

# **LCD for Application of Bioengineered Skin Substitutes (L30135)**

## **Contractor Information**

### **Contractor Name**

Wisconsin Physicians Service Insurance Corporation

### **Contractor Number**

00951, 00952, 00953, 00954, 05101, 05201, 05301, 05401, 05102, 05202, 05302, 05402, 52280

### **Contractor Type**

Carrier - MAC - FI

## **LCD Information**

### **LCD ID Number**

L30135

### **LCD Title**

Application of Bioengineered Skin Substitutes

### **Contractor's Determination Number**

GSURG-052

### **AMA CPT / ADA CDT Copyright Statement**

CPT codes, descriptions and other data only are copyright 2009 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS Clauses Apply. Current Dental Terminology, (CDT) (including procedure codes, nomenclature, descriptors and other data contained therein) is copyright by the American Dental Association. © 2002, 2004 American Dental Association. All rights reserved. Applicable FARS/DFARS apply.

### **CMS National Coverage Policy**

Title XVIII of the Social Security Act, Section 1862(a)(1)(A)  
Title XVIII of the Social Security Act, Section 1833(e)  
CMS Manual System, Pub 100-2, Medicare Benefit Policy Manual, Chapter 16, §180  
CMS Manual System, Pub 100-4, Medicare Claims Processing Manual,  
Chapter 17, §40 – Discarded drugs and biologicals.

### **Oversight Region**

Region V

**Original Determination Effective Date**

For services performed on or after 08/16/2009

**Original Determination Ending Date****Revision Effective Date**

For services performed on or after 12/16/2009

**Revision Ending Date****Indications and Limitations of Coverage and/or Medical Necessity**

Note: Providers should seek information related to National Coverage Determinations (NCD) and other Centers for Medicare & Medicaid Services (CMS) instructions in CMS Manuals. This LCD only pertains to the contractor's discretionary coverage related to this service.

This LCD covers the use of skin substitutes and related products in the treatment of lower extremity ulcer disease. The LCD does not pertain or otherwise apply to the use of any skin substitutes or related products in the treatment of burns, skin cancer, or for true reconstructive surgery.

**Indications**

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 that have failed to respond to documented conservative measures for greater than two (2) months' duration
3. Presence of neuropathic diabetic foot ulcers that have failed to respond to documented conservative measures for greater than one (1) month's duration. These measures must include appropriate steps to off-load pressure during treatment.
4. Presence of partial or full-thickness ulcers
5. Measurements of the initial ulcer size, the size following cessation of any conservative management and the size at the beginning of skin substitute treatment.

In all cases, the ulcer must be free of infection and underlying osteomyelitis. Documentation must be provided that these conditions have been successfully treated, resolved, prior to instituting skin substitute treatment.

**Surgical Preparation for Initial Wound Recipient Site Preparation**

CPT codes 15002-15005 Surgical Preparation

Note: CPT codes 15002-15005 describe burn and wound preparation or incisional or excisional release of scar contracture resulting in an open wound requiring a skin graft. These CPT codes are appropriately used in place of service inpatient hospital, outpatient hospital, ambulatory surgical center or office surgical suite with regional or general anesthesia to resurface an area damaged by burns, traumatic injury or surgery. An operative report is required and must be available upon request. If this procedure is performed in an office the claim can be resubmitted with a request for a redetermination and the medical staff will give the claim individual consideration.

CPT codes 15002-15005 are not intended to be reported for simple graft application alone or application stabilized with dressing (eg. by simple gauze wrap). They are not appropriate codes to use when treating small wounds or non-major skin loss.

### Surgical Preparation of Wound prior to Application of Skin Substitute

Tissue Cultured Allergenic Skin Substitutes CPT codes 15340-15341 and  
Tissue Cultured Allogeneic Dermal Substitutes CPT codes 15360-15366

These are surgical codes used to bill the preparation of a wound prior to the application of a skin substitute. When the service is performed in a non-facility setting, both the surgical procedure and the skin product must be billed on the same claim.

These CPT codes are not intended to be used to report simple graft or skin substitute application alone or graft or skin substitute application stabilized with dressing (eg, by simple gauze wrap) without surgical fixation of the skin substitute or graft. The graft/skin substitute is anchored using the surgeon's choice of fixation. While routine dressing supplies are not reported separately, the supply of the skin substitute is reported separately when the services are performed in the office setting. An operative report is required and must be available upon request.

