

PURIFIED NATIVE TYPE 1 COLLAGEN MATRIX PLUS POLYHEXAMETHYLENE BIGUANIDE (PHMB) ANTIMICROBIAL WOUND MATRIX (PCMP) IS ASSOCIATED WITH LOWER AMPUTATION RATES AMONG MEDICARE BENEFICIARIES WITH DIABETIC FOOT ULCERS

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INTRODUCTION

- Diabetic foot ulcers (DFUs) are a common complication of diabetes and a leading cause of non-traumatic lower-limb amputation^{1,2}
- Approximately 85% of diabetes-related amputations are preceded by a foot ulcer³
- Despite conventional care, many DFUs become chronic and ~40% recur within 1 year⁴
- Clinical guidelines recommend escalation to advanced wound therapies if adequate healing is not achieved after 4 weeks of conventional care, however, initiation is often delayed until ulcers become more severe⁵⁻⁷
- Purified native type 1 collagen matrix plus polyhexamethylene biguanide (PHMB) antimicrobial wound matrix (PuraPly AM; PCMP) is cleared for management of acute and chronic wounds, including DFUs
- Contemporary real-world data evaluating amputation outcomes associated with PCMP remain limited
- This analysis builds on prior comparative effectiveness findings by evaluating 6-month non-traumatic lower-limb amputation rates and treatment timing among beneficiaries treated with PCMP⁹

OBJECTIVE

- Compare 6-month non-traumatic lower-limb amputation rates among Medicare beneficiaries with DFUs treated with vs without PCMP
- Evaluate whether earlier initiation (≤ 45 , ≤ 60 , ≤ 90 days after DFU diagnosis) is associated with lower amputation risk

