Novatas
Skin Sub LCD / LCA

Used as a Guide only

Noridian does not have an LCD or LCA

- **Autologous skin grafts,** also referred to as autografts, are permanent covers that use skin from different parts of the individual’s body. These grafts consist of the epidermis and a dermal component of variable thickness. A split-thickness skin graft (STSG) includes the entire epidermis and a portion of the dermis. A full thickness skin graft (FTSG) includes all layers of the skin. Although autografts are the optimal choice for full thickness wound coverage, areas for skin harvesting may be limited, particularly in cases of large burns or venous stasis ulceration. Harvesting procedures are painful, disfiguring and require additional wound care.

- **Allografts** which use skin from another human (e.g., cadaver) and **Xenografts** which use skin from another species (e.g., porcine or bovine) may also be employed as temporary skin replacements, but they must later be replaced by an autograft or the ingrowth of the patient's own skin.

- **Bioengineered Skin / Cultured Epidermal Autografts (CEA)** are autografts derived from the patient's own skin cells grown or cultured from very small amounts of skin or hair follicle. Production time is prolonged. One such product is grown on a layer of irradiated mouse cells, bestowing some elements of a xenograft. Wide spread usage has not been available due to limited availability or access to the technology.

- **Bioengineered** Skin Substitutes **or Cellular and Tissue Based Products (CTPs), referred to as** Skin Substitutes **by CMS, The Current Procedural Terminology (CPT) and The Healthcare Common Procedure Coding Manuals**, have been developed in an attempt to circumvent problems inherent with autografts, allografts and xenografts. These constitute biologic covers for refractory wounds with full thickness skin loss secondary to 3rd degree burns or other disease processes such as diabetic neuropathic ulcers and the skin loss of chronic venous stasis or venous hypertension. The production of these biologic skin substitutes or CTPs varies by company and product, but generally involves the creation of immunologically inert biological products containing protein, hormones or enzymes seeded into a matrix which may provide protein or growth factors proposed to stimulate or facilitate healing or promote epithelization.
- A variety of biosynthetic and tissue-engineered skin substitution products marketed as **Human Skin Equivalents (HSE) or Cellular or Tissue-based Products (CTP)** are manufactured under an array of trade names and marketed for a variety of indications. All are procured, produced, manufactured, processed and promoted in sufficiently different manners to preclude direct product comparison for equivalency or superiority in randomized controlled trials. Sufficient data is available to establish distinct inferiority to human skin autografts and preclude their designation as skin equivalence.

Bioengineered skin substitutes or **CTPs** are classified into the following types:

- **Human skin allografts** derived from donated human skin (cadavers)
- •
- **Allogeneic matrices** derived from human tissue (fibroblasts or membrane)
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- **Composite matrices** derived from human keratinocytes, fibroblasts and xenogeneic collagen
- **Acellular matrices** derived from xenogeneic collagen or tissue

- **Human Skin Allografts** are bioengineered from human skin components and human tissue which have had intact cells removed or treated to avoid immunologic rejection. They are available in different forms promoted to allow scaffolding, soft tissue filling, growth factors and other bioavailable hormonal or enzymatic activity.

- **Allogeneic Matrices** are usually derived from human neonatal fibroblasts of the foreskin that may contain metabolically active or regenerative components primarily used for soft tissue support, though some have been approved for the treatment of full-thickness skin and soft tissue loss. Most are biodegradable and disappear after 3-4 weeks implantation.

- **Composite Matrices** are derived from human keratinocytes and fibroblasts supported by a scaffold of synthetic mesh or xenogeneic collagen. These are also referred to as human skin equivalent but are unable to be used as autografts due to immunologic rejection or degradation of the living components by the host. Active cellular components continue to generate bioactive compounds and protein that may accelerate wound healing and epithelial regrowth.

- **Acellular Matrices** are derived from other than human skin and include the majority of bioengineered skin substitutes. All are composed of allogeneic or xenogeneic derived collagen, membrane, or cellular remnants proposed to simulate or exaggerate the characteristics of human skin. All propose to promote healing by the creation of localized intensification of an array of hormonal and enzymatic activity to accelerate closure by migration of native dermal and epithelial components, rather than function as distinctly incorporated tissue closing the skin defect.

