Proposed LCD for Billing and Coding of Skin substitutes for the treatment of diabetic foot ulcers and venous leg ulcers (DL35041, DL36377) speaking points

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Goals of HHS & CMS1

* HHS: The mission of the U.S. Department of Health and Human Services (HHS) is to enhance the health and well-being of all Americans, by providing for effective health and human services and by fostering sound, sustained advances in the sciences underlying medicine, public health, and social services
* CMS: Establishing better coordination & communication between CMS, its contractors & health care providers

The proposed LCD goes against Patient and Clinician Evidence Driven Wound Care Treatment and thus against the above goals of HHS & CMS

Points of concern:

1. The guidance to use the smallest size should not be inadvertently translated into use the smallest size to fit any wound size. Rather, the meaning of “smallest” should be clarified to be in proportion of the size of a wound to achieve the maximum increment of closure in between applications, and following a final application for complete closure, to be determined by the sound judgement of a clinician for the interest of his/her patient’s wound closure. “As directed by CMS in L35041…Where multiple sizes of a specific product are available, the size that best fits the wound with the least amount of wastage will be utilized2.”
2. The number of applications within a period of weeks should consider the progression of a wound’s closure which in turn depends on the wound’s type and initial size of a wound as well as the patient’s medical case to be evaluated by his/her clinician using the IFU as an aid. A fixed number of applications allowable within those weeks runs risks of replacing sound clinical practices.

* “As directed by CMS in L35041…Skin substitute grafts will be allowed for the episode of wound care in compliance with FDA guidelines for the specific product 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… in a period of 12 weeks2.”
* Restricting the number of applications within the 12 weeks, is probably not the best clinical decision or “runs risks of replacing sound clinical practices” as it goes against existing clinical evidence. Wound healing outcomes were assessed in large propensity-matched cohorts in patients receiving advanced treatment (AT) with skin substitutes for lower extremity diabetic ulcers obtained from The Medicare Limited Dataset (1 October 2015 through 2 October 2018). The average number of applications was found to be 3.7 if followed according to IFU instructions3.
* Level 1 (multiple randomized controlled trials and systematic reviews) and real-world evidence demonstrate that repeated application can result in improved probability of wound closure or reduction in wound size, significant reductions in major and minor amputation, ED use, hospital readmission, cost of care, ulcer recurrence and mortality3,4. (See examples below-Fig.15,6: If restricted to two applications there is no difference in outcome when compared to no application). Following IFU parameters to achieve these results and not restricting number of applications against clinical judgement or existing practice is essential to achieve these results3. However, repeat or alternative applications of skin substitute grafts should not be considered medically reasonable and necessary when a previous full course of applications was unsuccessful2. 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 therapy2. Retreatment of healed ulcers, those showing greater than 75% size reduction and smaller than 0.5 square cm, is also not considered medically reasonable and necessary2.

1. LCD proposed Skin Substitutes limits are unclear but perceived to be only DFU and VLU as medically necessary – If this is the case, all other wound types will no longer be covered; example burns, or Pressure Ulcers/Injury

REFERENCES

* Centers for Medicare & Medicaid Services. The 11th SoW was designed to improve health and health care for all Medicare beneficiaries and promote quality of care to ensure the right care at the right time, every time. https://www.cms.gov/Medicare/Quality-Initiatives-Patient-Assessment-Instruments/QualityImprovementOrgs/Current
* Centers for Medicare & Medicaid Services. Application of Bioengineered Skin Substitutes to Lower Extremity Chronic Non-Healing Wounds. https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?LCDId=35041
* Armstrong DG, Tettelbach WH, Chang TJ, et al. Observed impact of skin substitutes in lower extremity diabetic ulcers: lessons from the Medicare Database (2015-2018). J Wound Care. Jul 1 2021;30(Sup7):S5-S16.
* DaVanzo J, Hartzman A, Surfield C, Dobson A. Cryopreserved placental membrane allograft reduces the likelihood of developing a new or recurring foot ulcer and all-cause mortality in diabetic patients, when compared to other cellular- and tissue-based products. Adv Wound Care (New Rochelle). Mar 9 2022.
* Lavery LA, Fulmer J, Shebetka KA, et al. The efficacy and safety of Grafix((R)) for the treatment of chronic diabetic foot ulcers: results of a multi-centre, controlled, randomised, blinded, clinical trial. Int Wound J. Oct 2014;11(5):554-560.
* Bianchi C, Cazzell S, Vayser D, et al. A multicentre randomised controlled trial evaluating the efficacy of dehydrated human amnion/chorion membrane (EpiFix((R)) ) allograft for the treatment of venous leg ulcers. Int Wound J. Feb 2018;15(1):114-122.

