

**Contractor Name**

Wisconsin Physicians Service (WPS)

**Contractor Number**

00951, 00952, 00953, 00954

05101, 05201, 05301, 05401, 05102, 05202, 05392, 05302, 05402

**Contractor Type**

Carrier

MAC A

MAC B

**LCD Database ID Number**

Wisconsin

Illinois

Michigan

Minnesota

Iowa

Kansas

Missouri

Nebraska

Part A

**LCD Version Number****LCD Title**

Application of Bioengineered Skin Substitutes: Ulcers of the Lower Extremities

**Contractor's Determination Number**

GSURG-052

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**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.

**Primary Geographic Jurisdiction**

Wisconsin

Illinois

Michigan

Minnesota

Iowa

Kansas

Missouri

Nebraska

**Oversight Region**  
Region V

**CMS Consortium**  
Midwest

**Original Determination Effective Date**

**Revision Effective Date**

**Indications and Limitations of Coverage and/or Medical Necessity**

**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 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. There *must* be measurements of the initial ulcer size, the size following cessation of any conservative management and the size at the beginning of skin substitute treatment.
6. 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**

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 or ambulatory surgical center 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.

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**

#### **CPT codes 15340-15341 and 15360-15366**

These are surgical codes used to bill the preparation of a wound prior to the application of a skin substitute. To ensure that these CPT codes are appropriately used for medically necessary services, 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.

#### **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**

A xenograft is the 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.

#### **Skin Substitute Tissue CPT codes J7340 - J7349**

**Note:** HCPCS codes J7343, J7345, J7346 and J7348 are not covered products; they are listed and described below only for information. (NOTE: J7345 discontinued as of 01/01/2008)

#### **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

**HCPCS Code J7340 (example APLIGRAF® (Graftskin))**

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 bilaminate 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. The surgical application of this product must be billed on the same claim as the skin substitute.

**\*HCPCS Code J7341 (example OASIS® Wound Matrix):**

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.

**HCPCS Code J7342 (example Dermagraft®)**

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 of J7342 is covered for the treatment of any given lesion.

**HCPCS code J7343 (No covered products currently meet this definition)**

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

**HCPCS code J7344 (example GraftJacket® which is non-covered)**

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

1. For any product 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.
2. At present, no product currently on the market is covered.

**Note:** GraftJacket® is not covered because there is a scarcity of available peer reviewed or published research on using this product for foot ulcers; therefore it is considered investigational and not medically necessary

**HCPCS code J7345 (CPT code endated 01/01/2008)**

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

1. For any product 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.
2. At present, no product currently on the market is covered.

**HCPCS Code J7346 Not covered under Medicare Part B**

Dermal (substitute) tissue, injectable, with or without other bioengineered or processed elements, but without metabolized active elements. Injectable dermal tissue, is not considered a "skin substitute". Services related to the use of such substances are included in the E/M service.

**HCPCS code J7347 (example 501(k) Number K021792 Integra Matrix)**

Dermal (substitute) tissue of nonhuman origin, with or without other bioengineered or processed elements, without metabolically active elements (Integra Matrix), per square centimeter Bilayer Matrix Wound Dressing is indicated for the management of wounds including: partial and full thickness wounds, pressure ulcers, venous ulcers, diabetic ulcers, chronic vascular ulcers, surgical wounds (donor sites/grafts, post-Moh's surgery, post-laser surgery, podiatric, wound dehiscence), trauma wounds (abrasions, lacerations, second-degree burns, and skin tears) and draining wounds. The device is intended for one-time use.

**HCPCS code J7348 - Not covered under Medicare Part B (Example TissueMend)**

TissueMed is designed for reinforcement of soft tissues repaired by sutures or suture anchors during tendon-repair surgery

**HCPCS code J7349 (example (501(k) K061407) - PriMatrix)**

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 (3) 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. **Coverage will not be provided under this LCD for any wound treatment that does not meet the definition of either 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 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, as noted in the HCPT code descriptors for J7340, J7341, and J7342, the product will be considered as not covered under the terms of this LCD.

Examples of such non-separately reimbursed "wound dressings/coverage" are Biovance™ (Biovance™ is described in its FDA-labeling as “wound covering”) and Integra™. These and others are considered wound dressings, not skin substitutes, and are not separately payable by Medicare. Payment for these products is packaged into the appropriate level of E/M service whether or not the E&M service is provided on the same or a previous day. Application of the wound dressing ins included in the E&M service.

8. Consistent with FDA product labeling, which limits the use of these products to clean wounds, in most instances CPT codes 15002 and 15004 are **not** appropriate. *Minimal wound preparation is considered a part of the procedure.* 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 that any amount of debridement was medically reasonable and necessary. [Providers should note that, as the literature clearly demonstrates that development of necrosis significant enough to require debridement as often as weekly usually means vascularity is insufficient to allow wound healing, the use of skin substitutes in this scenario would be questionable.] Billing for "debridement" performed during routine or other dressing changes in the course of treatment is **not** appropriate. Debridement by a Physical Therapist **must** be done within a Plan of Care certified and closely supervised by a physician.

