Contractor Name
Wisconsin Physicians Service (WPS)

Contractor Number
00951, 00952, 00953, 00954

Contractor Type
Carrier

LCD Database ID Number
L23438

LCD Version Number

LCD Title
Application of Bioengineered Skin Substitutes and Skin Grafting

Contractor's Determination Number
GSURG-037

AMA CPT/ ADA CDT Copyright Statement
CPT codes, descriptions, and other data only are copyright 2007 American Medical Association (or such other date of publication of CPT). All Rights Reserved. Applicable FARS/DFARS Clauses Apply. CDT-4 codes and descriptions are © 2003 American Dental Association. All rights reserved.

CMS National Coverage Policy
Title XVIII of the Social Security Act section 1862 (a)(1)(A). This section allows coverage and payment of those services that are considered to be medically reasonable and necessary.

Title XVIII of the Social Security Act section 1862 (a)(7). This section excludes routine physical examinations and services

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

Medicare National Coverage Determinations Manual, Chapter 1, Part 4, 270.5, CIM 45-12

Primary Geographic Jurisdiction
Wisconsin, Illinois, Michigan, Minnesota

Oversight Region
Region V

CMS Consortium
Midwest

Original Determination Effective Date
04/01/2001

Revision Effective Date
02/16/2007
Indications and Limitations of Coverage and/or Medical Necessity

Indications
This LCD covers the use of skin substitutes and related products in the outpatient treatment of lower extremity ulcer disease. The LCD does not restrict any skin substitutes or related products or services for the treatment of burns.

I. Wound Care
   If debridement of the wound is needed the guidelines listed under "B. Debridement of wound" must be followed

For the purposes of this policy wound care is defined as care of wounds that are refractory to healing or have complicated healing cycles either because of the nature of the wound itself or because of complicating metabolic and/or physiological factors.

This definition excludes management of, burns, acute wounds, the care of wounds that normally heal by primary intention such as clean, incised traumatic wounds, surgical wounds which are closed primarily, wounds which are closed via secondary intent, and other post-operative wound care not separately payable during the surgical global period.

Wound care should employ comprehensive wound management including appropriate control of complicating factors such as unrelieved pressure, infection, vascular and/or uncontrolled metabolic derangement, and/or nutritional deficiency.

A. Active Wound Care Management CPT 97597, 97598
   CPT codes 97597 and 97598 require the presence of devitalized tissue (necrotic cellular material).
   1. Active wound care procedures are performed to remove devitalized and/or necrotic tissue to promote healing of a wound on the skin. This service is billed when it is performed by a Medicare Part B provider or when rendered in place of service office under the incident to provisions.
   2. These services are billed when an extensive cleaning of a wound is needed prior to the application of dressings or skin substitutes placed over or onto a wound that is attached with dressings.
   3. 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

B. Debridement of the wound CPT codes 11040-11044
   Debridement is defined as removal of foreign material and/or devitalized or contaminated tissue from or adjacent to a traumatic or infected wound until surrounding healthy tissue is exposed. Removal of fibrin exudates, crusts and other non-tissue materials from a wound without removal of tissue does not meet the definition of debridement and must not be reported as such. The routine application of a topical or local anesthetic does not elevate active wound care management to surgical debridement.
   1. Any needed debridement is performed prior to the date of the application of human skin substitute.
2. Several methods of debridement are utilized to promote wound healing by exposing healthy tissue and allowing adequate epithelialization and the formation of good granulation tissue.

3. Documentation to support the medical necessity of the wound debridement must include: wound size, wound depth, presence or absence of obvious signs of infection, presence or absence of necrotic or devitalized tissue evidence of the progress of the wound’s response to treatment at each provider visit the level of tissue removed (i.e., skin, full or partial thickness; subcutaneous tissue; muscle; and/or bone), the method used to debride (i.e., hydrostatic vs. sharp vs. abrasion methods), and the character of the wound before and after debridement, the type of dressing/skin substitute (brand name) applied, and size of the graft and how the graft is attached (dressing, stitches, staples).