Tissue Cultured Allogeneic Skin Substitute CPT codes 15340-15341

CPT codes 15340-15341 are used for the application of cultured allogeneic skin with both a dermal and epidermal layer (example: Apligraf®).

Allogeneic Dermal Substitute CPT codes 15360-15366

CPT codes 15360-15366 are used for application of cultured allogeneic neonatal dermal fibroblasts (example: Dermagraft®).

Xenograft, Skin CPT codes 15400-15431

Application of a non-human skin graft or biologic wound dressing (eg. porcine tissue or pigskin) to a part of the recipient's body following debridement of the burn wound or area of traumatic injury, soft tissue infection and/or tissue necrosis, or surgery.

The application code will be paid no more frequently than at 90-day intervals. Wound care performed within the 90-day period is considered part of the surgical procedure. Claims must have the name of the product in the narrative field. The product must be:

- Provided in accordance with the material's Food and Drug Administration- (FDA) approved package label.
- Applied to partial- or full-thickness wounds (see individual product information for labeled indications) not involving tendon, muscle, joint capsule or exhibiting exposed bone or sinus tracts

Application of Bioengineered Skin Substitutes

Medicare B accepts the Federal Drug Administration's (FDA) classification and description of any bioengineered skin substitute. Application of a Bioengineered Skin Substitute is covered when the following conditions are met and documented as appropriate for the individual patient:

1. Beneficiaries with diabetes under current medical management and controlled with stable HgbA1c level.
2. Venous stasis ulcers that have failed to heal, using conservative measures, within three months.
3. Neuropathic diabetic foot ulcers that have failed to heal, using conservative measures, within one month.

4. Ulcers that, do not involve tendon, muscle or joint capsule, or have bone exposure, extend through the dermis.
5. Beneficiaries with adequate arterial blood supply to the foot evidenced by a palpable pulse on the foot (either dorsalis pedis or posterior tibial artery) or an Ankle Brachial Index (ABI) of 0.7 or greater
6. Neuropathic diabetic foot ulcers that have been treated with appropriate steps to off-load pressure.
7. The ulcer must be free of infection and underlying osteomyelitis

The following Skin Substitutes are currently covered under Medicare in an office setting:

Q4101 Skin substitute, apligraf, per square centimeter

Q4102 Skin substitute, oasis wound matrix, per square centimeter

Q4106 Skin substitute, dermagraft, per square centimeter

Q4110 Skin substitute, primatrix, per square centimeter

All products must be:

- Provided in accordance with the material's Food and Drug Administration- (FDA) approved package label.
- Applied to partial- or full-thickness wounds (see individual product information for labeled indications) not involving tendon, muscle, joint capsule or exhibiting exposed bone or sinus tracts

Q4101 Skin substitute, apligraf, per square centimeter

Dermal and epidermal, (substitute) tissue of human origin, with or without bioengineered or processed elements, with metabolically active elements, per square centimeter

1. This product is a manufactured viable bilaminar graft or skin substitute designed to be used for treatment of non-infected, partial, and full thickness skin ulcers due to venous insufficiency or neuropathic diabetic foot ulcers.
2. For any product appropriately billed under this code, there must be documentation that the FDA labeling instructions including at least the criteria, frequency and acceptable duration of treatment were followed.
3. If the skin product is going to be billed to Medicare Part B, it must be billed on the same claim as the surgical application of the product.

Q4102 Skin substitute, oasis burn matrix, per square centimeter

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

1. The product is intended to be used for the management of wounds including:
  - 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 regiment.
2. This product is covered when the medical record clearly documents that the product is being used in an office or clinic based comprehensive, organized wound management program.
3. The work value of CPT codes 15430/15431 includes repeated applications usually performed during the 90 post-operative days. It is incorrect to bill CPT codes 15430/15431 with modifier 58 - staged procedure when the service performed is the reapplication of the product.

Q4106 Skin substitute, dermagraft, per square centimeter

Dermal (substitute) tissue of human, with or without other bioengineered or processed elements, with metabolically active elements, per square centimeter

1. This product is covered for the treatment of full-thickness diabetic foot ulcers of greater than six weeks duration, which extend through the dermis, but without tendon, muscle, joint capsule or bone exposure.
2. A maximum of eight applications are covered for the treatment of any given lesion.

