

Kerecis included on the list of covered products for Diabetic Foot Ulcers in the final LCD policy

On 14 November 2024, the U.S. Centers for Medicare & Medicaid Services (CMS) issued a final Local Coverage Determination (LCD)¹ policy regarding skin substitute grafts/cellular and tissue-based products for the treatment of Diabetic Foot Ulcers (DFUs) and venous leg ulcers (VLUs) in the Medicare population.

The final LCD policy confirms the introduction of a technical qualification and a clinical efficacy qualification, proposed in a draft LCD policy² earlier this year. The final decision also introduces two separate lists for covered products for DFUs and covered products for VLUs. In addition, the application limit has been expanded from 4 to 8 and the duration of treatment has been increased from 12 to 16 weeks in the final policy. The implementation date of the final policy is set to 12 February 2025.

Based on the final evaluation, Kerecis is included on the final list of covered products for DFUs, however, Kerecis has not been included on the covered list for VLUs. Sales related to VLUs in the out-patient setting currently represent a low-single digit portion of the total Kerecis' sales. Kerecis has an ongoing clinical study on VLUs and will attempt to get coverage for VLUs as soon as the study is completed.

Coloplast's financial guidance for FY 2024/25 with organic growth of 8-9% and an EBIT margin before special items of around 28% is unchanged.

The financial assumptions for Kerecis with a 3-year CAGR of around 30% until 2025/26 and an EBIT margin of around 20% (ex. PPA amortization) in FY 2025/26 are also unchanged. Once the policy is implemented, we expect loss of sales related to VLUs in the out-patient segment. At the same time, given that a significant number of products are removed from the covered list for DFUs, we expect sales growth to accelerate in this segment, therefore offsetting the loss of sales related to VLUs.

1. [LCD - Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers \(L39764\)](#)
2. [Proposed LCD - Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers \(DL39764\) \(cms.gov\)](#)

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Coloplast was founded on passion, ambition, and commitment. We were born from a nurse's wish to help her sister and the skills of an engineer. Guided by empathy, our mission is to make life easier for people with intimate healthcare needs. Over decades, we have helped millions of people to live a more independent life and we continue to do so through innovative products and services. Globally, our business areas include Ostomy Care, Continence Care, Advanced Wound Care, Interventional Urology and Voice and Respiratory Care.

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