4. If the wound care is performed by a limited licensed provider and the beneficiary has diabetes, the medical record must include the name of the primary medical provider.

5. With appropriate management, it is expected that in most cases within twelve weeks, a wound will reach a state at which its care can safely be performed by the patient and/or the patient's caregiver with periodic provider assessment and supervision.

6. Wound care that can be performed by the patient or the patient's caregiver will be considered maintenance care. Re-assessment, by a Medicare provider, of a wound maintained by the patient or patient's caregiver is covered as an evaluation and management service.

7. CPT codes 11043 and 11044 are usually performed in place of service inpatient hospital, outpatient hospital, or ambulatory surgical center. Claims submitted in any other place of service will be denied. Appeals must be submitted with complete medical records including the operative report.

8. Debridement will not be allowed on the date of application of human skin equivalents. All preparation of the wound on the day of the application of skin substitute is included in the appropriate CPT code billed for the application of the human skin substitute.

II. 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.

A. Surgical Preparation for Initial Wound Recipient Site Preparation
CPT codes 15002-15005 (DOS on and after 01/01/2007)
CPT codes 15000-15001 (DOS prior to 01/01/2007)
Note: CPT codes 15002-15005 previously 15000-15001 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 (e.g. by simple gauze wrap). They are not appropriate codes to use when treating small wounds or non-major skin loss.

B. **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 (e.g. Apligraf®).

C. **Allogeneic Dermal Substitute CPT codes 15360-15366**
CPT codes 15360-15366 are used for application of cultured allogeneic neonatal dermal fibroblasts (e.g. Dermagraft®).

D. **Xenograft, Skin CPT codes 15400-15431**
A xenograft is the application of a non-human skin graft or biologic wound dressing (e.g. 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. Application of a xenograft is allowed only as an inpatient procedure.

III. **Skin Substitute Tissue CPT codes J7340 - J7346**
*Note*: HCPCS codes J7341, J7343, J7345, and J7346 are not covered products; they are listed and described below only for information.

A. **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.
B. **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.

C. **HCPCS Code J7341** (example EZ Derm™, Mediskin® - not covered by Medicare Part B)
Dermal (substitute) tissue of non-human origin, with or without other bioengineered or processed elements, with metabolically active elements, per square centimeter.

1. These products are xenografts and neither they nor the application (CPT 15430/15431) qualifies for separate reimbursement in an outpatient setting.
2. The application of these products (CPT 15430/15431) may be covered as an inpatient service.

D. **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 three applications of J7342 is covered for the treatment of any given lesion.

E. **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.

1. These products are a xenograft and neither they nor the application (CPT 15430/15431) qualifies for separate reimbursement.
2. The application of these products (CPT 15430/15431) may be covered as an inpatient service.

F. **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

G. **HCPCS code J7345** (No covered products currently meet this definition)
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.

H. **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 as a “skin substitute”. Services related to the use of such substances are included in the E/M service.

IV. Limitations

A. The following procedures are not considered debridement:
1. Removal of necrotic tissue by cleansing, scraping (other than by a scalpel or a curette), chemical application, and wet-to-dry dressing.
2. Washing bacterial or fungal debris from lesions.
3. Removal of secretions and coagulation serum from normal skin surrounding an ulcer.
4. Dressing of small or superficial lesions.
5. Trimming of callous or fibrinous material from the margin of an ulcer.
6. Paring or cutting of corns or non-planter 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.
7. 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.

Providers should report these procedures, using appropriate CPT or HCPCS codes when they represent covered, reasonable and necessary services.

B. Skin products that do not meet the definition of either J7340 or J7342 are not covered. All other products are included in the Evaluation & Management (E/M) service provided and are not separately payable.