- For the purpose of this LCD, consideration is given to the use of dermal or epidermal substitute tissue of human or non-human origin, with or without bioengineered or processed elements, with or without metabolically active elements, with a designated use as coverage for a superficial skin deficit that has persisted, despite optimal wound care for a period of 4 weeks or greater. These products are those referred to as **Human Cellular or Tissue Based Products (CTPs) or Skin Substitutes**.

- Evaluation of the clinical literature indicates that studies comparing the efficacy of bioengineered skin substitute to alternative wound care approaches with patients' autologous skin are limited in number, apply mainly to generally healthy patients, and examine only a small portion of the skin substitute products available in the United States. **Therefore, all products with U.S. Food and Drug Administration (FDA) clearance/approval or designated 361 HCT/P exemption used in accordance with that product's individualized application guidelines will be equally considered for the purpose of this LCD and may be considered reasonable and necessary.**

Human Cells, Tissues, and Cellular and Tissue-Based Products

- The FDA does not refer to any product or class of products as “;skin substitutes.” However, products commonly described as “;skin substitutes” are regulated by FDA under one of the four categories described below depending on the origin and composition of the product and listed as a “Skin Substitute” with a HCPCS code Q41XX.

- HCT/Ps are regulated by the Center for Biologics Evaluation and Research (CBER). The Center for Biologics Evaluation and Research is responsible for regulating biological and related products including blood, vaccines, allergenics, tissues, and cellular and gene therapies.

- Establishments producing HCT/Ps must register with FDA and list their HCT/Ps. HCT/Ps establishments are not required to demonstrate the safety or effectiveness of their products and FDA does not evaluate the safety or effectiveness of these products.

- **Premarket Approval** - Premarket approval (PMA) by FDA is the required process of scientific review to ensure the safety and effectiveness of Class III devices. Before Class III devices can be marketed, they must have an approved PMA application. Therefore, wound care products regulated under the PMA process will require evidence that they promote wound healing before they are approved for marketing.

- **510(k) Submissions** - According to FDA documents a "510(k) is a premarket submission made to FDA to demonstrate that the device to be marketed is at least as safe and effective, that is, substantially equivalent (SE), to a legally marketed device (21 CFR 807.92(a)(3)) that is not subject to PMA." Submitters must compare their device to one or more similar legally marketed devices and make and support their substantial equivalency claims. Unlike PMA, 510(k) confers reasonable assurance of safety and effectiveness via demonstration of substantial equivalence to a legally marketed device that does not require premarket approval. Therefore, wound care products regulated **under the 510(k) process will not typically require clinical evidence to establish effectiveness in wound healing**, as compared with products regulated under the PMA process in which substantial clinical evidence is always required.

- Currently, no product has demonstrated individual superiority for the treatment of diabetic foot ulcers (DFU) and venous leg ulcers (VLU) of the lower extremity, and, frequently such products are utilized inappropriately.

- Standard treatment of chronic lower extremity ulcers or skin loss (e.g., DFU or VLU) primarily includes infection and edema control, mechanical offloading, mechanical compression or limb elevation, debridement of necrotic or infected tissue, and management of concomitant and inciting medical issues (blood glucose control, tobacco use). Maintenance of a therapeutic environment with appropriate dressings to preclude further trauma facilitates development of healthy granulation tissue and encourages re-epithelialization.

- A wound that fails to show evidence of healing by contraction and advancement of epithelial margins following 4 weeks of optimization, including all aspects of standard therapy, is considered a chronic non-healing wound and falls into the auspices of this LCD

- The fundamental basis for non-healing of a wound is of paramount importance and must be corrected prior to consideration of additional therapy.

- The depth of skin loss is the determinant of its ability to return. Full thickness skin loss, implying the loss of all elements of the epidermis and dermis, will require re-epithelization of the surface once a clean granular base is established. Both full and partial thickness skin loss may benefit from enhanced products referred to as Skin Substitutes. Though no skin substitutes are capable of replacing the patient’s own skin, they have been demonstrated to allow scaffolding for the growth of epithelium, enzymatic cleansing and provision of growth factors beneficial to deficit reduction and re-epithelization

- This document addresses the management of chronic non-healing wounds or skin deficits of the lower extremities with the goal of wound and skin closure when standard or conservative measures have failed. While lower extremity ulcers have numerous causes such as burns, trauma, immobility, ischemia or other neurologic impairment, over 90% of the lesions are related to venous stasis disease and diabetic neuropathy. Therefore, the focus of this policy is the application of bioengineered skin substitute material to diabetic foot ulcers and venous leg ulcers of the lower extremities and the reasonable and necessary (R&N) threshold for utilization of skin substitutes. Particular emphasis is placed on the indications for application of bioengineered skin substitute material for DFU and VLU.

