEREOF (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
15365	TISSUE CULTURED ALLOGENEIC DERMAL SUBSTITUTE, FACE, SCALP, EYELIDS, MOUTH, NECK, EARS, ORBITS, GENITALIA, HANDS, FEET, AND/OR MULTIPLE DIGITS; FIRST 100 SQ CM OR LESS, OR 1% OF BODY AREA OF INFANTS AND CHILDREN
15366	TISSUE CULTURED ALLOGENEIC DERMAL SUBSTITUTE, FACE, SCALP, EYELIDS, MOUTH, NECK, EARS, ORBITS, GENITALIA, HANDS, FEET, AND/OR MULTIPLE DIGITS; EACH ADDITIONAL 100 SQ CM, OR EACH ADDITIONAL 1% OF BODY AREA OF INFANTS AND CHILDREN, OR PART THEREOF (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)

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.

15430	ACELLULAR XENOGRAFT IMPLANT; FIRST 100 SQ CM OR LESS, OR 1% OF BODY AREA OF INFANTS AND CHILDREN
15431	ACELLULAR XENOGRAFT IMPLANT; EACH ADDITIONAL 100 SQ CM, OR EACH ADDITIONAL 1% OF BODY AREA OF INFANTS AND CHILDREN, OR PART THEREOF (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
J7340	DERMAL AND EPIDERMAL, (SUBSTITUTE) TISSUE OF HUMAN ORIGIN, WITH OR WITHOUT BIOENGINEERED OR PROCESSED ELEMENTS, WITH METABOLICALLY ACTIVE ELEMENTS, PER SQUARE CENTIMETER
J7341	DERMAL (SUBSTITUTE) TISSUE OF NON-HUMAN ORIGIN, WITH OR WITHOUT OTHER BIOENGINEERED OR PROCESSED ELEMENTS, WITH METABOLICALLY ACTIVE ELEMENTS, PER SQUARE CENTIMETER
J7342	DERMAL (SUBSTITUTE) TISSUE OF HUMAN ORIGIN, WITH OR WITHOUT OTHER BIOENGINEERED OR PROCESSED ELEMENTS, WITH METABOLICALLY ACTIVE ELEMENTS, PER SQUARE CENTIMETER
J7343	DERMAL AND EPIDERMAL, (SUBSTITUTE) TISSUE OF NON-HUMAN ORIGIN, WITH OR WITHOUT OTHER BIOENGINEERED OR PROCESSED ELEMENTS, WITHOUT METABOLICALLY ACTIVE ELEMENTS, PER SQUARE CENTIMETER
J7344	DERMAL (SUBSTITUTE) TISSUE OF HUMAN ORIGIN, WITH OR WITHOUT OTHER BIOENGINEERED OR PROCESSED ELEMENTS, WITHOUT METABOLICALLY ACTIVE ELEMENTS, PER SQUARE CENTIMETER
J7346	DERMAL (SUBSTITUTE) TISSUE OF HUMAN ORIGIN, INJECTABLE, WITH OR WITHOUT OTHER BIOENGINEERED OR PROCESSED ELEMENTS, BUT WITHOUT METABOLICALLY ACTIVE ELEMENTS, 1 CC
J7347	

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.

DERMAL (SUBSTITUTE) TISSUE OF
NONHUMAN ORIGIN, WITH OR WITHOUT
OTHER BIOENGINEERED OR PROCESSED
ELEMENTS, WITHOUT METABOLICALLY
ACTIVE ELEMENTS (INTEGRA MATRIX), PER
SQUARE CENTIMETER

J7348

DERMAL (SUBSTITUTE) TISSUE OF
NONHUMAN ORIGIN, WITH OR WITHOUT
OTHER BIOENGINEERED OR PROCESSED
ELEMENTS, WITHOUT METABOLICALLY
ACTIVE ELEMENTS (TISSUEMEND), PER
SQUARE CENTIMETER

J7349

DERMAL (SUBSTITUTE) TISSUE OF
NONHUMAN ORIGIN, WITH OR WITHOUT
OTHER BIOENGINEERED OR PROCESSED
ELEMENTS, WITHOUT METABOLICALLY
ACTIVE ELEMENTS (PRIMATRIX), PER
SQUARE CENTIMETER

ICD-9 Codes that Support Medical Necessity

These are the only ICD-9-CM codes that support medical necessity:

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.