Q4110 - Skin substitute, primatrix, per square centimeter

PriMatrix is intended for the management of wounds that include:

Partial and full. thickness wounds, Pressure, diabetic, and venous ulcers

Limitations

Due to marked propensity for misuse of the entire range of "skin substitute" products, reimbursement may be made only when the medical record clearly documents that these products have been used in a comprehensive, organized wound management program.

1. Use of the skin substitute is limited to three separate applications to any given ulcer, or more often only when utilized with adherence to the product specific FDA labeling instructions and criteria.
2. 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 either a part of the FDA product specific labeling instructions or are clearly supported by medical record documentation of medically reasonable and necessary indications.
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 unless FDA product specific labeling provides for additional applications. If after twelve (12) weeks of compression treatment and the appropriate number of applications of the skin substitutes a 50 percent or greater improvement is noted and documented, then one or more subsequent re-application of the skin substitute will be considered for Medicare coverage. Otherwise, re-application of the skin substitute is not recommended and other treatment modalities should be considered.
5. Re-treatment within one (1) year of completion of any given course of skin substitutes 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 re-application of the skin substitute is not recommended and other treatment modalities should be considered.
7. All 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 part of the relevant Evaluation & Management (E/M) service provided and not separately payable. Furthermore, even in those instances when the labeled indications include venous stasis or neuropathic diabetic ulcers, if the product is not biologically active, they will be considered as not covered under the terms of this LCD.
8. Application of the wound dressing is included in the payment for the E&M service and should not be billed a separately; when the is provided on the same or a previous day,
9. Providers are reminded that CPT code Manual 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 WPS) When more substantial debridement is warranted, consider use of one of the debridement codes (CPT codes 11040-11042). In either instance, the medical record documentation must clearly support the medically reasonable and necessary of the debridement of the wound.
10. Minimal wound preparation is considered a part of the procedure. All other products are included in the Evaluation & Management (E/M) service and are not separately payable.
11. Application skin substitutes/skin grafts must be performed in the appropriate place of service
12. When performing the repair of ventral hernias, the CPT codes for acellular xenograft implants should not be used. This should be billed as CPT 49568, Implantation of mesh or other prosthesis of open incision of ventral hernia repair, rather than 15430 or 15430 and 15431.

Note: Medicare Part B is not changing the way the payment amounts are determined for the skin care products with the new HCPCS codes. To the extent that single source drugs or biologicals were within the same billing and payment code as of October 1, 2003, Medicare Part B will continue to treat them as multiple source drugs for payment purposes as required by Section 1847A(c)(6)(C)(ii).

### **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.**

### **CPT/HCPCS Codes**

#### **CPT/HCPCS Codes**

11043	DEBRIDEMENT; SKIN, SUBCUTANEOUS TISSUE, AND MUSCLE
11044	DEBRIDEMENT; SKIN, SUBCUTANEOUS TISSUE, MUSCLE, AND BONE
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	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 PART THEREOF, 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 PART THEREOF, OR EACH ADDITIONAL 1% OF BODY AREA OF INFANTS AND CHILDREN (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, OR PART THEREOF (LIST SEPARATELY IN ADDITION TO CODE FOR PRIMARY PROCEDURE)
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)
15400	XENOGRAFT, SKIN (DERMAL), FOR TEMPORARY WOUND CLOSURE, TRUNK, ARMS, LEGS; FIRST 100 SQ CM OR LESS, OR 1% OF BODY AREA OF INFANTS AND CHILDREN
15401	

XENOGRAFT, SKIN (DERMAL), FOR TEMPORARY WOUND CLOSURE, 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)

15420

XENOGRAFT SKIN (DERMAL), FOR TEMPORARY WOUND CLOSURE, 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

15421

XENOGRAFT SKIN (DERMAL), FOR TEMPORARY WOUND CLOSURE, 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)

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)

