A 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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INTRODUCTION

Lower extremity diabetic ulcers (LEDUs) are a major cause of morbidity, amputation, and cost among Medicare beneficiaries, with chronic wound management exceeding $22 billion annually.[1] Advanced biologic and matrix-based therapies, commonly referred to as cellular, acellular, and matrix-like products (CAMPs), have demonstrated improved outcomes in hard-to-heal wounds and are central to the future effective skin substitute Medicare Local Coverage Determinations (LCDs). The objective of this study was to compare clinical and economic outcomes of *Artacent* placental allografts (*Artacent Wound* and *Artacent AC*; Tides Medical, Lafayette, LA, US) with those of 18 other LCD-covered CAMPs for the treatment of LEDUs.

METHODS

A retrospective cohort analysis was conducted using the Centers for Medicare & Medicaid Services (CMS) Research Identifiable Files (2020–2023). Episodes of care (EOCs) were defined as ≥ 60 days without related claims. Medicare beneficiaries with diabetes who received *Artacent* or any of the 18 covered CAMPs were matched 1:1 across six baseline covariates (age, sex, frailty, episode year, time-to-treatment, and ulcer size > 20 cm²). The study design and inclusion process are summarized in Figure 1, illustrating the selection of 1,192 matched EOCs (596 per cohort) from 3.3 million diabetic wound episodes. Table 1 lists the CAMPs included by the HCPCS Q-code. Table 2 presents pre- and post-matching demographic and clinical baseline characteristics, confirming balance across all covariates after matching. Primary outcomes included major and minor amputation rates; secondary outcomes included inpatient admissions, emergency department (ED) visits, skilled nursing facility (SNF) admissions, intensive care unit (ICU) days, and 30-day readmissions. Non-inferiority was assessed using a ± 10-percentage-point absolute margin.

Figure 1. Determination of the Final Patient Cohorts

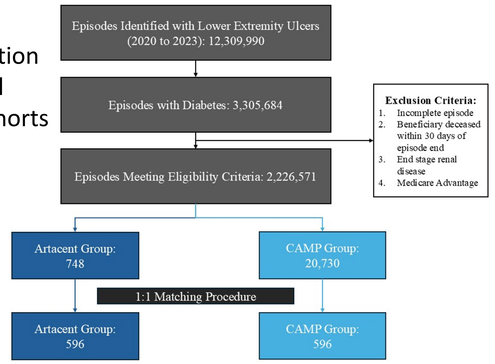


Table 1. Definition of Cohorts by Product-Specific HCPCS Code

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

Table 2. Baseline Characteristics of CAMP vs. Artacent Cohorts (Pre- and Post-Matching)

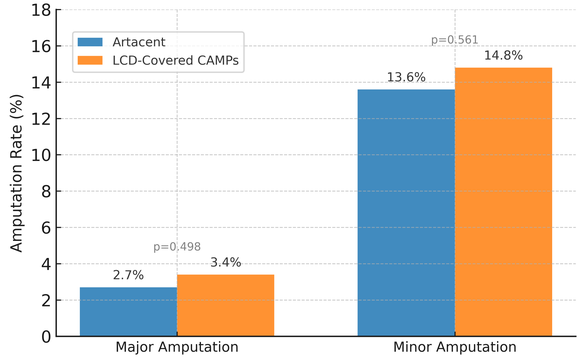
Baseline Characteristic	Pre-Match			Post-Match		
	CAMP (n=20,730)	Artacent (n=596)	p-value	CAMP (n=596)	Artacent (n=596)	p-value
Age	72.3 (10.7)	72.3 (10.3)	0.992	72.3 (10.1)	72.3 (10.3)	0.953
Male sex, %	64.2%	59.7%	0.024	59.7%	59.7%	1.000
Dual-eligible, %	22.8%	25.8%	0.079	24.5%	25.8%	0.593
Hospital 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.

RESULTS

Post-matching, cohorts were balanced with no statistically significant differences (Table 2). As shown in Figure 2**,** the *Artacent* cohort had numerically lower rates of major (2.7 % vs 3.4 %; p = 0.498) and minor (13.6 % vs 14.8 %; p = 0.561) amputations, meeting the pre-specified non-inferiority margin. Secondary outcomes also favored *Artacent* vs. the comparative LCD-Covered CAMP cohort, including inpatient admissions (485 vs 571 per 1,000 EOCs; p = 0.140), ED visits (535 vs 589; p = 0.384), SNF admissions (81 vs 89; p = 0.705), and 30-day readmissions (4.5 % vs 5.4 %; p = 0.594), though these differences were not statistically significant.

Figure 2. Comparative Amputation Rates: Artacent vs. LCD-Covered CAMPs



CONCLUSION

Analysis of national Medicare claims demonstrated that *Artacent* placental allografts achieved comparable clinical and economic outcomes to the 18 LCD-covered CAMPs in the management of LEDUs. As illustrated in Figure 1-2 and Tables 1-2, *Artacent* performed equivalently across amputation and healthcare utilization endpoints, supporting its inclusion within future CMS reimbursement frameworks and integration into evidence-based treatment paradigms for hard-to-heal diabetic ulcers. While direct cost calculations were not performed, reductions in Healthcare resource utilization suggest that *Artacent* may deliver comparable or lower overall episode-of-care costs relative to other covered CAMPs.

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