

Coloplast notes CMS' decision to withdraw the Local Coverage Determinations (LCDs) for skin substitutes in the out-patient setting

On December 24, 2025 the US Centers for Medicare and Medicaid Services (CMS) announced that its A/B Medicare Administrative Contractors (MACs) would withdraw the proposed new Local Coverage Determinations (LCDs) limiting the use of skin substitute grafts/cellular and tissue-based products for the treatment of diabetic foot ulcers, venous leg ulcers and various other wound types in the outpatient setting. These LCDs had been published on December 15, 2025¹, with an intended effective date of January 1, 2026, but have now been cancelled prior to implementation.

In summary the current Kerecis status in the outpatient setting is the following:

- The current LCDs at MACs such as CGS, Novitas and FCSO remain in place (the "Legacy Policies").
- The announced \$127/cm² pricing policies will go live on January 1, 2026^{2,3}.
- The now cancelled LCD had restricted coverage for various "other" types of wounds, which now remain covered. Those include for example pressure ulcers & surgical wounds that have failed 30-day conservative care.
- Frequency will remain 10 applications and not 8 as proposed in the cancelled policy.
- Approximately 20% of Kerecis total revenue comes from the outpatient setting and remains covered by Medicare.

Operating under the Legacy Policies over the past years has enabled Kerecis to build a significant market position in the outpatient setting covered by Medicare. The December 24th announcement confirms that these policies will continue, preserving the broader coverage framework under which Kerecis has successfully grown.

With an average outpatient Medicare price of \$110/cm², Kerecis remains well-positioned to compete in the out-patient setting once the new fixed payment rates take effect. Importantly, the continued applicability of the Legacy LCDs allows Kerecis to serve a wider range of wound types, including pressure ulcers and surgical wounds, rather than being limited solely to diabetic and venous foot ulcers.

While Kerecis performance in financial year 2025/26 remains subject to a higher degree of volatility due to these CMS announcements, we view the payment change as positive for the market and Kerecis in the long-term.

1. [Final Local Coverage Determinations \(LCDs\) for Certain Skin Substitutes Withdrawn](#)
2. [Calendar Year \(CY\) 2026 Medicare Physician Fee Schedule Final Rule \(CMS-1832-F\) | CMS](#)
3. [Calendar Year \(CY\) 2026 Medicare Hospital Outpatient Prospective Payment \(CMS-1834-FC\) | CMS](#)

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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, Voice and Respiratory Care, Wound and Tissue Repair and Interventional Urology.

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