Q4101

SKIN SUBSTITUTE, APLIGRAF, PER SQUARE CENTIMETER

Q4102

SKIN SUBSTITUTE, OASIS WOUND MATRIX, PER SQUARE CENTIMETER

Q4106

SKIN SUBSTITUTE, DERMAGRAFT, PER SQUARE CENTIMETER

Q4110

SKIN SUBSTITUTE, PRIMATRIX, PER SQUARE CENTIMETER

Non Covered

Q4100

SKIN SUBSTITUTE, NOT OTHERWISE SPECIFIED

Q4103

SKIN SUBSTITUTE, OASIS BURN MATRIX, PER SQUARE CENTIMETER

Q4104

SKIN SUBSTITUTE, INTEGRA BILAYER MATRIX WOUND DRESSING (BMWD), PER SQUARE CENTIMETER

Q4105

	SKIN SUBSTITUTE, INTEGRA DERMAL REGENERATION TEMPLATE (DRT), PER SQUARE CENTIMETER
Q4107	SKIN SUBSTITUTE, GRAFTJACKET, PER SQUARE CENTIMETER
Q4108	SKIN SUBSTITUTE, INTEGRA MATRIX, PER SQUARE CENTIMETER
Q4109	SKIN SUBSTITUTE, TISSUEMEND, PER SQUARE CENTIMETER
Q4111	SKIN SUBSTITUTE, GAMMAGRAFT, PER SQUARE CENTIMETER
Q4112	ALLOGRAFT, CYMETRA, INJECTABLE, 1CC
Q4113	ALLOGRAFT, GRAFTJACKET EXPRESS, INJECTABLE, 1CC
Q4114	INTEGRA FLOWABLE WOUND MATRIX, INJECTABLE, 1CC

### ICD-9 Codes that Support Medical Necessity

When billing for wound care for ulcers caused by diabetes, the provider must use both a primary ICD-9 code (List 1A) from the ulcer of lower limb range (707.10-707.19) and a secondary ICD-9 code (List 1B) from the diabetes range.

#### List 1A-Primary diagnoses:

454.0	VARICOSE VEINS OF LOWER EXTREMITIES WITH ULCER
454.2	VARICOSE VEINS OF LOWER EXTREMITIES WITH ULCER AND INFLAMMATION
459.0	HEMORRHAGE UNSPECIFIED
459.10 - 459.19	POSTPHLEBETIC SYNDROME WITHOUT COMPLICATIONS - POSTPHLEBETIC SYNDROME WITH OTHER COMPLICATION
459.81	VENOUS (PERIPHERAL) INSUFFICIENCY UNSPECIFIED
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

#### List 1B Secondary diagnoses:

249.60

	SECONDARY DIABETES MELLITUS WITH NEUROLOGICAL MANIFESTATIONS, NOT STATED AS UNCONTROLLED, OR UNSPECIFIED
249.70	SECONDARY DIABETES MELLITUS WITH PERIPHERAL CIRCULATORY DISORDERS, NOT STATED AS UNCONTROLLED, OR UNSPECIFIED
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
250.70	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
250.80	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

### **Diagnoses that Support Medical Necessity**

### **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, including but not limited to ICD-9 codes related to the following diagnoses:

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 of the HgbA1c level)
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
11. Patients who have undergone radiation and/or chemotherapy within the month immediately preceding proposed skin substitute treatment.
12. The service is considered investigational and/or for cosmetic purposes,

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

### **Diagnoses that DO NOT Support Medical Necessity**

#### **General Information**

##### **Documentation Requirements**

The medical record must clearly show that the criteria listed in “Indications and Limitation of Coverage and/or Medical Necessity” 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 inappropriate absent documentation of an appropriate rationale for doing so.