C. Minimal wound preparation is considered a part of the procedure.

D. Treatments must performed in an appropriate place of service.

E. 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.
Based on the *CPT Code Book 2006* and 2007 definitions, CPT codes 15000, 15001 (DOS prior to 01/01/2006) 15002, 15003, 15004, 15005, (DOS after 01/01/2007) 15330-15336 and 15400-15431 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**

97597  Removal of devitalized tissue from wound(s), selective debridement without anesthesia (eg, high pressure water jet with/without suction, sharp debridement with scissors, scalpel and forceps), with/without use of whirlpool, topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area less than or equal to 20 square centimeters.

97598  Removal of devitalized tissue from wound(s), selective debridement without anesthesia (eg, high pressure water jet with/without suction, sharp debridement with scissors, scalpel and forceps), with/without use of whirlpool, topical application(s), wound assessment, and instruction(s) for ongoing care, per session; total wound(s) surface area greater than 20 sq. cm.

11040  Debridement; skin, partial thickness

11041  Debridement; skin, full thickness

11042  Debridement; skin, and subcutaneous tissue

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. (DOS on and after 01/01/2007)

15003  ; 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) (use 15003 in conjunction with 15002) (DOS on and after 01/01/2007)

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 (DOS on and after 01/01/2007)

15005  ; 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) (use 15005 in conjunction with 15004) (DOS on and after 01/01/2007)

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

15410 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

15440 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

15441 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

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

J7345 Dermal (substitute) tissue of non-human origin, with or without other bioengineered or processed elements, without metabolically active elements, per square centimeter (DOS on and after 01/01/2007)

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 01/01/2007)

**ICD-9 Codes that Support Medical Necessity**

These are the only ICD-9-CM codes that support medical necessity for the application of a skin substitute: Consistent with FDA labeling, the use of skin substitute products (J7340 or J7342) are limited to lower limb ulcers caused by varicose veins or diabetes. When performing wound care or debridement of a wound for varicose veins the following ICD-9-CM codes may be used alone:

<table>
<thead>
<tr>
<th>Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>454.0</td>
<td>Varicose veins of lower extremities with ulcer</td>
</tr>
<tr>
<td>454.2</td>
<td>Varicose veins of lower extremities with ulcer and inflammation</td>
</tr>
<tr>
<td>459.81</td>
<td>Other specified disorders of circulation system, venous (peripheral) insufficiency, unspecified</td>
</tr>
</tbody>
</table>

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:**
<table>
<thead>
<tr>
<th>ICD-9-CM Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>707.10</td>
<td>Unspecified ulcer of lower limb</td>
</tr>
<tr>
<td>707.11</td>
<td>Ulcer of thigh</td>
</tr>
<tr>
<td>707.12</td>
<td>Ulcer of calf</td>
</tr>
<tr>
<td>707.13</td>
<td>Ulcer of ankle</td>
</tr>
<tr>
<td>707.14</td>
<td>Ulcer of heel and midfoot</td>
</tr>
<tr>
<td>707.15</td>
<td>Ulcer of other part of foot</td>
</tr>
<tr>
<td>707.19</td>
<td>Ulcer of other part of lower limb</td>
</tr>
</tbody>
</table>

**List 1B Secondary diagnoses:**

<table>
<thead>
<tr>
<th>ICD-9-CM Code</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>250.60</td>
<td>Diabetes with neurological manifestations, Type II or unspecified type, not stated as uncontrolled</td>
</tr>
<tr>
<td>250.61</td>
<td>Diabetes with neurological manifestations, Type I [juvenile type], not stated as uncontrolled</td>
</tr>
<tr>
<td>250.70</td>
<td>Diabetes with peripheral circulatory disorders, type ii or unspecified type, not stated as uncontrolled</td>
</tr>
<tr>
<td>250.71</td>
<td>Diabetes with peripheral circulatory disorders, type I [juvenile type], not stated as uncontrolled</td>
</tr>
<tr>
<td>250.80</td>
<td>Diabetes with other specified manifestations, type ii or unspecified type, not stated as uncontrolled</td>
</tr>
<tr>
<td>250.81</td>
<td>Diabetes with other specified manifestations, type I [juvenile type], not stated as uncontrolled</td>
</tr>
</tbody>
</table>

**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**

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.

