Comparative Effectiveness of Porcine Placental ECM Against Other CAMPs in Diabetic Foot and Venous Leg Ulcers from the Medicare Database

Brad Marcinek[1], Jenny Levinson[1], Serena Nally[1], Irene Varghese[2], Caitlin Sheetz[2], Peter Kardel[2], Cristin Taylor[1]

[1]Convatec Ltd., Deeside, United Kingdom; [2]ADVI Health LLC, Washington, DC, USA

Introduction

- Diabetic foot ulcers (DFU) and venous leg ulcers (VLU) are often hard-to-heal, and may require advanced treatment with cellular, acellular, and matrix-like products (CAMPs)
- In 2024, seven Medicare Administrative Contractors published aligned Local Coverage Determinations (LCDs), which would significantly restrict coverage of CAMPs

Aims

This retrospective cohort study examines the Medicare Fee-for-service (FFS) population to compare clinical outcomes and health resources utilization in patients receiving Porcine Placental Extracellular Matrix (PPECM*) against other CAMPs with LCD-coverage

Methods

- This study utilized 100% Medicare Research Identifiable Files to analyze patients with ICD-10 diagnosis codes for DFUs or VLUs and non-pressure chronic ulcers, who received CAMP treatment between January 2020 and June 2024
- Eligible patients were categorized into groups according to treatment received: (1) PPECM*, (2) all other LCD-covered CAMPs (LCC)‡, or (3) PPECM's 510(k) predicate (Predicate)†
- Patient demographics and comorbidities were assessed for cohort homogeneity via Inverse Probability of Treatment Weighting (IPTW), allowing for balanced comparison of health outcomes
- Relevant outcomes of interest included the rate of amputations and wound complications. Healthcare resource utilization (HRU) and Medicare reimbursement amounts were evaluated across various service sites

Results

Table 1. Patient Demographics

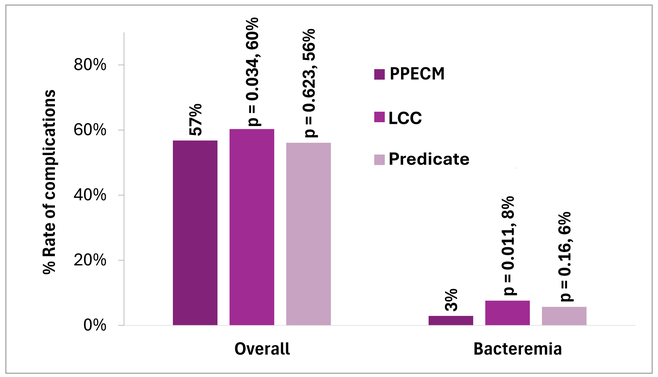
	DFU (N=34,664, 3.6% of DFU total patients)			VLU (N=16,771, 3.4% of VLU total patients)		
	PPECM*, n(%) (N=186)	LCC‡, n(%) (N=33,858)	Predicate†, n(%) (N=368)	PPECM*, n(%) (N=60)	LCC‡, n(%) (N=16,176)	Predicate†, n(%) (N=213)
Mean age (SD)	72.1 ± 11.2	69.9 ± 11.4	70.3 ± 11.7	77.5 ± 9.8	75.8 ± 10.8	75.1 ± 11.4
Male	121 (65%)	22,224 (66%)	227 (62%)	30 (50%)	7,647 (47%)	108 (51%)
Mean CCI	4.0 ± 1.6	4.8 ± 1.7	4.4 ± 1.7	2.4 ± 1.6	3.0 ± 1.9	2.6 ± 1.9
Peripheral vascular disease	104 (56%)	20,808 (61%)	218 (59%)	29 (48%)	8,976 (55%)	109 (51%)
Diabetes without complications	186 (100%)	33,738 (99.6%)	366 (99.5%)	22 (37%)	6,755 (42%)	80 (38%)
Diabetes with complications	157 (84%)	29,571 (87%)	317 (86%)	19 (32%)	5,274 (33%)	65 (31%)
Renal disease	83 (45%)	16,639 (49%)	164 (45%)	12 (20%)	4,589 (28%)	54 (25%)

*Patients receiving a combination of at least two treatment groups were evaluated but not reported in this poster

Table 2. Risk of Outpatient Amputations in Patients with a DFU, PPECM* vs other treatment groups