Note: For the procedures covered by this LCD, apply the appropriate ICD-9-CM code for both the CPT code (15340, 15341, 15360, 15361, 15465, 15366) as well as the appropriate product (designated by J7340, J7341 or J7342).

Note: Diagnosis criteria **do not apply** to the following CPT/HCPCS codes per this LCD: 15002, 15003, 15004, 15005, 15170, 15171, 15175, 15176, 15430, 15431, J7343, J7344, J7346, J7347, J7348, and J7349. These codes are listed for information only, as their use is not payable under this LCD, nor is appropriate use in such areas as burn and trauma care intended to be governed by the limitations in this LCD.

Group 1

For 15340, 15341, 15360, 15361, 15365 and 15366:

The following ICD-9-CM codes may be used alone:

454.0	VARICOSE VEINS OF LOWER EXTREMITIES WITH ULCER
454.2	VARICOSE VEINS OF LOWER EXTREMITIES WITH ULCER AND INFLAMMATION

Group 2

For 15340, 15341, 15360, 15361, 15365 and 15366:

The following ICD-9-CM codes must be used in pairs, i.e., one primary diagnosis and one secondary diagnosis.

Primary diagnoses:

707.10*	UNSPECIFIED ULCER OF LOWER LIMB
707.11*	ULCER OF THIGH
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
707.19*	ULCER OF OTHER PART OF LOWER LIMB

*Consistent with FDA labeling, this A/B MAC intends to limit the use of this product to lower limb ulcers caused by varicose veins or diabetes. When billing for ulcers caused by diabetes, the provider must use both a code from the diabetes range (250.60-250.83) and a code from the ulcer of lower limb range (707.10-707.19).

For 15340, 15341, 15360, 15361, 15365 and 15366:

Secondary diagnoses:

250.60*	DIABETES WITH NEUROLOGICAL MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
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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.

250.61*	DIABETES WITH NEUROLOGICAL MANIFESTATIONS, TYPE I [JUVENILE TYPE], NOT STATED AS UNCONTROLLED
250.62*	DIABETES WITH NEUROLOGICAL MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
250.63*	DIABETES WITH NEUROLOGICAL MANIFESTATIONS, TYPE I [JUVENILE TYPE], UNCONTROLLED
250.70*	DIABETES WITH PERIPHERAL CIRCULATORY DISORDERS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
250.71*	DIABETES WITH PERIPHERAL CIRCULATORY DISORDERS, TYPE I [JUVENILE TYPE], NOT STATED AS UNCONTROLLED
250.72*	DIABETES WITH PERIPHERAL CIRCULATORY DISORDERS, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
250.73*	DIABETES WITH PERIPHERAL CIRCULATORY DISORDERS, TYPE I [JUVENILE TYPE], UNCONTROLLED
250.80*	DIABETES WITH OTHER SPECIFIED MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
250.81*	DIABETES WITH OTHER SPECIFIED MANIFESTATIONS, TYPE I [JUVENILE TYPE], NOT STATED AS UNCONTROLLED
250.82*	DIABETES WITH OTHER SPECIFIED MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
250.83*	DIABETES WITH OTHER SPECIFIED MANIFESTATIONS, TYPE I [JUVENILE TYPE], UNCONTROLLED

*Consistent with FDA labeling, this A/B MAC intends to limit the use of this product to lower limb ulcers caused by varicose veins or diabetes. When billing for ulcers caused by diabetes, the provider must use both a code from the diabetes range (250.60-250.83) and a code from the ulcer of lower limb range (707.10-707.19).

Group 3

For J7340, J7341:

The following ICD-9-CM codes may be used alone:

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.

454.0	VARICOSE VEINS OF LOWER EXTREMITIES WITH ULCER
454.2	VARICOSE VEINS OF LOWER EXTREMITIES WITH ULCER AND INFLAMMATION
940.0 - 949.5*	CHEMICAL BURN OF EYELIDS AND PERIOCCULAR AREA - DEEP NECROSIS OF UNDERLYING TISSUES DUE TO BURN (DEEP THIRD DEGREE UNSPECIFIED SITE WITH LOSS OF A BODY PART

* 940.0-949.5 to be used only for TransCyte™, OrCel™ and other similar products when used in burn treatment when such use is medically reasonable and necessary and consistent with FDA labeling. These two products are listed in this LCD only because they are identified in HCPCS 2007 as included under the description of J7340.