Utilization Guidelines

1. Normally, active wound care (CPT codes 97597 or 97598) is not expected to be needed more frequently than once a week. The rationale and medical necessity for more frequent services must be clearly documented in the medical record.

*2. CPT codes 97597 and 97598 are based on the size on the wound(s) and, per the Medicare Fee Schedule Data Base, may not be billed as bilateral services.

3. If the debridement of chronic ulcers requires more than eight services, the rationale and medical necessity must be clearly documented in the medical record.

4. 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.

5. Use of the skin substitute is limited to three separate applications to any given ulcer.

6. 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.

7. 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.

8. Re-application of a skin product, within one year, is not covered.

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 bilaminate skin substitutes, developed by the CMD surgery/new technology surgery issues workgroup

8. Prescribing Information: Apligraf® (Graftskin® (TM)), Organogenesis Inc.


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


13. Change Request 1521, January 22, 2001


15. Richard A. Pollak, DPM, et. al., and the Dermagraft® Diabetic Ulcer Study Group, A Human Dermal Replacement for the Treatment of Diabetic Foot Ulcers -


17. A Metabolically Active Human Dermal Replacement for the Treatment of Diabetic Foot Ulcers- Gail Naughton, Jonathan Mansbridge, and Gary Gentzkow

18. Update of FDA, Humanitarian Device Exemption HDE - H020004


20. Noridian Administrative Services, LLC LCD Application of Bioengineered Skin Substitute


25. FDA Approval Notice, dated March 1, 1996 (Integra); April 19, 2002


27. CPT changes 2006, An Insider's View, November 2006

28. HCPCS changes for 2006 and 2007


Advisory Committee Meeting Notes

Meeting Dates:
Wisconsin: 05/05/2006; 01/26/2001
Illinois: 05/17/2006, 01/24/2001
Michigan: 05/03/2006; 01/10/2001
Minnesota: 05/11/2006; 01/18/2001

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

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

Start Date of Notice Period
(Published)
Wisconsin: *07/01/2007 article; 05/01/2007, article; 01/01/2007; 01/01/2006, Article; 01/01/2005, Article; 09/01/2004; 01/01/2004, article; 11/01/2003, Article; 06/01/2003, article; 05/01/2003, article; 01/01/2003, article; 03/01/2002; 04/01/2001
Illinois: *07/01/2007 article; 05/01/2007, article; 01/01/2007; 01/01/2006, Article; 01/01/2005, Article; 09/01/2004; 01/01/2004, article; 11/01/2003, Article; 06/01/2003, article; 05/01/2003, article; 01/01/2003, article; 03/01/2002; 04/01/2001
Michigan: *07/01/2007 article; 05/01/2007, article; 01/01/2007; 01/01/2006, Article; 01/01/2005, Article; 09/01/2004; 01/01/2004, article; 11/01/2003, Article; 06/01/2003, article; 05/01/2003, article; 01/01/2003, article; 03/01/2002; 04/01/2001
Minnesota: *07/01/2007 article; 05/01/2007, article; 01/01/2007; 01/01/2006, Article; 01/01/2005, Article; 09/01/2004; 01/01/2004, article; 11/01/2003, Article; 06/01/2003, article; 05/01/2003, article; 01/01/2003, article; 03/01/2002; 04/01/2001

