

# LCD for Biologic Products for Wound Treatment and Surgical Interventions (L29867)

## Contractor Information

### Contractor Name

NHIC, Corp.

### Contractor Number

14302

### Contractor Type

MAC - Part B

## LCD Information

### LCD ID Number

L29867

### LCD Title

Biologic Products for Wound Treatment and Surgical Interventions

### Contractor's Determination Number

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### CMS National Coverage Policy

Language quoted from CMS National Coverage Determinations (NCDs) and coverage provisions in interpretive manuals is italicized throughout the policy. NCDs and coverage provisions in interpretive manuals are not subject to the 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.

Unless otherwise specified, *italicized* text represents quotation from one or more of the following CMS sources:

#### Title XVIII of the Social Security Act (SSA):

Section 1862(a)(1)(A) excludes expenses incurred for items or services which are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member.

Section 1862 (a)(1)(D) defines investigational or experimental.

Section 1833(e) prohibits Medicare payment for any claim which lacks the necessary information to process the claim.

## CMS Publications:

- CMS Manual System, Pub 100-2, Medicare Benefit Policy Manual, Chapter 16,180  
Services related to and required as a result of services which are not covered under Medicare.
- CMS Manual System, Pub 100-4, Medicare Claims Processing Manual, Chapter 17, 40  
Discarded drugs and biologicals.
- CMS Transmittal No. 1664, Publication 100-04, Medicare Claims Processing Manual, Change Request #6315, January 9, 2009, January 2009 integrated outpatient code editor (I/OCE) specifications version 10.0.

## **Primary Geographic Jurisdiction**

New Hampshire

## **Oversight Region**

Region I

## **Original Determination Effective Date**

For services performed on or after 05/15/2009

## **Original Determination Ending Date**

## **Revision Effective Date**

For services performed on or after 06/07/2010

## **Revision Ending Date**

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

### **Abstract:**

In this LCD we considered the following types of wound coverings, skin substitutes, or other tissue substitutes:

- Dermal and/or epidermal, (substitute) tissue of human origin or non-human origin, with or without bioengineered or processed elements, with or without metabolically active elements, solid or injectable;
- Allograft skin for temporary wound closure;
- Xenograft, skin (dermal), for temporary wound closure;
- Tissue cultured epidermal autograft;
- Tissue cultured allogeneic skin substitute; and
- Tissue cultured allogeneic dermal substitute;
- Biologic Wound Dressings.

The FDA distinguishes between products according to function (wound management, e.g., wound dressings and wound treatment, e.g., bioactive skin substitutes.) The former (Class II) requires 510(k) pre-market notification for FDA clearance while the latter (Class III) requires pre-market approval.

Human tissue products (acellular) require no FDA clearance or approval and are intended for homologous use only. [Title 21 Code of Federal Regulations (CFR), Section 1271.10(a) 2005]

NHIC does not cover Class II or Human Tissue products unless otherwise specified in an attached article or a separate LCD.

NHIC will consider the use of Class III products eligible for coverage when used in keeping with the FDA's approved indications for those products.

Providers may request that a product be approved for use by submitting a request in writing and including the data supporting its use. The request should include the types of intervention for which a product is intended (e.g., venous stasis ulcer, diabetic foot ulcer, pressure ulcer, burn sites, hernias, reconstruction and donor sites).

Because wounds differ in their pathophysiology, it is difficult to generalize results obtained from a trial conducted in subjects with one wound type to patients with another wound type. Therefore, separate supporting evidence should be submitted for each type of wound coverage sought. However, if a scientific rationale and clinical data support clinical activity of a product in more than one wound type, it may be possible for the contractor to consider studies performed in one wound type to support another in establishing substantial evidence of efficacy and safety.

