

Comparative health resource utilization and cost analysis of Porcine Placental Extracellular Matrix versus standard of care and other advanced treatments in the treatment of diabetic foot ulcers in the Medicare Fee-For-Service population

Jenny Levinson¹, Janet Mackenzie MD¹, Rebecca Decker MSJ¹, Serena Nally MPH¹, Irene Varghese MS², Caitlin Sheetz MPH², Peter Kardel MA², Cristin Taylor PA¹

¹Convatec Technology Center, Lexington, MA; ²ADVI Health LLC, Washington, DC

INTRODUCTION

- Diabetic Foot Ulcers (DFU) are a common complication of poorly-managed diabetes, occurring in over 338,191 Medicare Fee-For-Service (FFS) patients in 2024 (1.0% of FFS patients).
- Prompt treatment of these ulcers is crucial as DFU are the primary cause of lower-extremity amputation.
- A novel advanced skin substitute product, Porcine Placental Extracellular Matrix (PPECM), has had sufficient utilization amongst Medicare beneficiaries to conduct this analysis of downstream healthcare resource utilization after treatment.

STUDY OBJECTIVE

To examine the comparative health resource utilization and cost of PPECM* versus standard of care (SOC) and other advanced treatments (AT) in the management of DFU using real world data from the Medicare FFS population.

METHODS

- Retrospective analysis of healthcare claims from 100% Medicare FFS Research Identifiable Files (2021 - 2024).
- Patients identified with DFU and L97.xx diagnosis code (non-pressure chronic ulcer of the lower limb) on the same day were categorized into groups according to treatment received: (1) PPECM*, (2) standard of care (SOC)‡, (3) other advanced treatments (AT)†.
- Patient demographics and comorbidities were assessed for homogeneity at baseline and balanced via Inverse Probability of Treatment Weighting (IPTW), to create a homogenous cohort for balanced comparison of health outcomes.
- Downstream outcomes analysis included healthcare resource utilization per beneficiary costs, and Medicare reimbursement amounts by site of care (Medicare Part A and B).

*PPECM: InnovaMatrix[®] AC, Convatec Triad Life Sciences, LLC, Memphis, TN, USA;
 ‡SOC: Surgical debridement, total contact casting, compression, non-surgical selective debridement and dressing changes, general debridement, SOC-dressing;
 †AT: Collagen dressings, platelet-rich plasma, negative pressure wound treatment, electrostimulation, MIST therapy, hyperbaric oxygen, topical oxygen

RESULTS

Table 1: Episode Demographics – After Application of IPTW Balancing

- IPTW used to control for differences found at age cohort (65-74), race (Hispanic), dual eligibility for Medicare/Medicaid, wound depth, and peripheral vascular disease.

	DFU (N=117,707 treatment episodes selected for analysis)		
	PPECM (N=225)	SOC (N=111,707)	AT (N=5,701)
Mean Age	74.0	73.3	73.2
Male	63%	62%	62%
Wound Location (heel/foot/lower leg)	No significant differences between groups		
Wound Depth (breakdown of skin)	18%	19%	18%
Wound Depth (with fat layer exposed)	40%	37%	37%
Wound Depth (other, unspecified, multiple)	42%	44%	45%
Charlson Comorbidity Index – Mean CCI	5.7	5.4	5.6
Peripheral Vascular Disease	52%	43%	51%

*Patients receiving a combination of at least two treatment groups were excluded from the analysis

