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RESEARCH ARTICLE

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.

Introduction

Diabetes continues to be a growing health concern in the United States with an increase in prevalence from 11.1% to 14.7% (38.1 million people at or over the age of 18) in the span of 10 years.[1] One of the major complications affecting approximately 34% of patients with diabetes is lower extremity diabetic ulcers (LEDUs) which, due to an increased likelihood of infection, may lead to approximately 20% of this patient population to require hospitalization to undergo lower limb amputation.[2] These complications not only adversely affect the quality of life for patients with diabetes, but also place a substantial burden on the healthcare system. In 2019 alone, Medicare expenditure exceeded an estimated $22.5 billion on chronic wound management with the majority of costs being attributed to hospital services for ongoing wound care.[3] Furthermore, according to the Agency for Healthcare Research and Quality (AHRQ) report published in 2020, hospital admissions cost on average $14,500 with readmissions costing 12.5% more at $16,300.[4] Finally, amputation costs have both short-term and long-term costs association with short-term costs exceeding $60,000 while long-term costs are in excess of $200,000.[5]

Use of advanced wound care therapies, including cellular and matrix-based products (CAMPs), have demonstrated improved healing rates when applied to chronic LEDUs, establishing these products as a potential option for LEDUs which have failed to heal with standard of care (SOC) alone.[6-11] Recently, a network meta-analysis demonstrated a higher probability of wound healing for placenta-based tissue products as compared to other advanced wound therapies.[12] Artacent Wound (Q4169) and Artacent AC (Q4190) are placental allografts developed by Tides Medical that are minimally manipulated and preserve the native characteristics of amniotic tissue. The human amniotic membrane - in which these products are derived - consists of multiple layers (epithelial cells, a basement membrane, and a stromal matrix) which provide a natural scaffold enabling cellular attachment or infiltration and growth factor storage.

A systematic review assessed several treatment options for LEDUs ranging from wound dressings to advanced therapies such as CAMPs or other skin substitutes in order to provide recommendations on the use of these various interventions for the treatment of diabetic foot ulcers (DFUs).[6] The review conducted by the International Working Group on the Diabetic Foot (IWGDF) recommends consideration of placenta-based tissue products as an adjunct to SOC for patients with chronic LEDUs which have failed to heal with SOC alone.[6] Although research of these interventions has significantly increased over the years leading to considerations such as these, there is still limited evidence of the economic and comparative performance of CAMPs.[8]

The Centers for Medicare & Medicaid Services (CMS) has proposed updates to Local Coverage Determinations (LCDs) across all Medicare Administrative Contractors to establish consistent, evidence-based policies for CAMPs in the management of LEDUs. Under the proposed framework, 18 products would remain covered for LEDUs, while all other products must demonstrate sufficient clinical benefit, supported by randomized trials or real-world evidence (RWE), to be considered for Medicare coverage.[13] Building on this proposed framework, the purpose of the present study was to assess the clinical and economic implications of integrating Artacent placental allografts into the treatment paradigm for LEDUs. Artacent was compared directly to the group of 18 CMS covered products, thereby evaluating whether its use could improve patient outcomes and reduce healthcare burden similar to the 18 CAMPs considered covered by the future effective LCDs (L35041).[13]

Methods

Data source

We conducted a retrospective cohort study using the Centers for Medicare & Medicaid Services (CMS) Research Identifiable Files (RIF) accessed via the Virtual Research Data Center (VRDC). Data included the Carrier, Outpatient, Inpatient, MedPAR, Home Health, and Master Beneficiary Summary Files (MBSF). The data was reviewed to analyze patients who received care for an LEDU between the years 2020 and 2023. Claims were reviewed using the International Classification of Diseases, Tenth Revision, Clinical Modification (ICD-10-CM) diagnosis codes to ensure inclusion of patients with a confirmed LEDU who either received Artacent Wound/AC or a list of other included CAMP products (*Table 1*). Patients included in the study had to have a confirmed diagnosis of diabetes (Type I or II) either during or within an episode of care (EOC). An EOC was defined by the presence of an initial claim for an LEDU that was preceded by a 60-day clean period without any LEDU-related claims. We defined a new episode whenever a patient began treatment for a wound after at least 60 days without related claims. Each episode captured a distinct period of active care, and any subsequent wound-related services were grouped within it until another 60-day gap appeared. This structure enabled the tracking of patients across multiple discrete episodes while maintaining consistent rules for episode start and end across analyses. Treatment with Artacent Wound/AC or other included CAMP products were defined as having an applicable Healthcare Common Procedure Coding System (HCPCS) Q code (*Table 1*).