- Patients receiving a skin substitute graft must be under the care of a physician licensed by the state with full scope of practice for the treatment of the systemic disease process(es) etiologic for the condition (e.g., venous insufficiency, diabetes, neuropathy). This concurrent medical management and the identity of the managing medical physician shall be clearly discernable in the medical record and available upon request.

- Medicare coverage for wound care on a continuing basis, for a single wound, in an individual patient is contingent upon evidence documented in the patient's medical record that the wound is improving in response to the wound care being provided. Since it is neither reasonable nor medically necessary to continue a given type of wound care in the absence of wound improvement, it is expected that the wounds response to treatment will be documented in the medical record at least once every 30 days for each episode of wound treatment and made available to the contractor upon request.

- **Documentation of response** requires measurements of the initial ulcer, measurements at the completion of at least four weeks of appropriate wound care and measurements immediately prior to placement and with each subsequent placement of the bioengineered skin substitute or CTP.

- **Covered Indications**
- Chronic Wounds are defined as wounds that do not respond to standard wound treatment for at least a 30 day period during organized comprehensive conservative therapy.
- For all wounds, documentation (as outlined in the documentation requirements of the policy) and a comprehensive treatment plan, before initiation of a specialized wound therapy product is required.
- For purposes of this LCD a **Failed Response** is defined as an ulcer or skin deficit that has:
  - failed to respond to documented appropriate wound-care measures,
  - has increased in size or depth, or
  - has not changed in baseline size or depth and
  - has no indication that improvement is likely (such as granulation, epithelialization or progress towards closing).

- Medicare covers application of skin substitutes to Ulcers or Wounds with **Failed Response** that are:
- •
- Partial- or full-thickness ulcers, not involving tendon, muscle, joint capsule or exhibiting exposed bone or sinus tracts, with a clean granular base;
- •
- Skin deficit at least 1.0 square centimeter (cm) in size;
- •
- Clean and free of necrotic debris or exudate;
- •
- Have adequate circulation/oxygenation to support tissue growth/wound healing as evidenced by physical examination (e.g., Ankle-Brachial Index [ABI] of no less than 0.60, toe pressure greater than 30 millimeters of mercury [mmHg]);
- For diabetic foot ulcers, the patient’s medical record reflects a diagnosis of Type 1 or Type 2 Diabetes and also reflects medical management for this condition.

Medicare covers application of skin substitutes to Ulcers or Wounds with **Failed Response** that are:

- Partial- or full-thickness ulcers, not involving tendon, muscle, joint capsule or exhibiting exposed bone or sinus tracts, with a clean granular base;
- Skin deficit at least 1.0 square centimeter (cm) in size;
- Clean and free of necrotic debris or exudate;
- Have adequate circulation/oxygenation to support tissue growth/wound healing as evidenced by physical examination (e.g., Ankle-Brachial Index [ABI] of no less than 0.60, toe pressure greater than 30 millimeters of mercury [mmHg]);
- For diabetic foot ulcers, the patient’s medical record reflects a diagnosis of Type 1 or Type 2 Diabetes and also reflects medical management for this condition.

- Wound healing is impaired by the systemic use of tobacco. Therefore, ideally patients who have smoked will have ceased smoking or have refrained from systemic tobacco intake for at least 4 weeks during conservative wound care and prior to planned bioengineered skin replacement therapy.

Pre-Service Record

- Documentation (in the pre-service record) specifically addressing circumstances as to
- why the wound has failed to respond to standard wound care treatment of greater than 4 weeks and
- must reference specific interventions that have failed.
- Such record should include updated medication history, review of pertinent medical problems that may have occurred since the previous wound evaluation, and
- explanation of the planned skin replacement surgery with
- choice of skin substitute graft product.
- The procedure risks and complications should also be reviewed and documented.
- Documentation of smoking cessation counseling and cessation measures prescribed, if applicable, must also be documented in the patient's record.