1. The medical record must clearly show that the criteria listed in “Indications and Limitations of Coverage and/or Medical Necessity” have been met.
2. The medical record must clearly document that conservative pre-treatment wound management has been tried and failed to induce healing.
3. There must be a documented plan of care with documented goals and documented provider follow-up present in the patient's medical record. Wound healing must be a medically reasonable expectation based on the clinical circumstances documented.
4. Documentation of the progress of the wound's response to treatment must be made for each service billed. At a minimum this must include current wound size, wound depth, presence and extent of or absence of obvious signs of infection, presence and extent of or absence of necrotic, devitalized or non-viable tissue, or other material in the wound that is expected to inhibit healing or promote adjacent tissue breakdown.
5. When debridements are performed, the debridement procedure notes must document tissue removal (i.e. skin, full or partial thickness; subcutaneous tissue; muscle; and/or bone), the method used to debride (i.e., hydrostatic versus sharp versus abrasion methods), and the character of the wound (including dimensions, description of necrotic material present, description of tissue removed, degree of epithelialization, etc.) before and after debridement.
6. Consistent with FDA product labeling, since the use of these products is limited to clean wounds, a description of wound must be documented in the medical records.
7. When, the documentation does not meet the criteria for the service(s) rendered or the documentation does not establish the medical necessity for the service(s), such service(s) will be denied as not reasonable and necessary under Section 1862(a)(1) of the Social Security Act.
8. If the active wound care is needed to clean an infected wound, the service (CPT codes 97597 or 97598) is not expected to be needed more than once a week. The rationale and medical necessity for more frequent services must be clearly documented in the medical record.
9. The literature demonstrates that survival of Q4106 decreases significantly when the 24 steps noted in the FDA labeling are not followed. The documentation must show that these steps were followed.

10. This contractor will cover a maximum of 8 applications of Q4106 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. For Dermagraft® (Q4106) 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. This requirement is based on the demonstrated decrement in survival of the dermal substitute when the 24 steps noted in the FDA labeling are not followed. The provider must take notice of these specific instructions for use. They will not be listed in this policy.

11. The medical record must document that wound treatment 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.

12. In most instances, consistent with FDA product labeling and current CPT language included in the introductory information on the family of Skin Substitute codes that limits the use of these products to clean wounds, CPT code 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. 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 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.

## **Appendices**

### **Utilization Guidelines**

1. If the debridement of chronic ulcers requires more than eight services, the rationale and medical necessity must be clearly documented in the medical record.
2. It is expected that, within twelve weeks, a wound will reach a state at which its care should be performed primarily by the patient and/or the patient's caregiver with periodic provider assessment and supervision. Wound care that can be performed by the patient or the patient's caregiver is considered maintenance care. Re-assessment of a wound maintained by the patient or patient's caregiver is covered as an evaluation and management service.
3. Use of the skin substitute is limited to three separate applications to any given ulcer.
4. For venous stasis ulcers, treatment will normally last no longer than twelve weeks. If after twelve weeks of compression treatment, and two 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.
5. For neuropathic diabetic foot ulcers, treatment will normally last no longer than twelve weeks. If after nine weeks of treatment, and three 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.
6. No re-treatment would be expected within the first year following successful initial treatment.

