

# Real-World Outcomes of a Placenta-Based Tissue Product Versus Standard of Care for Lower Extremity Diabetic Ulcers: A Medicare Cohort Study

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## INTRODUCTION

Hard-to-heal wounds affect more than 10 million Americans and generate an estimated \$20–30 billion in annual Medicare costs.<sup>1,2</sup> These chronic wounds impose a significant clinical and economic burden, leading to reduced mobility, lower quality of life, infection, and increased risk of amputation. Lower extremity diabetic ulcers (LEDUs), in particular, pose a growing public health concern due to their high morbidity, mortality, and treatment expenses. Despite following evidence-based standard of care (SoC) measures, which incorporate perfusion, offloading, infection control, and surgical debridement, healing outcomes often remain limited. Cellular, acellular, and matrix-like products (CAMPs), including placental-derived allografts, have emerged as adjunctive therapies, showing potential to improve outcomes. This study examined real-world outcomes of a dual-layer amniotic membrane (DLAM; Artacent Wound and Artacent AC, Tides Medical, Lafayette, LA, US) compared with debridement alone in Medicare beneficiaries with LEDUs.

## METHODS

A retrospective cohort analysis was performed using Centers for Medicare & Medicaid Services (CMS) Research Identifiable Files from 2020–2023. Episodes of care (EOCs) were defined by 60-day claim-free intervals. Beneficiaries with diabetes who received DLAM were matched 1:1 to SoC

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## METHODS

controls (n = 622 per group) on six baseline covariates: age, sex, frailty, episode year, time-to-treatment, and ulcer size. Outcomes included major and minor amputations, inpatient admissions, emergency department (ED) visits, hospital readmissions, and skilled nursing facility (SNF) admissions.

## RESULTS

In regard to major amputations, EOCs that included DLAM had a 2.6 % amputation rate compared with 5.6 % among SoC episodes, representing a 54 % relative risk reduction (RR 0.46; p = 0.0066). Thus, adjunctive DLAM use statistically prevented one major amputation for every 32 patients treated (NNT = 32). DLAM-treated cohorts also demonstrated significantly fewer inpatient admissions (479 vs 662 per 1000



Application of a donated Artacent AC graft by an Amanaki Fo'ou physician to a hard-to-heal lower-extremity diabetic ulcer at the Vaiola Hospital Diabetic Clinic, Kingdom of Tonga (July 17, 2025).



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## RESULTS

EOCs; p = 0.0010), ED visits (535 vs 690 per 1000; p = 0.011), and SNF admissions (84 vs 135 per 1000; p = 0.05). These benefits remained consistent across frailty subgroups and sensitivity analyses.

## CONCLUSION

Use of DLAM alongside SoC was linked to significantly lower major amputation rates and decreased use of healthcare resources among Medicare beneficiaries with LEDUs. These findings provide robust real-world evidence that placental-derived allografts are an effective adjunctive therapy that may lessen both clinical and economic burdens in this high-risk population.

### References

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