Open meeting skin substitute draft LCD speaking points

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Coverage Guidance

Coverage Indications, Limitations, and/or Medical Necessity

Compliance with the provisions in this LCD may be monitored and addressed through post payment data analysis and subsequent medical review audits.

History/Background and/or General Information

This LCD addresses the medically reasonable and necessary threshold for coverage of SKIN replacement surgery for application of SKIN substitute grafts for diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs).

Application of SKIN substitute grafts for wound care indications other than for DFU or VLU are not addressed by this LCD. Use of SKIN substitute grafts must meet the medically reasonable and necessary threshold for coverage and these devices must be used in accordance with their approved United States (U.S.) Food and Drug Administration (FDA) intended use.

Chronic wounds of the lower extremities, including venous stasis ulcers, DFUs and pressure sores, are a major public health problem. While lower extremity ulcers have numerous causes such as burns, trauma, mixed venous-arterial disease, immobility, and vasculitis, nutritional or other neuropathy, over 90% of the lesions in the U.S. are related to venous stasis disease and diabetic neuropathy.

Generally, depending on the purpose of the product and how it functions, SKIN substitutes are regulated by the FDA premarket approval (PMA) process, FDA 510(k) premarket notification process, or the FDA regulations for human cells, tissues, and cellular and tissue-based products (HCT/Ps)…………………………………………………………………………………………………………………………

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Coverage Guidance (continued)

It is the expectation that a specific SKIN substitute graft product will be used for the episode of SKIN replacement surgery forwound care (defined as 12 weeks from the first application of a SKIN substitute graft) assuming its use is not in conflict with the FDA assessments (e.g., indications, contraindications, how supplied and directions for use, etc.) and/or the American Association of Tissue Banks (AATB) approved use and assuming there is one related wound. Repeat application of a Skin substitute graft within the 12-week episode of SKIN replacement surgery for wound care may be appropriate per the package insert based on wound re-assessment and must be supported in the medical record documentation for that encounter. Additional applications of a SKIN substitute product beyond the 12-week episode of SKIN replacement wound care are not expected if the wound has responded to the SKIN replacement surgery with epithelialization and other progression. This LCD does not endorse particular products for separate payment. The medical record documentation must support the medical necessity for SKIN replacement surgery and that the product is being used within its approved FDA indications.

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Covered Indications

SKIN substitute grafts utilized per the approved FDA intended use.

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Limitations

The following are considered not medically reasonable and necessary:

1. Greater than two applications of a specific SKIN substitute graft product within the episode of SKIN replacement

surgery for wound care (defined as 12 weeks from the first application of a SKIN substitute graft).

The expectation is treatment will consist of the fewest repeat applications and amount of product to heal the wound. It is expected that products are used per the labeling. It is not expected that every ulcer, in every patient will require the maximum number of applications listed on the product label. This utilization pattern may be subject to focused medical review.

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Clinical Trials for SKIN Substitutes for Diabetic Foot Ulcer

Barbul et al conducted a retrospective, matched-cohort study to establish the efficacy of a cryopreserved human bioactive split-thickness SKIN allograft (BSA) (i.e., TheraSkin) plus SOC when contrasted to SOC alone for the treatment of diabetic ulcers.

Cazzell et al performed a prospective, randomized, controlled, open-label trial with a primary objective to contrast the healing rates of a human decellularized acellular dermal matrix (D-ADM) for chronic DFUs with a SOC arm and an active comparator, human acellular dermal matrix (ADM) arm for the treatment of DFUs. Secondary objectives studied differences in time to wound closure, economic burden, quality of life questionnaires and product utilization between D-ADM, SOC, and a second active comparator human ADM.

Driver et al conducted The Foot Ulcer New Dermal Replacement Study (FOUNDER) to assess the safety and effectiveness of the Integra Dermal Regeneration Template (IDRT) (i.e., Omnigraft Dermal Regeneration Matrix) for the treatment of nonhealing DFUs.

Lavery et al performed a prospective, multi-center, randomized, single-blinded study to contrast the effectiveness of a human viable wound matrix (hVWM) (i.e., Grafix) to standard wound care in treating chronic DFUs from May 2012 to April2013.

Sanders et al performed a prospective, multi-center, randomized, controlled trial to contrast an in vitro-engineered, humanfibroblast-derived dermal SKIN substitute (HFDS) (i.e., Dermagraft) to a biologically active cryopreserved human SKIN allograft (HSA) (i.e., TheraSkin) in the treatment of DFUs. The primary objectives were to establish the relative number of DFUs healed (100% epithelization without drainage) and the number of grafts needed by week 12. Secondary objectives involved the percentage of DFUs healed at weeks 16 and 20, time to heal during the study and wound size progression.

Zelen et al performed a prospective, randomized, controlled, multicenter study to evaluate the healing rates, safety, and cost using an open-structure human reticular acellular dermis matrix (HR-ADM) (i.e., AlloPatch Pliable™) plus SOC to facilitate wound closure in DFUs compared to treatment with SOC alone.

Cazzell conducted a multicenter, randomized, controlled, open-label trial designed to evaluate the safety and efficacy of human decellularized acellular dermal matrices (D-ADM) contrasted with SOC management in patients with chronic VLUs.

Harding et al conducted an open label, prospective, multicenter, randomized controlled study that assessed the human fibroblast-derived dermal substitute (HFDS) (i.e., Dermagraft) in addition to four-layer compression therapy contrasted with compression therapy alone in the treatment of VLUs.

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Analysis of Evidence (Rationale for Determination)

Despite the lack of studies, the moderate to low quality of current research and the likelihood of bias, coverage has been provided to increase the chances of improved health outcomes of interest which include patient quality of life and function. Coverage will be provided for products in the associated billing and coding guideline meeting the necessary FDA regulatory requirements as of publication. Each product has specific designated approved usage

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Article Guidance

Coding Guidance

Application codes billed must use the appropriate modifier (e.g., RT, LT) to identify the location where the skin substitute was applied, or the service will be denied.

Utilization Parameters

Application frequency must follow the product labeling. A maximum of two skin substitute graft product applications per wound will be allowed for the episode of skin replacement surgery for wound care (defined as 12-weeks from the first application of a skin substitute graft) for those products recommended per the labeling to require a second application.

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ICD-10-CM Codes that Support Medical Necessity

Group 1

L97.5- Non pressure chronic ulcer of foot (would include forefoot i.e. toe)