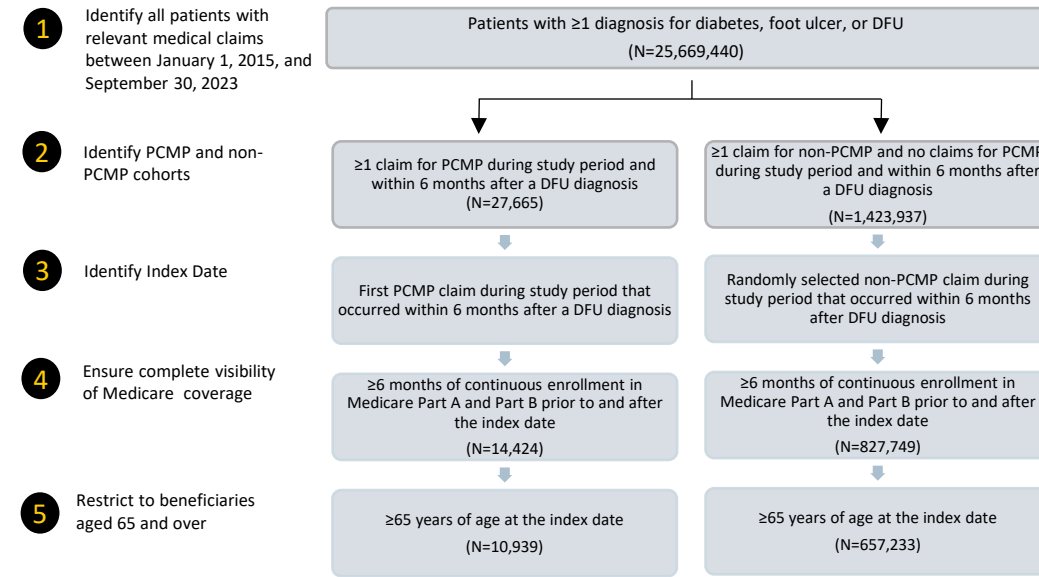
DATA SOURCE AND STUDY DESIGN

- Retrospective propensity score-matched cohort study using de-identified 100% Medicare Fee-For-Service (FFS) claims (Q1 2015-Q3 2023)
- Beneficiaries aged ≥ 65 years with a DFU diagnosis were classified as receiving PCMP within 6 months of diagnosis or receiving non-PCMP wound care (e.g., debridement, offloading, compression) without any skin substitute
- The index date was defined as the first PCMP claim (PCMP cohort) or a randomly assigned qualifying wound care claim within 6 months of diagnosis (non-PCMP cohort)
- Continuous Medicare Parts A and B enrollment was required 6 months pre-index (baseline) and 6 months post-index (follow-up)
- Cohorts were matched 1:1 using propensity scores to balance demographics, comorbidities, ulcer severity, prior treatments, and DFU-related costs

STUDY MEASURES

- Baseline demographics, comorbidities, ulcer severity proxies, prior DFU-related treatments, and DFU-related costs were compared between PCMP and non-PCMP cohorts before matching using Wilcoxon rank-sum tests; balance after matching was assessed using standardized mean differences
- Six-month non-traumatic lower-limb amputation rates (overall and by site) were compared between matched cohorts using Wilcoxon sign-rank tests and McNemar's tests, with additional stratified analyses by timing of PCMP initiation

STUDY POPULATION SELECTION

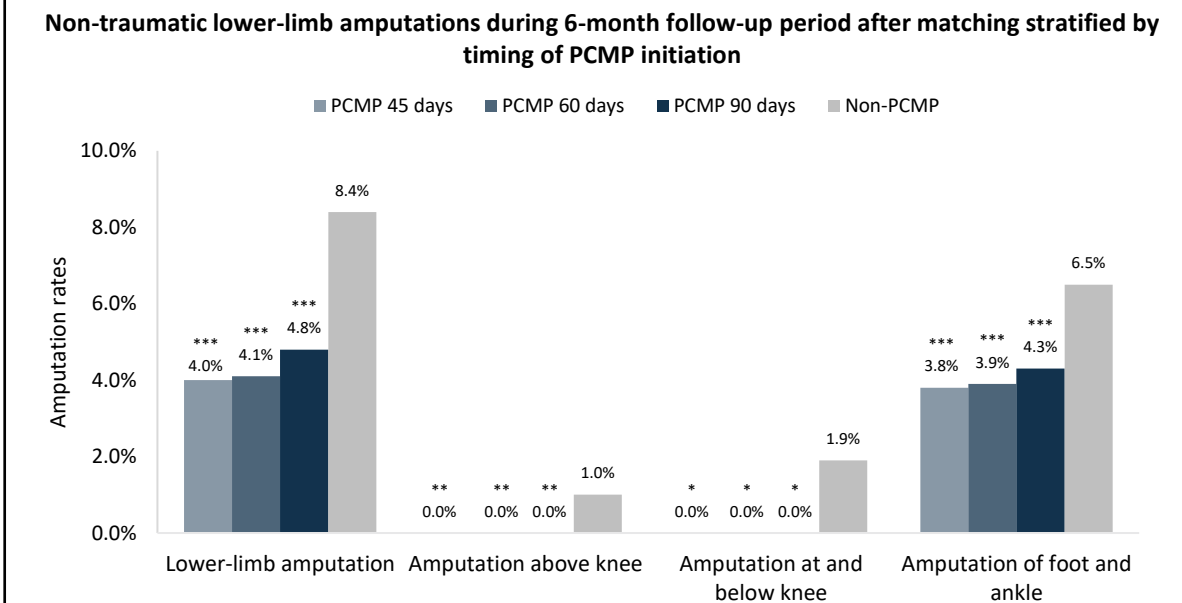
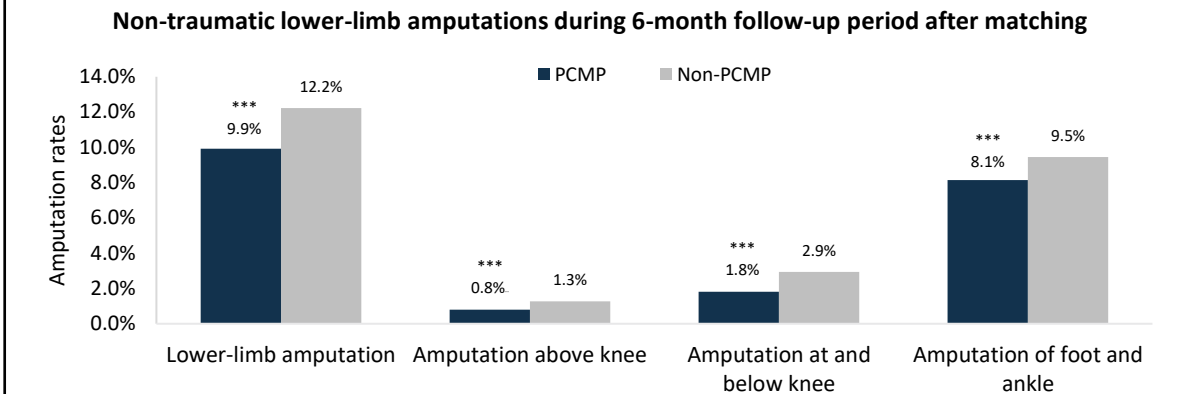