Application of a skin substitute graft for lower extremity chronic wound (DFU and VLU) will be covered when the following conditions are met for the individual patient:

- **DFU**: Presence of neuropathic diabetic foot ulcer(s) having failed to respond to documented conservative wound-care measures of greater than four weeks, during which the patient is compliant with recommendations, and without evidence of underlying osteomyelitis or nidus of infection.

- **VLU**: Presence of a venous stasis ulcer for at least 3 months but unresponsive to appropriate wound care for at least 30 days with documented compliance.

- **Other type of wound**: Presence of a full thickness skin loss ulcer that is the result of abscess, injury or trauma that has failed to respond to appropriate control of infection, foreign body, tumor resection, or other disease process for a period of 4 weeks or longer.

- In all wound management the ulcer must be free of infection and underlying osteomyelitis with documentation of the conditions that have been treated and resolved prior to the institution of skin substitute therapy. For purposes of this LCD, appropriate therapy includes, but is not limited to:

  - Control of edema, venous hypertension or lymphedema
  - Control of any nidus of infection or colonization with bacterial or fungal elements
  - Elimination of underlying cellulitis, osteomyelitis, foreign body, or malignant process
  - Appropriate debridement of necrotic tissue or foreign body (exposed bone or tendon)
  - For diabetic foot ulcers, appropriate non-weight bearing or off-loading pressure
  - For venous stasis ulcers, compression therapy provided with documented diligent use of multilayer dressings, compression stockings of greater than 20 mmHg pressure, or pneumatic compression
  - Provision of wound environment to promote healing (protection from trauma and contaminants, elimination of inciting or aggravating processes)

The following are considered not reasonable and necessary and therefore will be denied:

- **Due to the propensity for misuse of skin substitute and biological dressing 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**

- Partial thickness loss with the retention of epithelial appendages is not a candidate for grafting or replacement, as epithelium will repopulate the deficit from the appendages, negating the benefit of overgrafting.

- Skin substitute grafts will be allowed for the episode of wound care in compliance with FDA guidelines for the specific product (see utilization guidelines) not to exceed 10 applications or treatments. In situations where more than one specific product is used, it is expected that the number of applications or treatments will still not exceed 10.

- Simultaneous use of more than one product for the episode of wound is not covered. Product change within the episode of wound is allowed, not to exceed the 10 application limit per wound per 12 week period of care.

- Treatment of any chronic skin wound will typically last no more than twelve (12) weeks.

- Repeat or alternative applications of skin substitute grafts are not considered medically reasonable and necessary when a previous full course of applications was unsuccessful. Unsuccessful treatment is defined as increase in size or depth of an ulcer or no change in baseline size or depth and no sign of improvement or indication that improvement is likely (such as granulation, epithelialization or progress towards closing) for a period of 4 weeks past start of therapy.

- Retreatment of healed ulcers, those showing greater than 75% size reduction and smaller than 0.5 square cm, is not considered medically reasonable and necessary.

- Skin substitute grafts are contraindicated and are not considered reasonable and necessary in patients with inadequate control of underlying conditions or exacerbating factors (e.g., uncontrolled diabetes, active infection, and active Charcot arthropathy of the ulcer extremity, vasculitis or continued tobacco smoking without physician attempt to affect smoking cessation).

- Skin substitute grafts are contraindicated in patients with known hypersensitivity to any component of the specific skin substitute graft (e.g., allergy to avian, bovine, porcine, equine products).

- Repeat use of surgical preparation services in conjunction with skin substitute application codes will be considered not reasonable and necessary. It is expected that each wound will require the use of appropriate wound preparation code at least once at initiation of care prior to placement of the skin substitute graft.

- Re-treatment within one (1) year of any given course of skin substitute treatment for a venous stasis ulcer or (diabetic) neuropathic foot ulcer is considered treatment failure and does not meet reasonable and necessary criteria for re-treatment of that ulcer with a skin substitute procedure.