The data must include:

1. A use supported by clinical research that appears in at least two well designed and executed clinical trials that definitively demonstrate safety and effectiveness;  
The trials must come from different centers and be published in national or international peer-reviewed (editorial committee is comprised of physicians) journals. Peer-reviewed medical literature includes scientific and medical publications, it does not include in-house publications of manufacturing companies or abstracts (including meeting abstracts).  
Or;
2. A use that is an accepted standard of medical practice. (For example, a state of the art review article published in a recognized textbook or a reputable publication or published recommendations from specialty societies.) It should be noted that acceptance by individual health care practitioners, or even a limited group of health care practitioners normally does not indicate general acceptance by the medical community. Testimonials indicating such limited acceptance, and limited case studies distributed by sponsors with potential financial conflict of interest in the outcome, are not sufficient evidence of general acceptance by the medical community. The broad range of available evidence must be considered and its quality must be evaluated before a conclusion is reached. After such evidence is received, the contractor will, with appropriate help of specialty-specific consultants as indicated, make a coverage determination for the indication of the product. A product's use is based on substantial evidence and is reflective of the safety and efficacy of the product as determined in clinical investigations.

In principle, rankings of research design have been based on the ability of each study design category to minimize bias. The following is a representative list of study designs (some of which have alternative names) ranked from most to least methodologically rigorous in their potential ability to minimize systematic bias:

- Randomized controlled trials
- Non-randomized controlled trials
- Prospective cohort studies
- Retrospective case control studies
- Cross-sectional studies
- Surveillance studies (e.g., using registries or surveys)
- Consecutive case series
- Single case reports

The design, conduct and analysis of trials are important factors as well. For example, a well designed and conducted observational study with a large sample size may provide stronger evidence than a poorly designed and conducted randomized controlled trial with a small sample size.

In determining whether there is supportive clinical evidence for a particular use of a product, the quality of the published evidence must be considered. Such consideration involves the assessment of the following study characteristics:

- The adequacy of the number of subjects;
- The response rate;
- The effect on key status indications. That is, the effect on the healing of the wound and other responses to therapy that indicate effectiveness (e.g., reduction in wound size and/or depth, morbidity, decrease in limb amputation rate);
- The appropriateness of the study design, that is, whether the experimental design in light of the products and conditions under investigation is appropriate to address the investigative question. (For example, in some clinical studies, it may be unnecessary or not feasible to use randomization, double blind trials, placebos, or crossover); and
- The prevalence and life history of the disease when evaluating the adequacy of the number of subjects and the response rate.

The contractor may determine a product use to be reasonable and necessary for the treatment of wounds or other conditions if, on the basis of available or presented evidence, it is shown to be safe and effective and does not violate national or local Medicare determinations and regulations. The approval will be limited to specific indications and/or patient populations, practitioner categories, procedures, and/or place of service.

### **Indications:**

The following general indications and limitations to Medicare coverage and payment apply to all materials and services related to skin substitute / replacement. Specific coverage information including use of named products both existing and future materials meeting the definitions of specified codes will be set forth in attached articles.

The application of these products is defined by the procedure and the specific applicable State scope of practice. Unless specified otherwise in a product specific article, the application is limited to physicians (M.D., D.O., D.P.M., and NPP (non-physician practitioner) ) who are skilled in the wound care management and have experience in the use of these products for the treatment of wounds. The provider may be subject to a post pay review in order to verify his/her qualifications.

For the purposes of this LCD, a chronic cutaneous ulcer is defined as a wound that has failed to proceed through an orderly and timely series of events to produce a durable structural, functional, and cosmetic closure. A burn wound is defined as a cutaneous wound induced by thermal, chemical, or electrical injury. An acute wound is of recent occurrence and usually traumatic in nature.

Managed wounds should be clean and free of infection and are of reasonable size (at least 1.0 cm<sup>2</sup> and with adequate circulation/oxygenation to support tissue growth/wound healing as evidenced by physical examination (presence of acceptable peripheral pulses and/or Doppler toe signals and/or ABI of no less than 0.65).

Management of chronic wounds should include treating the underlying condition and co-morbidities, which might include optimizing blood glucose control in patients with diabetic ulcers, ensuring adequate nutrition status in debilitated patients, revascularization in patients with ischemic artery disease, and pain management.

In addition to the type of dressing used in treating chronic wounds, several common principles apply to the management of most chronic wounds:

- removal of dead and devitalized tissue which provides a nidus for bacterial infection (not colonization),
- aggressive antibiotic treatment of peri-wound and wound infections,
- mechanical measures which may favorably alter local hemodynamics or ameliorate adverse physical forces, (Most common are offloading and debridement for diabetic ulcers and compression for venous ulcers) and
- Optimization of general nutrition.

Expanded use of the products for other than closure of dermal wounds may be addressed in product specific articles.

