

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

05/01/2012

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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. 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.

Application of Skin substitute is a physician service (surgical procedure) and may only be covered when applied by a physician or Medicare non-physician practitioner such as a Physician Assistant, Clinical Nurse Specialists (CNS) or Nurse Practitioner (NP) in place of service inpatient hospital, outpatient hospital, ambulatory surgical center, or office setting:

Skin Replacement (CPT codes 15002 - 15005)

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.

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, 11044, and 11047 are usually appropriately billed in place of service inpatient hospital, outpatient hospital or ambulatory care center (ASC). Billing of these codes in another place of service is most likely a billing error and thus the service will be denied. If a provider feels that CPT 11043, 11046, 11044, or 11047 were actually performed in another place of service, a review of the denied claim should be requested and documentation, including an operative report, should be submitted.
4. Use CPT codes 15271 - 15278 for the surgical preparation or creation of recipient site for the tissue skin graft.
5. To bill for HCPCS Q4101, Apligraf per square centimeter, 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 HCPCS Q4101, indicate Apligraf® in Item 19 of the CMS 1500 Claim Form or the Comment Field for EMC claims.
6. Payment for HCPCS Q4101 for any single ulcer will not be made for re-treatment within 1 year after initial treatment.
7. HCPCS Q4106 Dermagraft, per square centimeter 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 HCPCS code Q1405 Integra dermal regeneration template (DRT), per square centimeter 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 HCPCS code Q1405 **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. HCPCS code Q4102, for services on or after November 1, 2007, is covered and separately payable when used according to FDA labeled indications and in accordance with accepted standards of medical/surgical practice
12. HCPCS code Q4121 TheraSkin, per square centimeter is payable under Medicare Part A in POS: outpatient hospital, (22), emergency room (23), urgent care facility (20), and independent clinic (49).
13. HCPCS code Q4121 TheraSkin, per square centimeter is payable if billed by the physician or non-physician practitioner in POS: office (11) and ambulatory surgical center (24).
14. HCPCS code Q4107 - GRAFTJACKET® Regenerative Tissue Matrix-Ulcer Repair will be considered reasonable and necessary for treatment of neuropathic diabetic foot ulcers (DFU) dates of service on and after 05/01/2012 when performed by physician or non-physician practitioner in POS office (11) and ambulatory surgical center (24).

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 Biologicals When Used As Implantable Devices (CR 7672) MM7672 page 9&10

In circumstances where the implanted biological has pass-through status as a device, separate payment for the device is made. In circumstances where the implanted biological does not have pass-through status, the OPPS payment for the implanted 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 codes, 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 OPPS, 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.

Hospitals are reminded that HCPCS codes describing skin substitutes (Q4100 – Q4130) should only be reported when used with one of the CPT codes describing application of a skin substitute (15271-15278). These Q codes for skin substitutes should not be billed when used with any other procedure besides the skin substitute application procedures.

Date Published/Website:

04/01/2012, 02/01/2012; 01/01/2012, 12/01/2011, 01/01/2011, 12/01/2010; 07/01/2009

Revision History/Explanation:

05/01/2012, added coverage of HCPCS code Q4107 GraftJacket claims submitted with dates of service on and after 5/1/2012, corrected typos in references to place of service, typos corrected; 04/01/2012, Updated Part A OPPS information, 02/01/2012, Removed information regarding MPFSDB; 01/01/2012, Added TheraSkin®, 2012 CPT code update, Per 2012 HCPCS update, added CPT codes 15271-15278, deleted CPT codes 15340-15431 and G0440-G0441, removed references to codes; 12/01/2011, Corrected by adding CPT codes 11043 and 11046 so that statement three now reads: 3. CPT codes 11043, 11046,

11044, and 11047 are usually appropriately billed in place of service inpatient hospital, outpatient hospital or ambulatory care center (ASC). Billing of these codes in another place of service is most likely a billing error and thus the service will be denied. If a provider feels that CPT 11043, 11046, 11044, or 11047 were actually performed in another place of service, a review of the denied claim should be requested and documentation, including an operative report, should be submitted.; 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.