

COMPARATIVE EFFECTIVENESS FOR MEDICARE BENEFICIARIES WITH DIABETIC FOOT ULCERS (DFUs) WITH AND WITHOUT HYPOTHERMICALLY STORED AMNIOTIC MEMBRANE (HSAM)

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INTRODUCTION

- DFUs are a common complication of diabetes, affecting 1-6% of diabetic patients annually, and up to 25% of diabetics over their lifetime, with annual costs in the US estimated up to \$13.2 billion^{1,2}
- The complications of DFUs are severe. They often require extensive healing time, are one of the major sources of hospitalization among patients with diabetes, and about 5% of DFU patients require a lower-limb amputation in the year following a diagnosis^{2,3}
- Prior economic research, based on clinical trial data and simulation models, suggests that improved efficacy of other advanced wound care products may result in cost offsets relative to use of conventional wound management alone⁴
- HSAM^(a) is an aseptically processed, hypothermically stored amniotic allograft intended for use as a covering for wounds, including DFUs
- Limited information exists about the real-world clinical and economic outcomes associated with using HSAM^(a) in patients with DFUs

^(a)Affinity®, Organogenesis Inc., Canton, MA

OBJECTIVE

- To better understand the profiles of patients with DFUs receiving HSAM as a cover for wounds versus patients with DFUs not receiving HSAM (non-HSAM)
- To compare the real-world rates of non-traumatic lower-limb amputations, all-cause medical use, and number of DFU-related medical events of patients with DFUs receiving HSAM vs non-HSAM

DATA SOURCE AND STUDY DESIGN

- The study used de-identified administrative claims data for the 100% sample of fee-for-service Medicare beneficiaries (Q1 2015-Q4 2021)
- The analysis is based on an “intent to treat” design with patients assigned to mutually exclusive categories based on whether or not they were treated with HSAM in 2016 or later years
- The first observed claim for HSAM or a randomly selected non-HSAM procedure during the study period that occurred within 1-year after a DFU diagnosis was designated as the index date
- Beneficiaries receiving HSAM were matched 1:1 to those not receiving HSAM using propensity score matching algorithm which accounted for baseline differences in patient characteristics outlined in Table 1
- The baseline and follow-up periods each consisted of the 6 months prior to and following the index date, respectively

STUDY MEASURES

- Baseline differences in demographics, comorbid conditions, wound severity, and healthcare resource use (HCRU) by place of service were compared before matching using Wilcoxon rank-sum tests for continuous measures and chi-square tests for categorical measures
- Baseline characteristics, rates of non-traumatic lower limb amputation, and HCRY over 6 months post-index were compared for matched cohorts using Wilcoxon sign-rank tests for continuous measures and McNemar’s tests for categorical measures

SAMPLE SELECTION

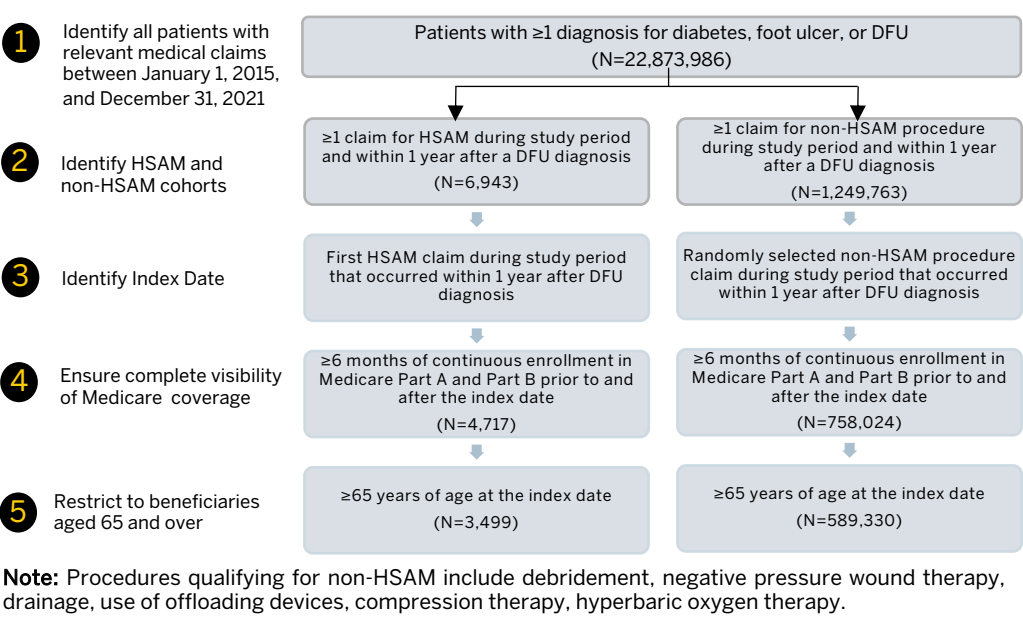
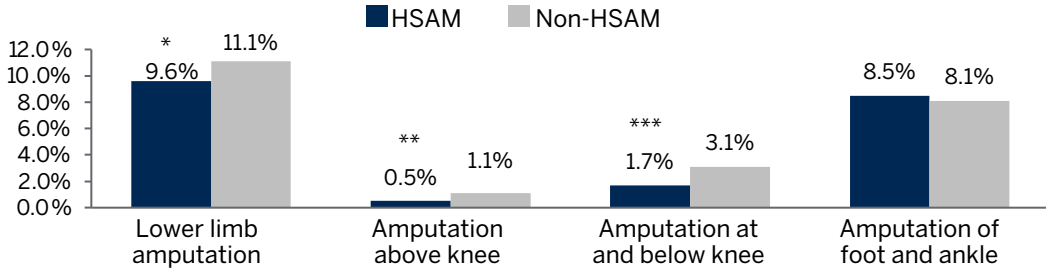