Group 4

For J7340, J7341:

The following ICD-9-CM codes must be used in pairs, i.e., one primary diagnosis and one secondary diagnosis.

Primary diagnoses:

707.10*	UNSPECIFIED ULCER OF LOWER LIMB
707.11*	ULCER OF THIGH
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
707.19*	ULCER OF OTHER PART OF LOWER LIMB

*Consistent with FDA labeling, this A/B MAC intends to limit the use of this product to lower limb ulcers caused by varicose veins or diabetes. When billing for ulcers caused by diabetes, the provider must use both a code from the diabetes range (250.60-250.83) and a code from the ulcer of lower limb range (707.10-707.19).

For J7340, J7341:

Secondary diagnoses:

250.60*	DIABETES WITH NEUROLOGICAL MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
250.61*	DIABETES WITH NEUROLOGICAL MANIFESTATIONS, TYPE I [JUVENILE TYPE], NOT STATED AS UNCONTROLLED

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.

250.62*	DIABETES WITH NEUROLOGICAL MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
250.63*	DIABETES WITH NEUROLOGICAL MANIFESTATIONS, TYPE I [JUVENILE TYPE], UNCONTROLLED
250.70*	DIABETES WITH PERIPHERAL CIRCULATORY DISORDERS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
250.71*	DIABETES WITH PERIPHERAL CIRCULATORY DISORDERS, TYPE I [JUVENILE TYPE], NOT STATED AS UNCONTROLLED
250.72*	DIABETES WITH PERIPHERAL CIRCULATORY DISORDERS, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
250.73*	DIABETES WITH PERIPHERAL CIRCULATORY DISORDERS, TYPE I [JUVENILE TYPE], UNCONTROLLED
250.80*	DIABETES WITH OTHER SPECIFIED MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
250.81*	DIABETES WITH OTHER SPECIFIED MANIFESTATIONS, TYPE I [JUVENILE TYPE], NOT STATED AS UNCONTROLLED
250.82*	DIABETES WITH OTHER SPECIFIED MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
250.83*	DIABETES WITH OTHER SPECIFIED MANIFESTATIONS, TYPE I [JUVENILE TYPE], UNCONTROLLED

*Consistent with FDA labeling, this A/B MAC intends to limit the use of this product to lower limb ulcers caused by varicose veins or diabetes. When billing for ulcers caused by diabetes, the provider must use both a code from the diabetes range (250.60-250.83) and a code from the ulcer of lower limb range (707.10-707.19).

Group 5

For J7342:

The following ICD-9-CM code may be used alone:

757.39*	OTHER SPECIFIED CONGENITAL ANOMALIES OF SKIN
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*ICD-9-CM code 757.39 may be used only for epidermolysis bullosa

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.

Group 6

For J7342:

The following ICD-9-CM codes must be used in pairs, i.e., one primary diagnosis and one secondary diagnosis.

Primary diagnoses:

707.10*	UNSPECIFIED ULCER OF LOWER LIMB
707.11*	ULCER OF THIGH
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
707.19*	ULCER OF OTHER PART OF LOWER LIMB

*Consistent with FDA labeling, this A/B MAC intends to limit the use of this product to lower limb ulcers caused by varicose veins or diabetes. When billing for ulcers caused by diabetes, the provider must use both a code from the diabetes range (250.60-250.83) and a code from the ulcer of lower limb range (707.10-707.19).

For J7342:

Secondary diagnoses:

250.60*	DIABETES WITH NEUROLOGICAL MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
250.61*	DIABETES WITH NEUROLOGICAL MANIFESTATIONS, TYPE I [JUVENILE TYPE], NOT STATED AS UNCONTROLLED
250.62*	DIABETES WITH NEUROLOGICAL MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
250.63*	DIABETES WITH NEUROLOGICAL MANIFESTATIONS, TYPE I [JUVENILE TYPE], UNCONTROLLED
250.70*	DIABETES WITH PERIPHERAL CIRCULATORY DISORDERS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
250.71*	

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.