A 30-day re-admission was defined as any unplanned inpatient admission to an acute care hospital that occurred within 30 days of discharge from a prior index hospitalization. Diagnosis for complications such as major or minor

TABLE 1 | Definition of Cohorts by Product-Specific HCPCS Code

Trade Name	Company	Q Code
Artacent Cohort		
Artacent Wound	Tides Medical	Q4169
Artacent AC	Tides Medical	Q4190
CAMP Cohort		
Affinity	Organogenesis	Q4159
AmnioBand or guardian	MTFBiologics	Q4151
Apligraf	Organogenesis	Q4101
DermACELL, awm, porous	LifeNet Health	Q4122
Derma-Gide	Stimlabs	Q4203
Dermagraft	Organogenesis	Q4106
EpiCord	MiMedx Group, Inc.	Q4187
EpiFix	MiMedx Group, Inc.	Q4186
FlexHD, AllopatchHD	MTFBiologics	Q4128
Grafix stravix prime pl	Smith & Nephew	Q4133
GraftJacket	Stryker	Q4107
Integra or Omniograft DRT	Integra LifeSciences	Q4105
Kerecis Omega3	Kerecis	Q4158
Kerecis Omega3 Marigen Shield	Kerecis	A2019
NuShield	Organogenesis	Q4160
Oasis wound matrix	Smith & Nephew	Q4102
PriMatrix	Integra LifeSciences	Q4110
Theraskin	LifeNet Health	Q4121

amputation, end stage renal disease, and osteomyelitis were defined using the appropriate Current Procedural Terminology (CPT) or ICD-10 diagnosis codes.

The Research Identifiable Files (RIF) accessed through the CMS VRDC do not contain direct patient identifiers (e.g., name, Social Security Number) as specified by the HIPAA Privacy Rule. However, because the files include beneficiary-level detail such as dates of service and geographic information, they are classified as identifiable data. Access to this data required an approved CMS Data Use Agreement (DUA), and all analyses were conducted within the secure VRDC environment under CMS privacy and security safeguards. Because the study used secondary analysis of CMS claims data which does not involve direct patient contact, individual informed consent was not required. Therefore, an Institutional Review Board (IRB) waiver of authorization was obtained, and the study was granted an exemption in accordance with federal regulations for research involving existing data.

Retrospective cohort study

Eligible patients identified in the CMS database included those with a confirmed diagnosis of diabetes during an episode of care (EOC) or within 60 days prior to EOC initiation. Patients were excluded from the study if they met any of the following criteria: end stage renal disease; enrollment in Medicare Advantage during the study period; episodes beginning within the first 60 days or extending into the last 60 days of the study window; beneficiary death within 30 days of episode completion.

The approach to defining study eligibility criteria and constructing episodes of care was informed by prior Medicare claims-based analyses of skin substitutes in diabetic foot and venous leg ulcers, which used similar logic to identify eligible patients and define episodes of care.[14-18] While our definitions were not identical, they were conceptually aligned with these published methods to ensure comparability with existing real-world evidence.

For the purposes of this study, two cohorts were evaluated: the Artacent cohort which included beneficiaries with ≥ 1 claim for Artacent and the CAMP cohort consisting of a pooled group of patients treated with CAMPs currently reimbursed under Medicare (*Table 1*). The two treatment cohorts were matched 1:1 across six covariates: age (categorical), sex, frailty score (categorical) defined using the Hospital Frailty Risk Score (HFRS), episode start year, time to CAMP treatment initiation (categorical) and ulcer size, defined by debridement exceeding 20 cm^2.
Two indices were used to determine baseline patient comorbidity. The Hospital Frailty Risk Score uses 109 ICD-10 codes associated with frailty syndromes (e.g. falls, delirium, incontinence) to identify older adults at risk of poor health outcomes.[19] The Charlson Comorbidity Index (CCI) is a claims-based measure that summarizes the overall comorbidity burden by assigning weighted scores to 17 major chronic conditions with a higher score indicating greater risk of mortality.[20] The HFRS was chosen over CCI since it demonstrated a broader distribution of values for this cohort, allowing for finer stratification of risk (six versus three categories). Beyond its use in evaluating group comparability, the CCI was applied in sensitivity analyses to test the stability of study results under varying assumptions of comorbidity burden.