Note: Procedures qualifying for non-PCMP included debridement, incision/drainage, offloading devices, and compression therapy.

TABLE 1. BASELINE STUDY POPULATION CHARACTERISTICS

Selected characteristics	Pre-match			Post-match		
	PCMP (N=10,939)	Non-PCMP (N=657,233)	P-value	PCMP (N = 10,862)	Non-PCMP (N= 10,862)	P-value
Patient Demographics/Comorbidities						
Age, mean	76.1	77.5	<0.001	76.1	76.1	0.968
Male	62.7%	54.6%	<0.001	62.6%	63.5%	0.183
Charlson comorbidity index, mean	3.3	3.0	<0.001	3.3	3.3	0.325
DFU Severity						
Months of active ulceration	3.4	1.9	<0.001	3.4	3.5	<0.001
DFU related infections, %	69.2%	48.2%	<0.001	69.0%	67.2%	0.018
Osteomyelitis	33.7%	15.0%	<0.001	33.3%	32.4%	0.120
Gangrene	19.2%	9.6%	<0.001	13.2%	13.7%	0.311
Lower-limb amputation	12.2%	6.4%	<0.001	12.1%	11.8%	0.472
Number of unique DFU diagnosis, mean	17.3	5.3	<0.001	16.6	14.1	<0.001
Treatment Intensity and Resource Use						
Prior DFU-related treatments, %	93.8%	61.0%	<0.001	93.8%	78.6%	<0.001
Debridement	92.5%	56.3%	<0.001	92.4%	75.3%	<0.001
Negative pressure wound therapy	13.4%	3.0%	<0.001	13.0%	11.7%	0.012
Hyperbaric oxygen	7.7%	1.3%	<0.001	7.2%	4.7%	<0.001
DFU-related medical costs	\$26,372	\$11,902	<0.001	\$26,008	\$26,149	<0.001

RESULTS



Statistical significance of difference between skin substitutes and non-skin substitutes: * $P < 0.05$, ** $P < 0.01$, *** $P < 0.001$.

LIMITATIONS AND CONCLUSIONS

- As a retrospective claims-based analysis, findings depend on accurate coding and do not capture detailed wound characteristics (e.g., wound size, depth)
- Residual confounding may persist despite matching, and results apply to Medicare FFS beneficiaries aged ≥ 65 years
- PCMP use was associated with significantly lower 6-month non-traumatic lower-limb amputation rates after adjustment for baseline differences
- Earlier PCMP initiation (≤ 90 days from DFU diagnosis) was associated with further reductions in amputation risk, highlighting the potential importance of timely treatment

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