	DIABETES WITH PERIPHERAL CIRCULATORY DISORDERS, TYPE I [JUVENILE TYPE], NOT STATED AS UNCONTROLLED
250.72*	DIABETES WITH PERIPHERAL CIRCULATORY DISORDERS, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
250.73*	DIABETES WITH PERIPHERAL CIRCULATORY DISORDERS, TYPE I [JUVENILE TYPE], UNCONTROLLED
250.80*	DIABETES WITH OTHER SPECIFIED MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, NOT STATED AS UNCONTROLLED
250.81*	DIABETES WITH OTHER SPECIFIED MANIFESTATIONS, TYPE I [JUVENILE TYPE], NOT STATED AS UNCONTROLLED
250.82*	DIABETES WITH OTHER SPECIFIED MANIFESTATIONS, TYPE II OR UNSPECIFIED TYPE, UNCONTROLLED
250.83*	DIABETES WITH OTHER SPECIFIED MANIFESTATIONS, TYPE I [JUVENILE TYPE], UNCONTROLLED

***Consistent with FDA labeling, this A/B MAC intends to limit the use of this product to lower limb ulcers caused by varicose veins or diabetes. When billing for ulcers caused by diabetes, the provider must use both a code from the diabetes range (250.60-250.83) and a code from the ulcer of lower limb range (707.10-707.19).**

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.

Diagnoses that Support Medical Necessity

All ICD-9-CM codes listed under ICD-9-CM Codes That Support Medical Necessity above.

ICD-9 Codes that DO NOT Support Medical Necessity

All ICD-9-CM codes not listed under ICD-9-CM Codes That Support Medical Necessity above.

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

Diagnoses that DO NOT Support Medical Necessity

All ICD-9-CM codes not listed under ICD-9-CM Codes That Support Medical Necessity above, including but not limited to the following:

1. Infected ulcer
2. Osteomyelitis
3. Allergy to bovine collagen
4. Neuropathic diabetic foot ulcers without pedal pulses
5. Uncontrolled diabetes ("controlled" diabetes for purposes of this policy would be based on documentation in the medical record)
6. Active charcot arthropathy of the ulcer extremity
7. Vasculitis
8. Uncontrolled rheumatoid arthritis and/or rheumatoid ulcers
9. Other uncontrolled collagen vascular disease
10. Patients being treated with high dose corticosteroids or immunosuppressants (This A/B MAC considers the definition of "high dose" to be a medical determination based on medical record documentation and to be outside the purview of this LCD, so we do not set a dose limit.)
11. Patients who have undergone radiation and/or chemotherapy within the month immediately preceding proposed skin substitute treatment.

General Information

Documentation Requirements

The medical record must clearly show that the criteria listed in Indications and Limitation of Coverage and/or Medical Necessity section have been met. The ulcer must be measured at the beginning of conservative treatment, following cessation of conservative treatment and at the beginning of the skin substitute treatment. Clearly, if during treatment the ulcer shows obvious signs of worsening or lack of treatment response, continuing skin substitute treatment would be considered questionable absent documentation of a reasonable rationale for doing so.

General Information

Documentation Requirements

Studies have documented that, for J7342, survival of the dermal substitute decreases significantly when the 24 steps noted in the FDA labeling are not followed. The documentation must show that these 24 steps were followed.

This A/B MAC will cover a maximum of 8 applications of J7342 for the treatment of any given lesion. In addition, the medical record must clearly document that conservative pre-treatment wound management has been tried and failed to induce healing. Also, when used for billing of Dermagraft®, the record must document that the **twenty-four (24) steps** involved in the correct use of this product, as described in the clinical trials leading to FDA approval and included in the manufacturer's "Directions for Use" as of the date of development of this LCD have been followed. The provider must take notice of these specific instructions for use. They will not be listed in this policy.

The medical record must document that wound treatment by this method is accompanied by appropriate wound dressing during the healing period and by appropriate compressive therapy for foot ulcer(s) and appropriate steps to off-load wound pressure during follow-up. Adequate patient compliance must be clearly ascertained and documented during such treatment.

Since application of Oasis®, Apligraf®, or Dermagraft® as well as any subsequently-accepted similar product is considered a physician service, it must be applied by either a physician or a non-physician provider (NPP), and NOT by non-advance practice nurses, therapists or medical assistants.

In addition, due to marked propensity for mis-use of the entire range of “Skin Substitute” products, after the effective date of this policy update, this A/B MAC will pay **only** when the medical record clearly documents that these products have been used in a comprehensive, organized wound management program, either office- or clinic-based.