### **Limitations:**

- Medicare would not expect to be billed for CPT codes 15002/15004 in conjunction with application of skin substitutes/replacements as applied to chronic wounds. Per CPT 2006 instructions (introductory comments to the "Skin Replacement Surgery and Skin Substitutes" chapter), minimal wound preparation is considered a part of the material application procedure.
- If a use is identified as not indicated by CMS or the FDA, or if it is determined, based on peer-reviewed medical literature, that a particular use of a product is not safe and effective, the indicated usage is not supported and therefore, the product is not covered for that indication.
- Regardless of the evidence supporting coverage for a particular use, payment may only be made if the use is reasonable and necessary for the treatment of the wound, burn, physiological or anatomic defect of the specific patient receiving the product.
- Services related to non-covered services are also not covered (e.g., application services).
- The automatic use of the CPT codes listed for the application of a particular product is inappropriate. The code selected should reflect the actual work involved in applying the product. This will be further defined in individual articles related to specific products.

## **Coding Information**

### **Bill Type Codes:**

**Contractors may specify Bill Types to help providers identify those Bill Types typically used to report this service. Absence of a Bill Type does not guarantee that the policy does not apply to that Bill Type. Complete absence of all Bill Types indicates that coverage is not influenced by Bill Type and the policy should be assumed to apply equally to all claims.**

12x	Hospital-inpatient or home health visits (Part B only)
13x	Hospital-outpatient (HHA-A also) (under OPPTS 13X must be used for ASC claims submitted for OPPTS payment -- eff. 7/00)
23x	SNF-outpatient (HHA-A also)
71x	Clinic-rural health
73x	Clinic - Free-standing
83x	Special facility or ASC surgery-ambulatory surgical center (Discontinued for Hospitals Subject to Outpatient PPS; hospitals must use 13X for ASC claims submitted for OPPTS payment -- eff. 7/00)
85x	Special facility or ASC surgery-rural primary care hospital (eff 10/94)
99x	Reserved-reserved for national assignment

### Revenue Codes:

**Contractors may specify Revenue Codes to help providers identify those Revenue Codes typically used to report this service. In most instances Revenue Codes are purely advisory; unless specified in the policy services reported under other Revenue Codes are equally subject to this coverage determination. Complete absence of all Revenue Codes indicates that coverage is not influenced by Revenue Code and the policy should be assumed to apply equally to all Revenue Codes.**

Revenue codes only apply to providers who bill these services to the fiscal intermediary. Revenue codes do not apply to physicians, other professionals and suppliers who bill these services to the carrier.

Please note that not all revenue codes apply to every type of bill code. Providers are encouraged to refer to the FISS revenue code file for allowable bill types. Similarly, not all revenue codes apply to each CPT/HCPCS code. Providers are encouraged to refer to the FISS HCPCS file for allowable revenue codes.

All revenue codes billed on the inpatient claim for the dates of service in question may be subject to review.

Revenue codes 096X, 097X and 098X are to be used only by Critical Access Hospitals (CAHs) choosing the optional payment method (also called Option 2 or Method 2) and only for services performed by physicians or practitioners who have reassigned their billing rights. When a CAH has selected the optional payment method, physicians or other practitioners providing professional services at the CAH may elect to bill their carrier or assign their billing rights to the CAH. When professional services are reassigned to the CAH, the CAH must bill the FI using revenue codes 096X, 097X or 098X.

036X	Operating room services-general classification
045X	Emergency room-general classification
049X	Ambulatory surgical care-general classification
051X	Clinic-general classification
0636	Drugs requiring specific identification-detailed coding (eff 3/92)
076X	Specialty Services - General Classification (effective 08/10/09)

## CPT/HCPCS Codes

XX000

Not Applicable

## ICD-9 Codes that Support Medical Necessity

It is the responsibility of the provider to code to the highest level specified in the *ICD-9-CM* (e.g., to the fourth or fifth digit). The correct use of an ICD-9-CM code listed below does not assure coverage of a service. The service must be reasonable and necessary in the specific case and must meet the criteria specified in this determination.