Treatment group	Point estimate	95% Wald confidence limits	P value
LCC‡	1.309	1.251 – 1.371	<.0001
Predicate†	1.162	1.109 – 1.217	0.1311

Figure 1. Wound Complications in patients with a DFU



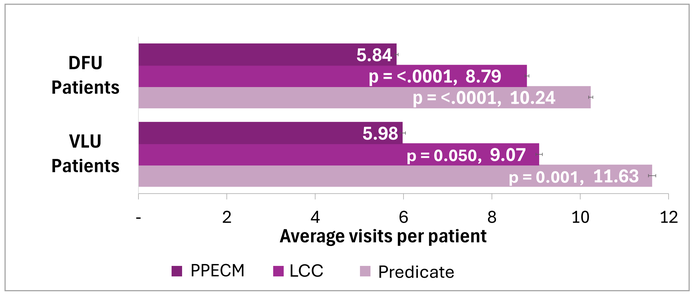
DFU

- Patients receiving LCC‡ were 1.309 times more likely to undergo outpatient amputation compared to the PPECM* group (**Table 2**)
- A Cox-hazard analysis on time to first amputation in the 6-month period post-episode found that risk of amputation was 5.8% higher in the LCC‡ (HR:1.058, CI:1.022-1.095, p=0.002) vs the PPECM* group. There was no difference for the Predicate† group (p=0.176)
- Bacteremia was 2.75 times more likely in LCC‡ group (95% CI, 2.47–3.05; p<0.0001) and 1.99 times more likely in the Predicate† group compared to PPECM* after applying logistic regressions (**Figure 1**; results without regression applied)

VLU

- PPECM* demonstrated significantly fewer outpatient hospital visits compared to LCC‡ and the Predicate† groups (**Figure 2**)
- Risk of amputation did not differ across treatment groups (LCC ‡ p=0.65; Predicate † p=0.84) and there were no significant differences observed in overall wound complications (LCC ‡ p=0.22; Predicate † p=0.21)

Figure 2. Outpatient Hospital Visits for DFU and VLU Patients



Discussion

- This study builds on previous analyses of Medicare claims data[1,2] by providing comparative data for clinical outcomes and health resource utilization for PPECM* vs its 510(K) Predicate† and other LCCs ‡
- In DFU patients, PPECM* showed significantly less risk for outpatient amputations and bacteremia compared to the LCC‡ group
- In VLU patients, PPECM* performed as well as the other treatment groups, with no significant differences observed in amputations or complications
- Additionally, PPECM* patients showed fewer outpatient hospital visits and costs for both disease cohorts suggesting a more cost-effective treatment strategy and improved long-term care management

Conclusion

PPECM* performed clinically as well as, or better, than other established CAMPs with LCD-coverage

References:

1. Armstrong DG, Tettelbach WH, Chang TJ, et al. Observed impact of skin substitutes in lower extremity diabetic ulcers: lessons from the Medicare Database (2015-2018). J Wound Care. 2021;30(Sup7):S5-S16. 2. Tettelbach WH, Driver V, Oropallo A, et al. Treatment patterns and outcomes of Medicare enrolees who developed venous leg ulcers. J Wound Care. 2023;32(11):704-718.

***PPECM:** InnovaMatrix® AC, Convatec Triad Life Sciences, LLC, Memphis, TN, USA; **† PPECM 510(k) Predicate:** OASIS® Wound Matrix, Cook Biotech Inc., West Lafayette, IN, USA; **‡ LCC:** Marigen Shield and Omega3 (Kerecis, Ísafjörður, Iceland); Integra Dermal Regeneration Template and Primatrix (Integra LifeSciences, Princeton NJ, USA); GraftJacket (Stryker, Portage, MI, USA); Theraskin and Dermacell (LifeNet Health, Virginia Beach, VA, USA); FlexHD/AllopatchHD and Amnioband (MTF Biologics, Edison, NJ, USA); Grafix/Stravix (Smith+Nephew, Andover, MA, USA); Epicord and Epifix (MiMedx, Marietta, GA, USA); Affinity, Apligraf, Dermagraft, and Nushield (Organogenesis, Canton, MA).

Presented at the Symposium on Advanced Wound Care (SAWC) Spring Conference, April 30th-May 4th, 2025, Grapevine, TX, USA