In most instances, consistent with FDA product labeling, and current CPT language included in the introductory information on the family of Skin Substitute codes, which limit the use of these products to clean wounds, CPT codes 15002-15005 are **not** appropriate. Standard, routine minimal wound preparation is considered a part of the procedure. In any instance of utilization of a separate debridement code, there is a high likelihood of Contractor record review; therefore the medical record documentation must clearly support that any amount of separately-billed debridement was substantial and was medically reasonable and necessary, both in terms of extent and frequency. Providers are reminded that FDA-labeling should be reviewed in order to determine that the skin substitute itself is even indicated in such cases of significant same-day debridement.

The medical record must be available upon request to the Medicare Carrier.

The HCPCS/CPT code(s) may be subject to Correct Coding Initiative (CCI) edits. This policy does not take precedence over CCI edits. Please refer to the CCI for correct coding guidelines and specific applicable code combinations prior to billing Medicare.

When the documentation does not meet the criteria for the service rendered or the documentation does not establish the medical necessity for the services, such services will be denied as not reasonable and necessary under Section 1862(a)(1) of the Social Security Act.

When requesting a written redetermination (formerly appeal), providers must include all relevant documentation with the request.

Appendices

General Information

Documentation Requirements

Utilization Guidelines

1. For venous stasis ulcers treatment will normally last approximately twelve (12) weeks. If after twelve weeks of compression treatment, and the appropriate number of applications of the skin substitute, consistent with Indications and Limitations above, satisfactory healing progress is not noted then reapplication of the skin substitute should not be billed and other treatment modalities should be considered.
2. For neuropathic diabetic foot ulcers, treatment will normally last approximately twelve (12) weeks. If after nine (9) weeks of treatment, and three (3) applications of the skin substitute, satisfactory healing progress is not noted, then reapplication of the skin substitute is not recommended and other treatment modalities should be considered.
3. No re-treatment would be expected within the first year following successful initial treatment.

Sources of Information and Basis for Decision

FDA Approval Notice, dated May 22, 1998

FDA Approval Notice for neuropathic diabetic foot ulcers Decision dated June 20, 2000

CMD Surgery/Surgery New Technology Workgroup

Consultants from Podiatry, Vascular Surgery, Orthopedic Surgery, Plastic Surgery

“Diabetic Foot Disorders, A Clinical Practice Guideline (2006 revision),” supplement to The Journal of Foot & Ankle Surgery, September/October 2006, Volume 45, Number 5

Falanga, V., & Sabolinski, M., " Bilayered living skin construct (Apligraf) accelerates complete closure of hard-to-heal venous ulcers," Wound Repair and Regeneration, Vol. 7, No. 4, July-August 1999.

Prescribing Information: Apligraf (graftskin), Organogenesis Inc.

Olin, J.W., Beusterien, K.M., Childs, M. B., Seavy, C., Griffiths, R.I., "Medical costs of treating venous stasis ulcers: evidence from a retrospective cohort study," Vascular Medicine, Volume 4, pp. 1-7, 1999.

Behavior of Tissue Engineered Skin, A Comparison of a Living Skin Equivalent, Autograft, and Occlusive Dressing in Human Donor Sites, Muhart, et al., Archives of Dermatology, August 1999 (Reprint).

Cadaveric Allograft as Adjunct Therapy for Nonhealing Ulcers, Snyder, et al., Journal of Foot and Ankle Surgery, March/April, 1999 (Abstract).

Rapid Healing of Venous Ulcers and Lack of Clinical Rejection with an Allogenic Cultured Human Skin Equivalent, Falanga, et al., Archives of Dermatology, March, 1998 (Abstract).

Other carriers' policies

General Information

Documentation Requirements

Advisory Committee Meeting Notes

This policy does not reflect the sole opinion of the contractor or Contractor Medical Director. Although the final decision rests with the contractor, this policy was developed in cooperation with advisory groups, which include representatives from the affected provider community.

Contractor Advisory Committee meeting dates:

California -
Hawaii -
Nevada -

Start Date of Comment Period

End Date of Comment Period

Start Date of Notice Period

06/16/2008

Revision History Number

Revision #1, 08/04/2008

Revision History Explanation

Revision #1, 08/04/2008

This LCD is being revised to add Bill Type 999X because the automated system transcription process was incomplete.

Reason for Change

Other

Last Reviewed On Date

06/12/2008

Related Documents

This LCD has no Related Documents.

LCD Attachments

There are no attachments for this LCD.

Other Versions

Updated on 06/08/2008 with effective dates 08/04/2008 - N/A