TABLE 1. BASELINE SAMPLE CHARACTERISTICS

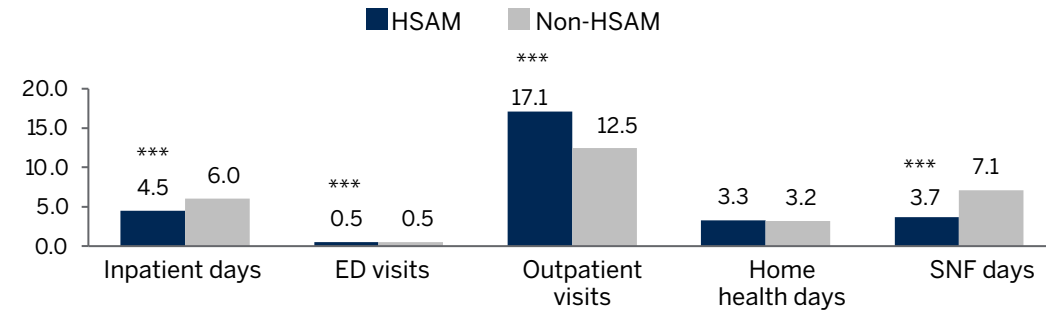
Selected characteristics	Pre-match			Post-match		
	HSAM (N=3,499)	Non-HSAM (N=589,330)	P-value	HSAM (N = 3,465)	Non-HSAM (N = 3,465)	P-value
Patient Demographics/Comorbidities						
Age, mean	75.5	77.3	<0.01	75.5	75.5	0.453
Male	64.2%	54.6%	<0.01	64.1%	65.4%	0.247
Charlson comorbidity index, mean	3.0	3.0	0.013	3.0	2.9	0.054
Select comorbid conditions, %						
Diabetes with complications	79.4%	67.1%	<0.01	79.4%	72.5%	<0.01
Peripheral vascular disease	65.6%	53.8%	<0.01	65.5%	61.8%	<0.01
Cerebrovascular disease	20.5%	21.9%	0.045	20.6%	21.3%	0.474
Congestive heart failure	36.1%	34.9%	0.133	36.1%	35.4%	0.529
COPD	20.3%	22.0%	0.016	20.3%	22.1%	0.062
Renal disease	44.3%	39.4%	<0.01	44.4%	43.6%	0.529
Myocardial infarction	12.8%	12.5%	0.621	12.7%	15.0%	<0.01
Number of unique DFU diagnosis, mean	14.9	6.0	<0.01	14.7	13.3	<0.01
Severity						
Months of active ulceration	6.5	3.7	<0.01	6.4	6.2	<0.01
DFU related infections	62.8%	49.1%	<0.01	62.5%	61.6%	0.415
Non-traumatic lower limb amputation	11.3%	6.9%	<0.01	11.2%	10.7%	0.566

RESULTS

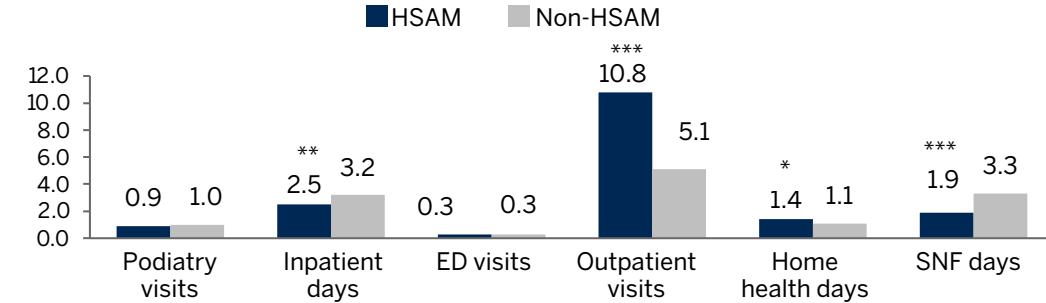
Non-traumatic lower-limb amputations during 6-month follow-up period after matching



All-cause medical use during 6-month follow-up period after matching



Number of DFU-related medical events during 6-month follow-up period after matching



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

LIMITATIONS AND CONCLUSIONS

- While the study controlled for numerous proxies for wound severity, clinical measures (e.g., wound size and depth) were not directly observable in the database
- Study findings are limited to fee-for-service Medicare beneficiaries aged ≥ 65 years
- HSAM is disproportionately used in more complex patients, with more severe DFUs
- Despite this, use of HSAM, as a cover for wounds, is associated with improved patient outcomes and healthcare resource utilization – particularly with respect to inpatient and SNF use over the 6 months post-treatment compared with not using HSAM in patients with DFUs

REFERENCES

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