### **Sources of Information and Basis for Decision**

1. FDA Approval Notice, May 22, 1998 (Apligraf®); September 28, 2002
2. FDA Approval Notice, September 28, 2001 (Dermagraft®)
3. FDA Approval Notice for Neuropathic diabetic foot ulcers dated June 20, 2000
4. CMD Surgery/Surgery New Technology Workgroup
5. Template LMRP for bilaminar skin substitutes, developed by the CMD surgery/new technology surgery issues workgroup
6. Consultants from Podiatry, Vascular Surgery, Orthopedic Surgery Plastic Surgery
7. Falanga, V., & Sabolinski, M., "A 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.
8. Prescribing Information: Apligraf® (Graftskin® (TM)), Organogenesis Inc.
9. Olin, J.W., Beussterien, 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.
10. Muhart, et al., Behavior of Tissue Engineered Skin, A Comparison of a Living Skin Equivalent Autograft, and Occlusive Dressing in Human Donor Sites. Archives of Dermatology, August 1999
11. Snyder, et al., Cadaveric Allograft as Adjunct Therapy for Nonhealing Ulcers, Journal of Foot and Ankle Surgery, March/April, 1999
12. Falanga, et al., Rapid Healing of Venous Ulcers and Lack of Clinical Rejection with an Allogenic Cultured Human Skin Equivalent, Archives of Dermatology, March, 1998
13. Change Request 1521, January 22, 2001
16. C. Keith Bowering, MD, The Use of Dermagraft® in the Treatment of Diabetic Foot Ulcers –FRCP
17. Richard A. Pollak, DPM, et. al., and the Dermagraft® Diabetic Ulcer Study Group, A Human Dermal Replacement for the Treatment of Diabetic Foot Ulcers -
18. Gary D. Genzkow, MD, et. al. Improved Healing of Diabetic Foot Ulcers after Grafting with a Living Human Dermal Replacement - - The Dermagraft® Diabetic Ulcer Study Group
19. A Metabolically Active Human Dermal Replacement for the Treatment of Diabetic Foot Ulcers- Gail Naughton, Jonathan Mansbridge, and Gary Genzkow
20. Update of FDA, Humanitarian Device Exemption HDE - H020004
21. 2006 HCPCS Update.
22. Noridian Administrative Services, LLC LCD Application of Bioengineered Skin Substitute
23. Marston, W. A., J. Hanft, et al. (2003). "The Efficacy and Safety of Dermagraft in Improving the Healing of Chronic Diabetic Foot Ulcers: Results of a prospective randomized trial." Diabetes Care 26(6): 1701-5.
23. Marston, W. A., Risk Factors Associated with Healing Chronic Diabetic Foot Ulcers: The Importance of Hyperglycemia Ostomy/Wound Management - ISSN: 0889-5899 - Volume 52 - Issue 3 - March 2006 - Pages: 26 - 39
24. CPT 2006. AMA, Chicago, 2006.
25. CPT Assistant. Chicago. October 2006, vol 16, issue 10.
26. FDA Approval Notice, dated March 1, 1996 (Integra); April 19, 2002
27. FDA Approval Notice, dated July 19, 2006 (Oasis).
28. CPT changes 2006, An Insider's View, November 2006
29. HCPCS changes for 2006 and 2007
30. Molnar, Joseph A., et al; Acceleration of Integra Incorporation in Complex Tissue Defects with Subatmospheric Pressure, Plastic & Reconstructive Surgery, Vol. 113 No. 5, April 2004
31. The FDA Center for Biologics Evaluation & Research, Processing of Orthopedic, Cardiovascular & Skin Allografts Workshop, November 11, 2007. <http://www.fda.gov/cber/minutes/allog101107t.pdf>
32. Division of Medical Assistance Clinical Coverage Policy No.: 1G-2 Bioengineered Skin Original Effective Date: November 1, 2000 Revised Date: May 1, 2007. <http://www.ncdhhs.gov/dma/physician/1G2.pdf>

## Advisory Committee Meeting Notes

Meeting Date:

Wisconsin 09/26/2008

Illinois 09/17/2008

Michigan 09/24/2008

Minnesota 09/11/2008

Iowa 10/16/2008

Kansas 10/16/2008  
Missouri 10/17/2008  
Nebraska 10/16/2008

This policy does not reflect the sole opinion of the contractor or the Contractor Medical Director(s). Although the final decision rests with the contractor, this policy was developed in cooperation with the Carrier Advisory Committee(s), which include representatives of various medical specialty societies.

**Start Date of Comment Period**

10/18/2008

**End Date of Comment Period**

12/03/2008

**Start Date of Notice Period**

07/01/2009

**Revision History Number**

3

**Revision History Explanation**

\*11/01/2009, three, removed typo information on HCPCS code Q4104, this has been and continues to be, as stated in matrix, a non-covered service, removed typo range (250.60-250.81) just under ICD-9 codes

09/01/2009, two, ICD-9 codes 250.82 and 252.83 inadvertently omitted from ICD-9-CM secondary diagnosis list. Effective 08/16/2009.

Removed contractor 05392 since it is being joined with WMO contractor number effective 08/01/2009

07/01/2009, one, this LCD replaces GSURG-037 and GSURG-537 and L28357;

04/15/2009 This draft was also known as DL 28721 which is being deleted since this updated draft version was posted. AB

**Reason for Change**

**Last Reviewed On Date**

07/01/2009

**Related Documents**

This LCD has no Related Documents.

**LCD Attachments**

**All Versions**

Updated on 12/18/2009 with effective dates 12/16/2009 - N/A

Updated on 11/06/2009 with effective dates 08/16/2009 - 12/15/2009

Updated on 10/01/2009 with effective dates 08/16/2009 - N/A

Updated on 08/13/2009 with effective dates 08/16/2009 - N/A

Updated on 07/17/2009 with effective dates 08/16/2009 - N/A

Updated on 07/14/2009 with effective dates 08/16/2009 - N/A

Updated on 07/14/2009 with effective dates 06/01/2009 - N/A