Additional baseline variables that were analyzed include dual-eligibility status, diagnosis of osteomyelitis, and ulcer depth into the fat layer. Wound size and depth were approximated from patient claims using debridement HCPCS/CPT codes indicating procedures involving areas greater than 20 cm^2 and ICD-10 diagnosis codes denoting ulcer involvement at the subcutaneous fat layer. The primary outcomes included rate of major and minor amputations in both groups. Secondary outcomes included number of inpatient admissions, hospital readmissions, emergency department visits, skilled nursing facility admissions and intensive care unit duration measured in days. All outcomes were evaluated across the full duration of each episode of care and were required to be LEDU-related, as identified through the presence of corresponding ICD-10 diagnosis codes on the claims.

Statistical analyses

Descriptive statistics were used when evaluating demographic and baseline characteristics. Between-group outcome comparisons were conducted using chi-square tests for categorical variables and t-tests for continuous variables.
A non-inferiority test was performed on the primary and secondary outcomes. A 10-percentage-point absolute margin was selected as the pre-specified margin based on regulatory precedent and conventions for comparative effectiveness research.[21,22] Sensitivity analyses evaluated the robustness of results by repeating matching with the CCI in place of frailty score. Statistical analyses were performed in SAS within the VRDC. Statistical significance was defined as a p-value <0.05.

Results

Data reviewed from the CMS database between 2020 and 2023 revealed a total of 3,305,684 episodes where a confirmed diagnosis of diabetes and a lower extremity ulcer was identified. After factoring in eligibility criteria, a total of 1,192 LEDU episodes were deemed eligible for analysis, 596 in each cohort (*Figure 1*). Prior to conducting the 1:1 matching procedure, the CAMP cohort had statistically higher rates of ulcers extending to the muscle, incidence of osteomyelitis and an index ulcer greater than 20 cm^2 after debridement. Significant differences were also observed in the timing of episode initiation. Once 1:1 matching was performed, all baseline covariates were balanced and no statistically significant differences between the groups was observed (*Table 2*).

Both groups were comprised of 59.7% males, and the mean age was 72.3±10.1 years in the CAMP cohort and 72.3±10.3 years in the Artacent cohort. The HFRS was 21.2±15.2 and 21.3±15.2 points in the CAMP and Artacent cohorts, respectively. Treatment started in approximately 90 days for both groups and the mean episode length was 224.3±185.6 days (CAMP cohort) and 227.6±194.0 days (Artacent cohort), p=0.763. The mean number of applications was similar between the two cohorts as well (4.3 versus 4.8 in the CAMP and Artacent groups, p=0.075).
The rates of major and minor amputations were slightly lower for the Artacent group as compared to the CAMP group (Table 3). The rate of major and minor amputations in the Artacent group was 2.7% and 13.6% while in the CAMP group it was 3.4% and 14.8%, respectively. The differences were not statistically significant (p=0.498 for major and p=0.561 for minor amputations). Inpatient admission, emergency department visits, skilled nursing admission and ICU days were all lower in the Artacent group with no statistically significant differences observed (*Table 3*). The 30-day readmission rates were 4.5% for the Artacent group as compared to 5.4% for the CAMP group (p=0.594).
When applying a prespecified absolute non-inferiority margin of 10 percentage points to major and minor amputations as well as hospital readmission, the upper bounds of the confidence intervals were below the threshold, and non-inferiority was demonstrated for these endpoints (*Table 3*). However, for continuous outcomes (e.g., counts of

