

■ ABSTRACT

Comparative outcomes of a placenta-based tissue product to other LCD covered cellular and matrix-based products for the treatment of lower extremity diabetic ulcers: A Medicare real world evidence study

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Abstract

Objective: To compare clinical and economic outcomes of the Artacent placental allograft to 18 other covered cellular and matrix-based products (CAMPs) using data from a Medicare database. **Methods:** We conducted a retrospective cohort study using data from the Centers for Medicare and Medicaid Services (CMS), employing a 1:1 matching procedure based on six pre-specified baseline covariates for Medicare patients who received Artacent or 18 other covered CAMPs for the treatment of lower extremity diabetic ulcer (LEDUs) between 2020 and 2023. LEDU episodes were constructed from claims data by linking sequential services until a 60-day clean period without LEDU related claims was observed, which signified the end of an episode. Outcomes assessed within each completed episode included major and minor amputations, as well as emergency department visits, hospital readmissions, or care transitions to other sites of service. **Results:** A total of 2,226,571 episodes were identified in the CMS database, of which 1,192 LEDU episodes (596 in each cohort) met the study eligibility criteria and were analyzed. Rate of major and minor amputation in the Artacent group was 2.7% and 13.6% respectively as compared to 3.4% and 14.8% in the pooled CAMP group ($p = 0.498$ and 0.561 respectively). Visits or re-admissions to a hospital were also lower in the Artacent group; however, the results were not statistically significant. **Conclusion:** Analysis of CMS data revealed similar outcomes when comparing Artacent placental allograft to 18 other covered CAMPs available on the market. It is reasonable to conclude that Artacent may be integrated into the treatment paradigms for LEDUs.

Conflicts of interest: Travis Tucker and Kim Kot are consultants to Tides Medical (Lafayette, LA, USA). William Tettelbach has declared that no financial support was received from any organization for the submitted work.

Data availability statement: The data used in this study were obtained from the Centers for Medicare & Medicaid Services (CMS) Virtual Research Data Center (VRDC) under a data use agreement. These Research Identifiable Files (RIF) contain

protected health information and are not publicly available. Access to the data requires CMS approval and an active Data Use Agreement.

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