Figure 1. Per Patient Per Month Spending in 180-Day Post Period

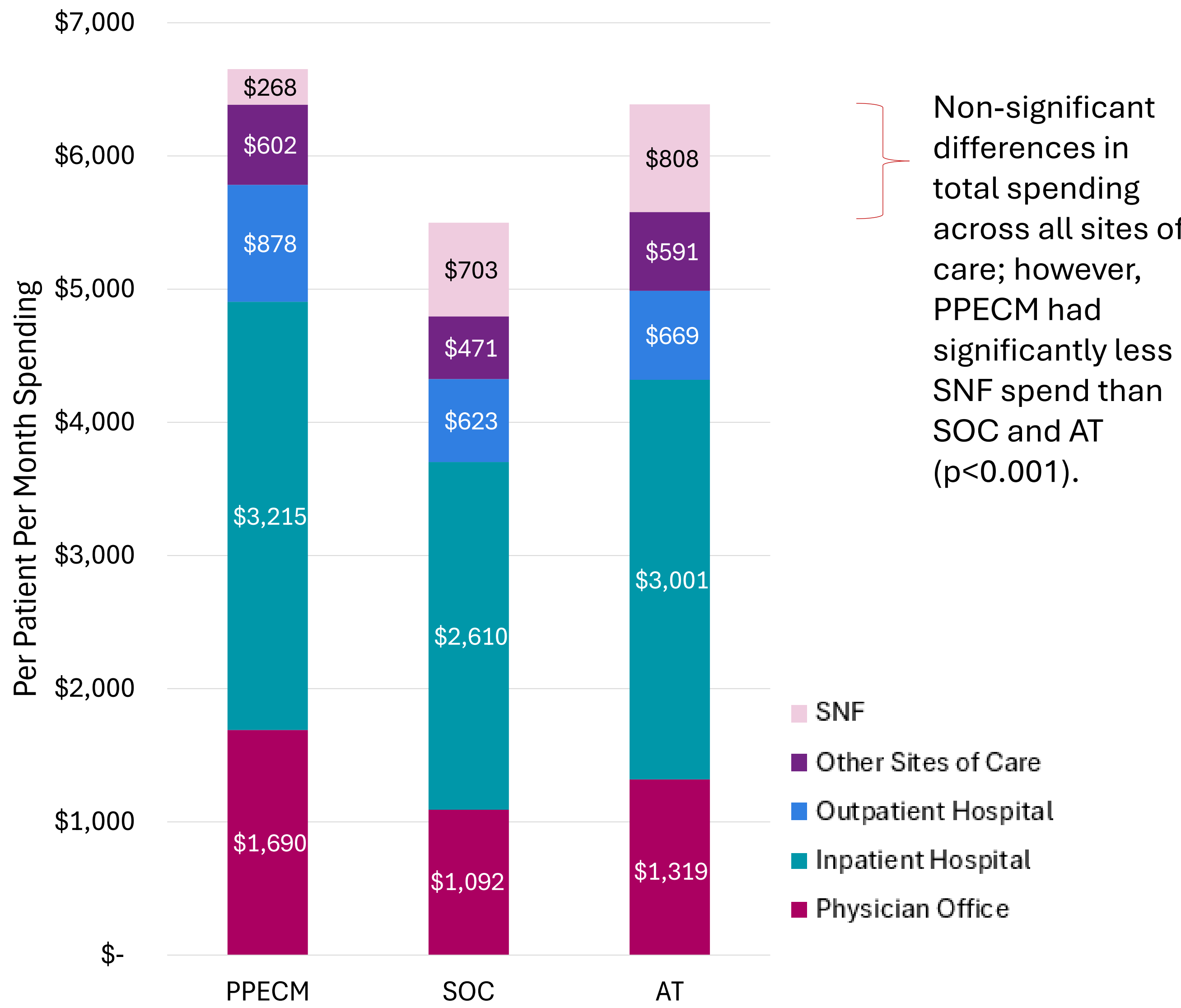


Figure 2. Utilization Rates by Major Sites of Care

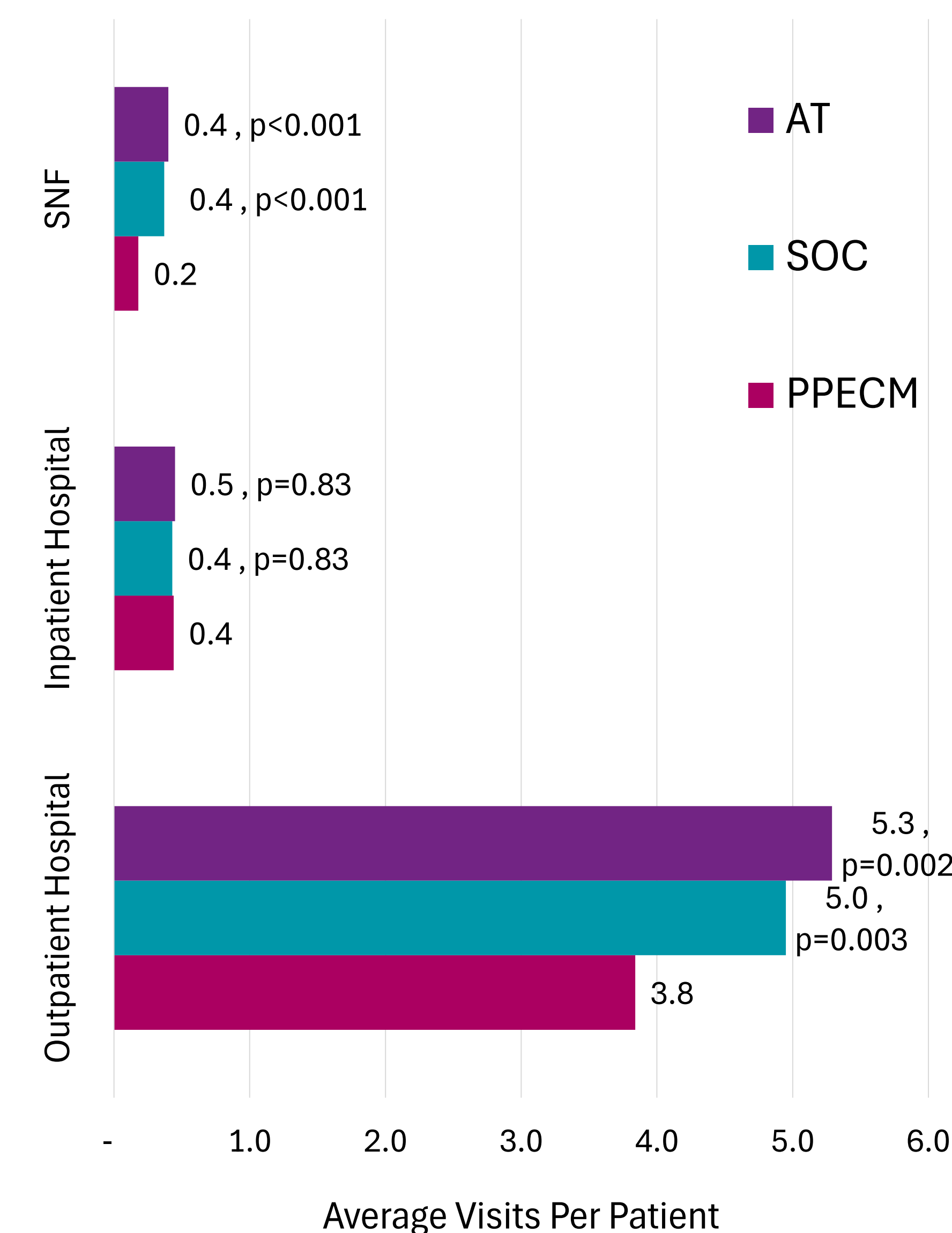


Table 2. Weighted Regression Analysis on Utilization Rates and Per Beneficiary Spending By Site of Care; 6-Month Post-Period Post Treatment Episodes

Site of Care	PPECM		SOC		AT	
	Point Estimate	95% CI	Point Estimate	95% CI	Point Estimate	95% CI
Physician Office Visits	18.36	[18.32-18.40]	18.76**	[18.72-18.80]	22.05**	[22.01-22.09]
Outpatient Hospital Visits	3.84	[3.82-3.86]	4.95**	[4.93-4.97]	5.29**	[5.27-5.31]
Inpatient Hospital Visits	0.44	[0.44-0.45]	0.43	[0.43-0.44]	0.45**	[0.44-0.46]
Readmissions (<30 days)	0.15	[0.14-0.15]	0.15**	[0.15-0.16]	0.19**	[0.18-0.19]
ICU Visits	0.19	[0.18-0.19]	0.20**	[0.20-0.20]	0.21**	[0.21-0.22]
Inpatient - Medical DRGs	0.39	[0.38-0.40]	0.42**	[0.41-0.42]	0.41**	[0.40-0.42]
Inpatient - Surgical DRGs	0.22	[0.22-0.23]	0.17**	[0.17-0.17]	0.19**	[0.19-0.20]
SNF Visits	0.18	[0.18-0.19]	0.37**	[0.36-0.37]	0.40**	[0.39-0.40]

**Significantly different from PPECM (p<0.05)

DISCUSSION

- Prior to IPTW balancing, PPECM patients were found to have notably different baseline characteristics (deeper wounds, rates of comorbidities), compared to SOC and other AT.
- Compared to SOC, PPECM had significantly lower downstream skilled nursing facility (SNF) and outpatient hospital costs; lower rates of healthcare utilization in physician office, outpatient hospital, and SNF settings, and no significant differences in inpatient hospital visits and spending.
- PPECM had significantly lower rates of bacteremia, sepsis, amputations, and any wound complication compared to other AT.
- When controlling for confounding variables, weighted regression analyses found that PPECM had significantly lower rates of utilization in hospital readmission, intensive care unit (ICU) visits, and inpatient medical diagnosis-related groups (DRG) but higher rates of inpatient surgical DRG, which may be due to surgical debridement required for skin bed preparation.
- While the PPECM is relatively new, this analysis demonstrates the lower cost and resource use of this novel treatment.

CONCLUSION

These findings suggest that PPECM* patients had significantly less downstream utilization and costs at multiple sites of care, compared to SOC and other AT.