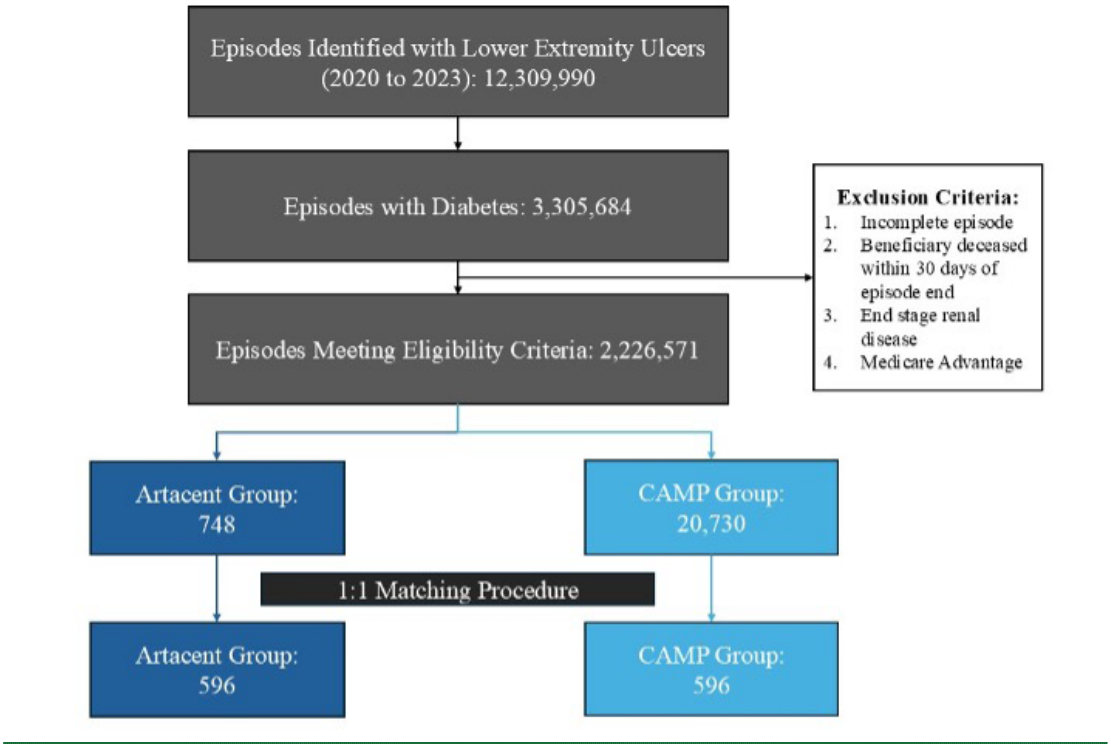

FIGURE 1 | Determination of the final patient cohorts.

TABLE 2 | Baseline characteristics of CMP vs. Artacent cohorts (pre- and post-matching)

Baseline characteristic	Pre-match			Post-match		
	CAMP (n=20,730)	Artacent (n=596)	P-value	CAMP (n=596)	Artacent (n=596)	P-value
Age	72.3 (10.7)	72.3 (10.3)	0.992	72.3 (10.1)	72.3 (10.3)	0.953
Male sex, %	64.2%	59.7%	0.024	59.7%	59.7%	1.000
Dual-eligible, %	22.8%	25.8%	0.079	24.5%	25.8%	0.593
Hospital Frailty Risk Score	20.4 (14.5)	21.3 (15.2)	0.137	21.2 (15.2)	21.3 (15.2)	0.900
Charlson Comorbidity Index	5.78 (2.6)	5.62 (2.6)	0.163	5.9 (2.6)	5.62 (2.6)	0.063
Ulcer depth fat, % deep	80.7%	76.0%	.0039	78.2%	76.0%	0.371
Osteomyelitis, %	32.5%	28.5%	.0436	29.9%	28.5%	0.610
Debridement >20 cm², %	18.4%	12.6%	.0003	12.6%	12.6%	1.000
Days to treatment start	99.46 (106.7)	90.9 (113.5)	0.055	91.9 (114.4)	90.9 (113.5)	0.874
Episode start year = 2020, %	31.3%	25.7%	.0036	25.7%	25.7%	1.000
Episode start year = 2021, %	34.4%	36.6%	0.279	36.6%	36.6%	1.000
Episode start year = 2022, %	26.0%	31.0%	0.006	31.0%	31.0%	1.000
Episode start year = 2023, %	8.3%	6.7%	0.170	6.7%	6.7%	1.000

All values are represented as mean (SD) unless otherwise noted.
All baseline variables were balanced after matching, with no statistically significant differences.

inpatient admissions, SNF, ICU, and ED visits), the upper bounds of the confidence intervals exceeded the fixed 0.10 margin. As a result, non-inferiority could not be established for these outcomes.