Revision History Number/Explanation
Wisconsin: *07/01/2007 twelve, corrected error number 2 utilization guidelines; 05/01/2007, eleven, CPT codes 11043 and 11044 added place of service outpatient hospital; 12/01/2006, ten, CAC updates, 2007 HCPCS updates; 01/01/2006, nine, 2006 HCPCS update; 01/01/2005, eight, 2005 HCPCS update added J7343, J7344, ended Q0182, Q0183; 10/15/2004, seven, Converted to LCD format, added ICD-9 code 459.81, Removed ICD-9 codes (250.02-250.03) for uncontrolled diabetes to correct information that is exclude in written policy, re-wrote text, added billing and coding article; 01/01/2004, six, 2004 HCPCS update, 11/01/2003, five, addition of ICD-9 757.39 to Dermagraft®; 06/01/2003, four, clarification of new pricing for Apligraf®/Dermagraft®; 05/01/2003, three, clarification of coding; 01/01/2003-two, added new code for Dermagraft®; 01/01/2002-one (Added Dermagraft® and new code for Apligraf®)
Illinois: *07/01/2007 twelve, corrected error number 2 utilization guidelines; 05/01/2007, eleven, CPT codes 11043 and 11044 added place of service outpatient hospital; 12/01/2006, ten, CAC updates, 2007 HCPCS updates; 01/01/2006, nine, 2006 HCPCS update; 01/01/2005, eight, 2005 HCPCS update added J7343, J7344, ended Q0182, Q0183; 10/15/2004, seven, converted to LCD format, added ICD-9 code 459.81, removed ICD-9 codes (250.02-250.03) for uncontrolled diabetes to correct information that is exclude in written policy, re-wrote text, added billing and coding article; 01/01/2004, six, 2004 HCPCS update, 11/01/2003, five, addition of ICD-9 757.39 to Dermagraft®; 06/01/2003, four, clarification of new pricing for Apligraf®/Dermagraft®; 05/01/2003, three, clarification of coding; 01/01/2003-
two, added new code for Dermagraft®; 01/01/2002-one (Added Dermagraft® and new code for Apligraf®)

Michigan: *07/01/2007 twelve, corrected error number 2 utilization guidelines; 05/01/2007, eleven, CPT codes 11043 and 11044 added place of service outpatient hospital; 12/01/2006, ten, CAC updates, 2007 HCPCS updates; 01/01/2006, nine, 2006 HCPCS update; 01/01/2005, eight, 2005 HCPCS update added J7343, J7344, endated Q0182, Q0183; 10/15/2004, seven, converted to LCD format, added ICD-9 code 459.81, removed ICD-9 codes (250.02-250.03) for uncontrolled diabetes to correct information that is exclude in written policy, re-wrote text, added billing and coding article; 01/01/2004, six, 2004 HCPCS update, 11/01/2003, five, addition of ICD-9 757.39 to Dermagraft®; 06/01/2003, four, clarification of new pricing for Apligraf®/Dermagraft®; 05/01/2003, three, clarification of coding; 01/01/2003, two, added new code for Dermagraft®; 01/01/2002, one (Added Dermagraft® and new code for Apligraf®)

Minnesota: *07/01/2007 twelve, corrected error number 2 utilization guidelines; 05/01/2007, eleven, CPT codes 11043 and 11044 added place of service outpatient hospital; 12/01/2006, ten, CAC updates, 2007 HCPCS updates; 01/01/2006, nine, 2006 HCPCS update; 01/01/2005, eight, 2005 HCPCS update added J7343, J7344, endated Q0182, Q0183; 10/15/2004, seven, converted to LCD format, added ICD-9 code 459.81, removed ICD-9 codes (250.02-250.03) for uncontrolled diabetes to correct information that is exclude in written policy, re-wrote text, added billing and coding article; 01/01/2004, six, 2004 HCPCS update, 11/01/2003, five, addition of ICD-9 757.39 to Dermagraft®; 06/01/2003, four, clarification of new pricing for Apligraf®/Dermagraft®; 05/01/2003, three, clarification of coding; 01/01/2003, two, added new code for Dermagraft®; 01/01/2002-one (Added Dermagraft® and new code for Apligraf®)

Last Reviewed On
12/01/2006

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

See Billing and Coding Guidelines for GSURG-037 Application of Bioengineered Skin Substitutes and Skin Grafting

Does this LCD contain a "Least Costly Alternative" Provision?
No