XX000

Not Applicable

## Diagnoses that Support Medical Necessity

## ICD-9 Codes that DO NOT Support Medical Necessity

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

## Diagnoses that DO NOT Support Medical Necessity

## General Information

### Documentation Requirements

The patient's medical record must contain documentation that fully supports the medical necessity for services included within this LCD. (See "Indications and Limitations of Coverage.") This documentation includes, but is not limited to, relevant medical history, physical examination, and results of pertinent diagnostic tests or procedures.

- The medical record documentation supporting medical necessity should be legible, maintained in the patient's medical record, and made available to Medicare upon request.
- Each claim must be submitted with ICD-9-CM codes that reflect the condition of the patient, and indicate the reason(s) for which the service was performed. Claims submitted without ICD-9-CM codes will be returned.

- The medical record documentation must confirm and support that all requirements set forth in the "Indications" section of this policy (and applicable article) have been satisfied with regards to the clinical characteristics of the ulcer, the presence of qualifying or disqualifying conditions, and the duration and intensity of pre-treatment conservative/conventional management.
- Documentation of response or lack thereof, requires measurement of the ulcer at baseline and following cessation of conservative or conventional management and must be included in the medical record. Documentation should also include measurement of the ulcer immediately prior to the placement of skin substitutes/replacements. Skin substitutes/replacements may be applied to wounds that have demonstrated a failed or insufficient response to no fewer than four weeks of conservative wound care measures. For initial applications of skin substitutes/replacements, a failed response to conservative measures is defined as an ulcer that has increased in size or depth or for which there has been less than 30% closure from baseline. For purposes of this LCD conservative treatment includes, but is not limited to: reduction or elimination of underlying cellulitis or other infection; reduction of edema; appropriate debridement of necrotic tissue; appropriate non-weight bearing and/or other means of off-loading pressure; and optimization of wound environment to promote healing.”
- The medical record must document that wound treatments with skin substitutes/replacements are accompanied by appropriate wound dressing changes during the healing period and by appropriate compressive dressings during follow-up, including, for neuropathic diabetic foot ulcers, appropriate steps to off-load wound pressure during the follow-up.
- The medical record documentation must clearly document the medical necessity and performance of the extent of site preparation procedures billed.
- Rationale for the selection of a biological product for surgical interventions in repair of anatomic defects or reconstruction work must be documented in the medical record and submitted to Medicare upon request.

### **Product Wastage Documentation Requirements**

Although a reasonable amount of product wastage is permitted, an exact amount of the tissue used per application should be documented in the patient's medical record with:

- Date and time.
- Amount of product used.
- Amount of product wasted.
- The reason for the wastage.

### **Appendices**

Not applicable

### **Utilization Guidelines**

Not applicable

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

AHRQ Technology Assessment. Usual Care in the Management of Chronic Wounds: A Review of the Recent Literature. 3/8/2005.

Brem H, Sheehan P, Boulton A. Protocol for treatment of diabetic foot ulcers. American Journal of Surgery. 2004;187:5:Supplement 1.

Callow AD, Ernst CB. Vascular Surgery: Theory and Practice. Stamford Appleton and Lange; 1995.

Horch RE, Kopp J, Kneser U, Beier J and Back AD. Tissue engineering of cultured skin substitutes. J Cell Mol Med. 2005; 19;3:592-608.

Li W, Dasgeb B, Phillips T, et al. Wound-Healing Perspectives. Dermatology Clinics. [serial on line]. 2005; 23:2.

Scott PG, Tredget EE. Skin construct or biological bandage? Comment. The Lancet. [serial on line]. 2005; 336:788-789.

Smeltzer SC, Bare BG, Cheever KH, Hinkle JL. Brunner & Suddarth's Textbook of Medical-Surgical Nursing. Biosynthetic and synthetic dressings. 10th ed. Lippincott Williams & Wilkins. 2004.

Supp D, Boyce S. Engineered skin substitutes: practices and potentials. Clinics in Dermatology. 2005; 23:403-412.

The FDA draft guidance document for the industry: chronic cutaneous ulcer and burn wounds - developing products for treatment. June 2006.

Ruszczak Z, Schwartz RA, Joss-Wichman E, Wichman R, Zalewska A. Surgical dressings. eMedicine. January 2009. <http://emedicine.medscape.com/article/1127868-overview> Accessed 08/27/2009.