TABLE 3 | Clinical Outcomes by Cohort (Post-Matching)

Outcome	CAMP (n=596)	Artacent (n=596)	P-value
Major amputation, %	3.4%	2.7%	0.498
Minor amputation, %	14.8%	13.6%	0.561
Inpatient admits (per 1,000)	571	485	0.140
ED visits (per 1,000)	589	535	0.384
ICU days (per 1,000)	797	713	0.627
SNF admits (per 1,000)	89	81	0.705
30-day readmission, %	5.4%	4.5%	0.594

Abbreviations: ED – emergency department, ICU – intensive care unit, SNF – skilled nursing facility
Bolded p-values indicate non-inferior outcomes.

Discussion

The current study was designed in the context of the recently proposed CMS Local Coverage Determination update for cellular and/or tissue-based products (CAMPs) used in the treatment of LEDUs. Under this proposal, 18 products would remain covered for LEDUs, with additional products required to demonstrate sufficient clinical benefit, supported by randomized trials or real-world evidence (RWE), to qualify for Medicare reimbursement. The current study, therefore, directly compared Artacent placental allografts to the group of 18 covered CAMP products listed in the recent LCD to evaluate whether Artacent could achieve comparable clinical and economic outcomes.

Our results demonstrated that Artacent achieved similar outcomes to the listed CAMPs across all major clinical and economic measures. Importantly, when applying a prespecified 10% non-inferiority margin, Artacent met criteria for non-inferiority in major and minor amputations as well as 30-day readmission rates. Although non-inferiority was not established for certain continuous use outcomes, the observed effect sizes consistently trended towards lower resource use in the Artacent group, including inpatient admissions, skilled nursing facility stays, ICU days, and emergency department visits. These findings suggest that Artacent performs within the same therapeutic class as the 18 LCD covered CAMPs, supporting its potential clinical appropriateness for inclusion under CMS reimbursement frameworks.

Although none of the between-group differences reached statistical significance, the consistent directional trends, particularly toward lower rates of hospital admissions, skilled nursing stays, and ICU use among Artacent-treated patients, may still hold practical relevance. These findings align with CMS's emphasis on evidence-based and value-focused coverage decisions, suggesting that Artacent performs comparably to covered CAMPs while potentially supporting more efficient use of healthcare resources.

From a policy standpoint, these findings align with the CMS emphasis on evidence-based coverage and the role of RWE in assessing medical technologies. Demonstrating comparable performance to currently covered CAMPs strengthen the case for considering Artacent within future reimbursement determinations. Moreover, expanding the set of clinically validated products has implications for both patient access and provider flexibility in managing complex LEDUs, while maintaining consistency with CMS efforts to ensure value-based use of advanced wound care products.

Limitations

There were several limitations to the current study. Despite matching on age, sex, frailty, ulcer size, treatment timing, and other key factors, some residual confounding is still possible. Claims data does not capture certain clinical details such as direct measures of wound size, ulcer duration, or patient adherence. Proxies were used where possible (e.g., procedure codes and supply use as indicators of wound size; claims-based clean periods as indicators of episode length), but these are necessarily indirect. As noted in prior works, such tradeoffs are inherent to claims-based research.[23] The study population was also limited to Medicare fee-for-service beneficiaries with LEDUs, which may not fully reflect outcomes in younger patients or those with commercial coverage. However, Medicare is the dominant payer for LEDU care, and the analytic framework described here can be readily applied to other populations in future studies. Finally, the overall sample size was modest (596 episodes in each cohort). Matching achieved strong balance between groups, and the results demonstrated that Artacent achieved statistically comparable outcomes across all measures and met criteria for non-inferiority in major amputation, minor amputation, and hospital readmissions. These

considerations should be considered when interpreting results, but they also highlight the strength of using nationally representative claims data to generate real-world evidence at such a scale.

Conclusion

The current study demonstrated similar outcomes when comparing Artacent placental allografts to other covered CAMPs available on the market. Given the comparable results in rates of major and minor amputation as well as other outcomes associated with high economic burden (hospital readmission, ED visits, SNF and ICU stay) between Artacent and other CAMPs available on the market, it is reasonable to conclude that Artacent placental allografts can 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.

Author contributions

Acquisition, analysis, or interpretation of data: Travis Tucker, Drafting of the manuscript: Kim Kot, Travis Tucker, William Tettelbach, Concept and design: Travis Tucker, Critical review of the manuscript for important intellectual content: William Tettelbach, Travis Tucker, Kim Kot, Supervision: William Tettelbach, Travis Tucker, Kim Kot. All authors have reviewed the final version to be published and agreed to be accountable for all aspects of the work.

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