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

10. The following procedures are not considered debridement:

Removal of necrotic tissue by cleansing, scraping (other than by a scalpel or a curette) chemical application, and wet-to-dry dressing.

Washing bacterial or fungal debris from lesions.

Removal of secretions and coagulation serum from normal skin surrounding an ulcer.

Dressing of small or superficial lesions.

Trimming of callous or fibrinous material from the margin of an ulcer.

Paring or cutting of corns or non-plantar calluses. Skin breakdown under a dorsal corn that begins to heal when the corn is removed and shoe pressure eliminated is not considered an ulcer and does not require debridement unless there is extension into the subcutaneous tissue.

Incision and drainage of abscess including paronychia, trimming or debridement of mycotic nails, avulsion of nail plates, acne surgery, destruction of warts, or burn debridement.

11. Providers should report these procedures, using appropriate CPT or HCPCS codes when they represent covered, reasonable and necessary services
12. Skin products that do not meet the definition of either HCPCS codes J7340, J7341, or J7342 are not covered. All other products are included in the Evaluation & Management (E/M) service provided and are not separately payable.
13. Minimal wound preparation is considered a part of the procedure.
14. Treatments must be performed in an appropriate place of service
15. Repeated debridement for an individual wound is rarely medically necessary. For wounds requiring repeated debridement, the medical record must demonstrate the circumstances that justify repeated debridement and must demonstrate that debridement of tissue was performed
16. Based on the *CPT Code Book* definitions, CPT codes 15000, 15001 (DOS prior to 01/01/2006) 15002, 15003, 15004, 15005, (DOS after 01/01/2007) 15330-15336 and 15400-15421 typically are services used to treat severe skin burns. Therefore, these services are rarely performed in any place of service other than an inpatient setting.

## Coverage Topic

Surgery

## CPT/HCPCS Codes

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 one percent of body area of infants and children
15361	Tissue cultured allogeneic dermal substitute; each additional 100 sq cm, or each additional one percent 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 one percent 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 one percent 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 one percent of body area of infants and children
15401	each additional 100 sq cm or each additional one percent of body area of infants and children
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 one percent of body area of infants and children
- 15421           each additional 100 sq cm or each additional one percent of body area of infants and children
- 15430           Acellular xenograft implant, first 100 sq cm or less, or one percent of body area of infants and children
- 15431           each additional 100 sq cm or each additional one percent of body area of infants and children
- 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
- J7347           Dermal (substitute) tissue of nonhuman origin, with or without other bioengineered or processed elements, without metabolically active elements (INTEGRA MATRIX), 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

**Non Covered**

- 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 (DOS on and after 01/01/2008)
- J7348           Dermal (substitute) tissue of nonhuman origin, with or without other bioengineered or processed elements, without metabolically active elements
- 454.0           Varicose veins of lower extremities with ulcer
- 454.2           Varicose veins of lower extremities with ulcer and inflammation
- 459.81          Other specified disorders of circulation system, venous (peripheral) insufficiency, unspecified

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 (250.60-250.83).

**List 1A-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

**List 1B 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
- 250.70 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

**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 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,

**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

The literature demonstrates that survival of J7342 decreases significantly when the 24 steps noted in the FDA labeling are not followed. The documentation must show that these steps were followed.

This contractor 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. For Dermagraft® (J7342), 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.

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.

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.

## 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 Dates:**

Wisconsin: 05/05/2006; 01/26/2001, 09/26/2008  
 Illinois: 05/17/2006, 01/24/2001, 09/17/2008  
 Michigan: 05/03/2006; 01/10/2001, 09/24/2008  
 Minnesota: 05/11/2006; 01/18/2001, 09/11/2008  
 Iowa  
 Kansas  
 Missouri  
 Nebraska

#### **Start Date of Comment Period**

Wisconsin: 05/17/2006, 01/24/2001  
 Illinois: 05/17/2006, 01/24/2001  
 Michigan: 05/17/2006, 01/24/2001  
 Minnesota: 05/17/2006, 01/24/2001  
 Iowa  
 Kansas  
 Missouri  
 Nebraska

#### **End Date of Comment Period**

Wisconsin: 07/03/2006; 04/01/2001  
 Illinois: 07/03/2006; 04/01/2001  
 Michigan: 07/03/2006; 04/01/2001  
 Minnesota: 07/03/2006; 04/01/2001

Iowa  
Kansas  
Missouri  
Nebraska

**Start Date of Notice Period**

**Published**

Wisconsin:  
Illinois:  
Michigan:  
Minnesota:  
MAC J-5  
Iowa  
Kansas  
Missouri  
Nebraska

**Revision History Number/Explanation Utilization**

**This LCD replaces GSURG-037**

Wisconsin:  
Illinois:  
Michigan:  
Minnesota:  
Iowa  
Kansas  
Missouri  
Nebraska

**Last Reviewed On**

**Notes**

\* - An asterisk indicates a revision to that section of the policy.

[See Billing and Coding Guidelines for GSURG-052 Application of Bioengineered Skin Substitutes and Skin Grafting](#)

**Does this LCD contain a "Least Costly Alternative" Provision?**

No