Stillman R. Wound Care, eMedicine Clinical Knowledge Base, Institutional Edition, Surgery-General Surgery, June 24, 2005; <http://www.imedicine.com/printtopic.asp?bookid=6&topic=2754>. Accessed 08/24/2009.

### **Advisory Committee Meeting Notes**

02/22/2010

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

02/22/2010

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

04/07/2010

### **Start Date of Notice Period**

04/23/2010

### **Revision History Number**

R5

## Revision History Explanation

R5

06/07/2010

Added the word "State" to the following sentence under Indications of Coverage section: "The application of these products is defined by the procedure and the specific applicable State scope of practice."

Replaced the following language in documentation requirements: " A "failed response" is defined as an ulcer that has increased in size or depth, or for which there has been no change in baseline size or depth and no sign of improvement or indication that improvement is likely, such as granulation, epithelialization or progress toward closing" with the following language: Skin substitutes/replacements may be applied to wounds that have demonstrated a failed or insufficient response to no fewer than four weeks of conservative wound care measures. For initial applications of skin substitutes/replacements, a failed response to conservative measures is defined as an ulcer that has increased in size or depth or for which there has been less than 30% closure from baseline. For purposes of this LCD conservative treatment includes, but is not limited to: reduction or elimination of underlying cellulitis or other infection; reduction of edema; appropriate debridement of necrotic tissue; appropriate non-weight bearing and/or other means of off-loading pressure; and optimization of wound environment to promote healing."

R4

02/22/2010

Added J14 Part B Contractor numbers 14102, 14202, 14302, 14402, 14502.

Added the following CMS National Coverage Policy:

- CMS Transmittal No. 1664, Publication 100-04, Medicare Claims Processing Manual, Change Request #6315, January 9, 2009, January 2009 integrated outpatient code editor (I/OCE) specifications version 10.0.

Added the following new article:GRAFTJACKET® Regenerative Tissue Matrix-Ulcer Repair and GRAFTJACKET® XPRESS Flowable Soft Tissue Scaffold.

Updated all related articles: Oasis, Integra,Apligraf,Dermagraft, and Biologic Products

Bibliography updated

R3

06/05/2009 In accordance with Section 911 of the Medicare Modernization Act of 2003, J14 contractor numbers 14301-NH and 14501-VT were added. Prior to 06/05/2009 this policy was National Government Services (NGS) Part A LCD #L26003). No coverage changes were made. Only references to NGS were removed.

R2

06/01/2009- In accordance with Section 911 of the Medicare Modernization Act of 2003, J14 MAC-Part A - 14401 Contractor number (formerly Part A Pinnacle -00021) was added to this LCD.

R1

05/15/2009

Attachments added

05/15/2009 In accordance with Section 911 of the Medicare Modernization Act of 2003, J14 contractor numbers 14101-ME and 14201-MA were added. Prior to 05/15/2009 this policy was National Government Services (NGS) Part A LCD #L26003. No coverage changes were made. Only references to NGS were removed.

8/10/2009 - The description for Revenue code 0760 was changed

8/10/2009 - The description for Revenue code 0761 was changed

8/10/2009 - The description for Revenue code 0762 was changed

8/10/2009 - The description for Revenue code 0769 was changed

3/7/2010 - The description for Bill Type Code 73 was changed

### **Reason for Change**

Coverage Change (actual change in medical parameters)

Narrative Change

### **Last Reviewed On Date**

04/13/2010

### **Related Documents**

#### **LMRP(s)**

#### **Article(s)**

A48910 - Apligraf ®

A48793 - Biologic Products for Wound Treatment and Surgical Interventions - Supplemental Instructions Article

A48911 - Dermagraft ®

A49516 - GRAFTJACKET® Regenerative Tissue Matrix-Ulcer Repair and GRAFTJACKET® XPRESS Flowable Soft Tissue Scaffold – Related to LCD L29867

A49111 - Integra ® Dermal Regeneration Template, Integra ® Bilayer Matrix Wound Dressing – Related to LCD L29867

A49162 - OASIS® Wound Matrix and Oasis® Burn Matrix – Related to LCD L29867

#### **LCD(s)**

### **LCD Attachments**

Biologic Products (a comment and response document) (HTM - 9,132 bytes)

### **All Versions**

Updated on 04/14/2010 with effective dates 06/07/2010 - N/A