Other Specialized Wound Treatment Therapies

- CMS has guidance regarding other specialized wound treatment technology and specifically addresses platelet rich plasma systems (e.g., Autologet, Magellan); negative pressure wound therapy devices and electro-magnetic/ultrasound/mist therapies. They are not addressed in this LCD as their role in the treatment of the two major types of lower extremity wounds discussed here is limited. For more information on negative pressure wound therapy please see L35125-Wound Care. Utilization remains at the provider's discretion and must be reasonable and necessary. Note that combination therapy with any bioengineered skin substitute (CTP) will be considered not reasonable and necessary. **Please Note: Autologous Platelet Rich Plasma (PRP) systems used in the treatment of Chronic Non-Healing Wounds is not considered reasonable and necessary except as described in National Coverage Determination (NCD) for Blood-Derived Products for Chronic Non-Healing Wounds (270.3). Please refer to the NCD for coverage details.**

Documentation Requirements

- 1. All documentation must be maintained in the patient's medical record and made available to the contractor upon request.

- 2. Every page of the record must be legible and include appropriate patient identification information (e.g., complete name, dates of service[s]). The documentation must include the legible signature of the physician or non-physician practitioner responsible for and providing the care to the patient.

- 3. Medical record documentation must support the medical necessity of the services as stated in this policy.

- 4. The documentation must support that the service was performed and must be included in the patient's medical record. This information is normally found in the history and physical, office/progress notes, hospital notes, and/or procedure report.

- 5. The medical record must clearly show that the criteria listed under the Covered Indications and Limitations sections have been met, as well as, the appropriate diagnosis and response to treatment.

- 6. The documentation must support the need for skin substitute application and the product used.

Documentation Requirements

- 7. A description of the wound(s) must be documented at baseline (prior to beginning conservative treatment) relative to size, location, stage, duration, and presence of infection, in addition to type of treatment given and response.•
  - This information must be updated in the medical record throughout treatment.
  - Wound description must also be documented pre and post treatment with the skin substitute graft being used.
  - If obvious signs of worsening or lack of treatment response is noted, continuing treatment with the skin substitute would not be considered medically reasonable and necessary without documentation of a reasonable rationale for doing so.

- 8. Documentation of smoking history, and that the patient has received counseling on the effects of smoking on surgical outcomes and treatment for smoking cessation (if applicable) as well as outcome of counselling must be in the medical record.

- 9. The amount of utilized and wasted skin substitute must be clearly documented in the procedure note with the following minimum information:
  - Date, time and location of ulcer treated;
  - Name of skin substitute and how product supplied;
  - Amount of product unit used;
  - Amount of product unit discarded;
  - Reason for the wastage;
  - Manufacturer’s serial/lot/batch or other unit identification number of graft material. When manufacturer does not supply unit identification, record must document such.

- **Note:** Novitas expects that where multiple sizes of a specific product are available, the size that best fits the wound with the least amount of wastage will be utilized. Please refer to article A54117 for coding/billing instructions regarding drug wastage.

Additional Information

- Please see the article A54117, Billing and Coding: Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds, for additional information.
- It is the expectation that a specific skin substitute product will be used for the episode of each documented wound, and in compliance with FDA assessments and submitted guidelines for the specific product.
- Greater than ten (10) applications for the treatment of a single wound within a 12-week period of time will be considered Not Reasonable and Necessary and will be subject to review.
- Separately billed repeated use of the skin substitute after 12 weeks for a single wound or episode is non-covered.
- Alternative or additional skin substitute products used within the 12 week initial wound episode are similarly non-covered when the sum of applications of all Skin Substitutes is greater than ten (10) for a single wound.
- The utilization of bioengineered skin substitute non-compliant with medical necessity or designated guidelines for that specific product may necessitate review or non-coverage as not medically necessary.
- Labeling for most skin substitute grafts include language suggesting multiple applications; however, Medicare does not expect that every ulcer in every patient will require the maximum number of applications listed on the product label or allowed for reimbursement.
- Utilization rates that exceed peer norms, identified through data analysis may prompt prepayment or post payment medical review.

Comments

- This LCD was written by Novatas.
- It was removed because of a united response by wound care advocates; doctors, manufacturers, wound care centers, writers, scientists and patient advocates

- We can use sections of the LCD to guide us in the thinking of CMS.

- The prior slide should be taken as suggestions, not as a threat of denial. Documentation of Medical Necessity will be the rule.

- Documentation of improvements should allow the continued use of the grafts. Excessive use will not pass audit.