

## **Billing and Coding Guidelines:**

### **Contractor Name**

Wisconsin Physicians Service Insurance Corporation

### **Title**

GSURG-052 Application of Bioengineered Skin Substitutes

### **LCD Database ID Number**

L30135

### **Effective Date**

08/16/2009

### **Revision Effective Date**

12/01/2011

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### **CMS National Coverage**

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.

NCD section on xenograft (270.5)

Benefits Manual section on surgical dressings (Ch.15 sect.100)

### **Coding Guidelines**

Application of Bioengineered Skin Substitutes and Skin Grafting is performed on ulcers that are free of infection and underlying osteomyelitis.

These guidelines include both the care of the wounds prior to the application of the skin substitute.

### **Skin Replacement (CPT codes 15002 - 15005)**

**(Below also applies to CPT codes 15000-15001 for DOS 01/01/2006-12/31/2006)**

1. Per the definitions and the guidelines in *CPT Code Book* codes CPT codes 15002/15005 are not appropriate codes to use when performing a non-surgical application of a skin substitute.
2. CPT code 15002/15005 are only 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.

G0440 Application of tissue cultured allogeneic skin substitute or dermal substitute; for use on lower limb, includes the site preparation and debridement if performed; first 25 sq cm or less

G0441 Application of tissue cultured allogeneic skin substitute or dermal substitute; for use on lower limb, includes the site preparation and debridement if performed; each additional 25 sq cm

### **Application of Skin Substitute (G0440-G0441)**

1. HCPT codes G0440 – G0114 are used for the application of cultured allogeneic skin substitute or dermal substitute.
2. The name of the skin substitute must be placed in the narrative field of the claim.
3. Claims submitted for the application of a skin substitute without the name of the skin product in the narrative section of the claim will be denied

### **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

1. When this service is rendered in place of service office, both the application of the skin graft (CPT codes 15430 - 15431) and the product used must be billed on the same claim.
2. This service has a 90-day global period under the Medicare Fee Schedule Data Base (MFSDB). 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
3. These codes may not be billed with a modifier 58 (staged procedure).
4. CPT code 15431 is always related to CPT code 15430 and, per the MFSDB is always included in the global period of the other service.
5. Per the MFSDB - payment for bilateral procedures does not apply.
6. The following products may be billed with CPT codes 15430-15431
  - Q4102 Skin Substitute, Oasis wound Matrix, per square centimeter
  - Q4110 Skin substitute, primatrix, per square centimeter

### **Coding Guidelines**

1. Active wound care, performed with minimal anesthesia is billed with either CPT code 97597 or 97598.
2. Significant debridement of a wound, performed before the application of a topical or local anesthesia is billed with CPT codes 11042 – 11047.
3. CPT codes 11043, 11046 and 11044, 11047 may only be billed in place of service inpatient hospital, outpatient hospital or ambulatory care center (ASC).
4. Use CPT code 15340-15341 or CPT code 15360-15366 for the surgical preparation or creation of recipient site for the tissue skin graft.
5. To bill for an Apligraf® (HCPCS Q4101) package (equal to 44-sq. cm.). If more than 44-sq. cm. is needed for additional grafting, bill according to the number of single units of Apligraf®, indicate Apligraf® in Item 19 of the CMS 1500 Claim Form or the Comment Field for EMC claims.
6. Payment for Apligraf® for any single ulcer will not be made for re-treatment within 1 year after initial treatment.
7. Dermagraft® (HCPCS Q4106) is supplied frozen in a clear bag containing one piece of approximately 2 in. x 3 in. (5 cm. x 7.5 cm.) for a single use application.
8. Claims submitted for skin substitutes should bill the actual size used rounding up to the next whole number.
9. When submitting a claim for skin substitutes, providers are required to accept assignment for this service. Providers, who do not accept assignment, should bill the skin product on a separate claim from other services performed on the same day.
10. Products such as Integra are classified by the Federal Drug Administration as wound dressing and are thus not payable separately by Medicare Part B for outpatient services. The application of Integra **or similar FDA classified products** may be payable as an inpatient for its FDA approved indication for the treatment of life-threatening full-thickness or deep partial-thickness burns.

11. For services on or after November 1, 2007, the Oasis® Wound Matrix is covered and separately payable when used according to FDA labeled indications and in accordance with accepted standards of medical/surgical practice.
12. The application of Oasis® Wound Matrix (CPT code 15430 - 15431) will be paid no more frequently than at 90-day intervals. Though payment for the product is allowed appropriate to the clinical considerations, it is inappropriate to bill application codes multiple times within a 90-day period using such modifiers as 58, suggesting a staged procedure.

### **Documentation Requirements**

1. The medical record must clearly show that the criteria listed in LCD GSURG-052 under “Indications and Limitation 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 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.

### **Part A**

#### **Correct Reporting of Drugs and Biologicals When Used As Implantable Devices**

When billing for biologicals where the HCPCS code describes a product that is solely surgically implanted or inserted, whether the HCPCS code is identified as having pass-through status or not, hospitals are to report the appropriate HCPCS code for the product. In circumstances where the implanted biological has pass-through status, a separate payment for the biological is made. In circumstances where the implanted biological does not have pass-through status, the OPSS payment for the biological is packaged into the payment for the associated procedure. When billing for biologicals where the HCPCS code describes a product that may either be surgically implanted or inserted or otherwise applied in the care of a patient, hospitals should not separately report the biological HCPCS code, with the exception of biologicals with pass-through status, when using these items as implantable devices (including as a scaffold or an alternative to human or nonhuman connective tissue or mesh used in a graft) during surgical procedures. Under the OPSS, hospitals are provided a packaged APC payment for surgical procedures that includes the cost of supportive items, including implantable devices without pass-through status. When using biologicals during surgical procedures as implantable devices, hospitals may include the charges for these items in their charge for the procedure, report the charge on an uncoded revenue

center line, or report the charge under a device HCPCS code (if one exists) so these costs would appropriately contribute to the future median setting for the associated surgical procedure.

Note: This information does not apply to skin substitutes.

**Date Published/Website:**

12/01/2011, 01/01/2011, 12/01/2010; 07/01/2009

**Revision History/Explanation:**

12/01/2011, Corrected by adding CPT codes 11043 and 11046 so now reads 3. CPT codes 11043, 11046 and 11044, 11047 may only be billed in place of service inpatient hospital, outpatient hospital or ambulatory care center (ASC), does not change claims processing system; 01/01/2011, CPT code update 2011; 12/01/2010, two, added information regarding Q4110 Skin substitute, PriMatrix, use in POS office, per FDA, CPT Code 15360 and 15361 not covered for Dermagraft; 12/01/2009

**Notes**

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

NCDs and coverage provisions in interpretive manuals are not subject to the Local Coverage Determination (LCD) Review Process (42 CFR 405.860[b] and 42 CFR 426 [Subpart D]). In addition, an administrative law judge may not review an NCD. See §1869(f)(1)(A)(i) of the Social Security Act.