UPDATES ON CGS MEDICARE

NOVEMBER 16 2024

OHFAMA ANNUAL BUSINESS MEETING

ANIMESH BHATIA DPM

CARRIER ADVISORY REP TO CGS MEDICARE

CMS MACS RELEASE LCD ON SKIN SUBSTITUTES/CTP EFFECTIVE 2/12/2025

•The term 'Failure to respond' has been replaced with the phrase '50% ulcer area reduction.' Clarification of documentation requirements, additional definitions and other clarifying language added as recommended by commenters.

Ankle-Brachial Index (AB) was replaced with vascular assessment, uncontrolled diabetes removed examples of contraindications and Class III compression requirement removed.

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Language added to clarify that standard of care is expected to be continued throughout the course of treatment.

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Application limit expanded from 4 to 8 and duration increased from 12 to 16 weeks based on submitted literature, comments received, and recommendations from SMEs.

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Use of the KX-modifier is added as an attestation of medical necessity for use over 4 applications.

Further description of wastage documentation requirements added to the B & C article.

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Clarified use of product over exposed muscle, tendon, or bone when consistent with the labeled indication. The relevant ICD-10-CM codes were added to B & C article.

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Additional references were added to section on product classification and further clarification of porcine dressings were detailed in the LCD.

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Four systematic reviews and a new section entitled "Real World Evidence"(RWE) with summary of previous and newly submitted RWE were added to evidence review section.

Additional literature was added for to product section for Apis, Derma-Gide, DermaPure, Grafix, Kerecis, NuShield, Phoenix wound Matrix, PuraPly AM, Restrata, Supra SDRM, and Theragenesis (Pelnac). Derma-Gide, Kerecis and NuShield were added to the DFU covered list.

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The product Oasis Tri-Layer Wound was found to have insufficient evidence for coverage in DFUs and VLUs, therefore, it was removed from tables 1 & 2 and placed in table 3 in the LCD.

- The evidence for DFU and VLU was placed in separate tables and corresponding sections of the B&C article to ensure clarity that coverage is based on evidence for the indication in which has been studied.

- Additional literature added to the Societal Guidance section.

- Analysis of Evidence section expanded and provides further discussion on the limitations of the current body of literature, clarity on the methodology utilized to assess the literature, and explanation for the above changes. Multiple published sources to aid investigators in development of high-quality future studies have been added as requested by Stakeholders.

- Additional ICD-10-CM codes with clarifications were added to Billing and Coding Article.

- List of 17 Products approved for DFU
- KERECIS OMEGA3 MARIGEN SHIELD,
- INTEGRA DERMAL REGENERATION TEMPLATE (DRT) OR INTEGRA OMNIGRAFT DERMAL REGENERATION MATRIX,
- GRAFTJACKET,
- PRIMATRIX,
- THERASKIN,
- DERMACELL, DERMACELL AWM OR DERMACELL AWM POROUS, FLEX HD, OR ALLOPATCH HD,
- GRAFIX PRIME, GRAFIXPL PRIME, STRAVIX AND STRAVIXPL,
- KERECIS OMEGA3,
- AFFINITY,
- NUSHIELD,
- EPICORD,
- DERMA-GIDE,
- APLIGRAF,
- OASIS WOUND MATRIX,
- DERMAGRAFT,
- AMNIOBAND OR GUARDIAN,
- EPIFIX,

List of 5 products approved for VLU

APLIGRAF,

OASIS WOUND MATRIX,

DERMAGRAFT,

AMNIOBAND OR GUARDIAN,

EPIFIX