

# COMPARATIVE EFFECTIVENESS FOR MEDICARE BENEFICIARIES WITH DIABETIC FOOT ULCERS (DFUs) WITH AND WITHOUT DEHYDRATED AMNION/CHORION MEMBRANE (dACM)

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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<sup>1,2</sup>
- 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<sup>2,3</sup>
- 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 alone<sup>4</sup>
- dACM<sup>(a)</sup> is a sterile, dehydrated placental allograft intended for use as a covering for wounds, including DFUs
- Currently, little is known about the characteristics and outcomes of patients with DFUs receiving dACM

<sup>(a)</sup>NuShield®, Organogenesis Inc., Canton, MA

## OBJECTIVE

- To better understand the profiles of patients with DFUs receiving dACM as a cover for wounds versus patients with DFUs not receiving dACM (non-dACM)
- 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 dACM vs non-dACM

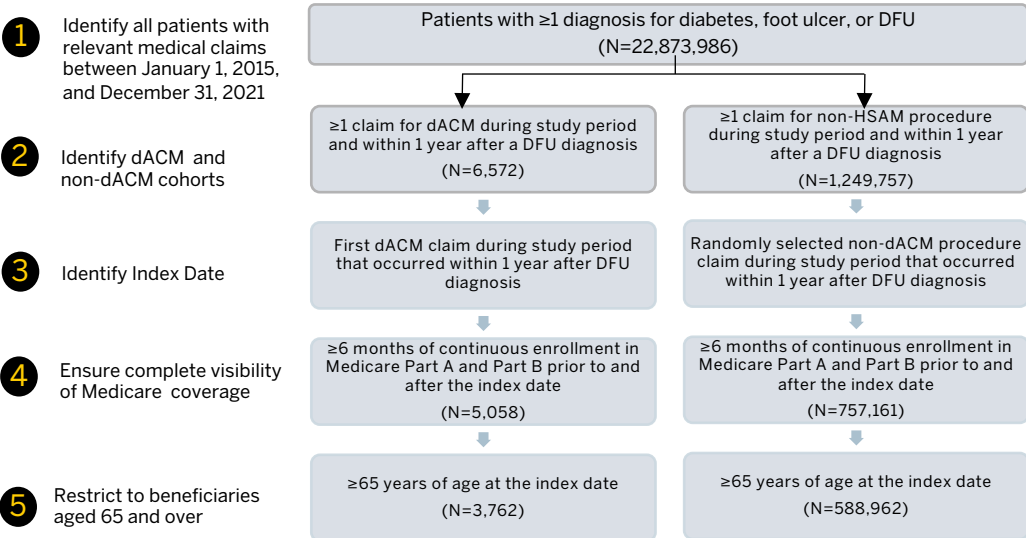
## DATA SOURCE AND STUDY DESIGN

- 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 dACM or a randomly selected non-dACM procedure during the study period that occurred within 1-year after a DFU diagnosis was designated as the index date
- Beneficiaries receiving dACM were matched 1:1 to those not receiving dACM 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 six 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 healthcare resource utilization over 6 months post-index were compared for dACM and non-dACM using Wilcoxon sign-rank tests for continuous measures and McNemar’s tests for categorical measure

## SAMPLE SELECTION



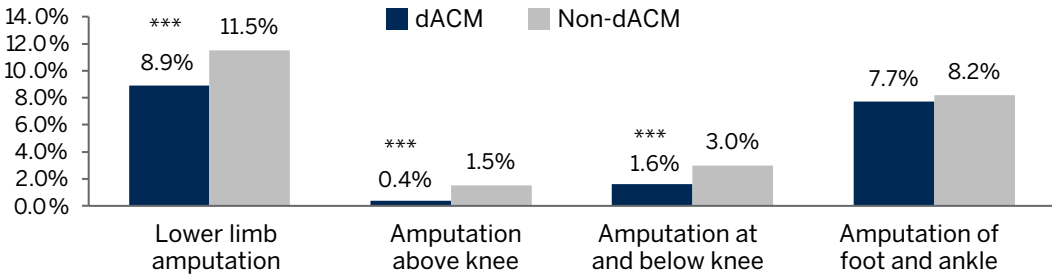
**Note:** Procedures qualifying for non-dACM include debridement, negative pressure wound therapy, drainage, use of offloading devices, compression therapy, hyperbaric oxygen therapy.

## TABLE 1. BASELINE SAMPLE CHARACTERISTICS

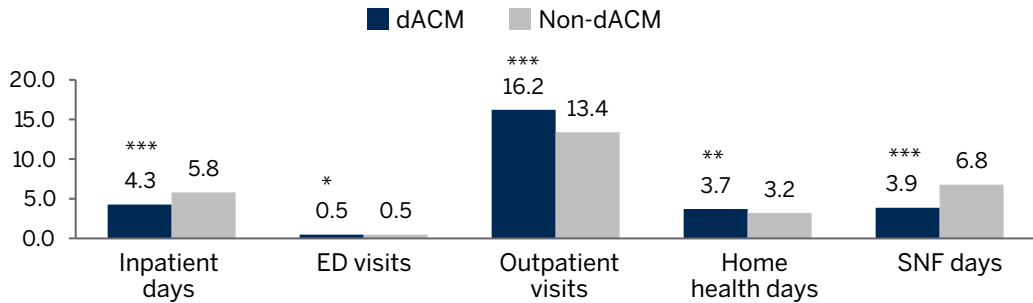
Selected characteristics	Pre-match			Post-match		
	dACM (N=3,762)	Non-dACM (N=588,962)	P-value	dACM (N = 3,717)	Non-cACM (N= 3,717)	P-value
Patient Demographics/Comorbidities						
Age, mean	75.7	77.3	<0.01	75.6	75.6	0.205
Male	63.9%	54.6%	<0.01	63.8%	65.6%	0.110
Charlson comorbidity index, mean	3.1	3.0	<0.01	3.1	3.1	0.645
Select comorbid conditions, %						
Diabetes with complications	79.9%	67.1%	<0.01	79.9%	76.2%	<0.01
Peripheral vascular disease	69.2%	53.8%	<0.01	69.1%	66.4%	0.011
Cerebrovascular disease	20.4%	21.9%	0.030	20.3%	22.4%	0.031
Congestive heart failure	38.1%	34.9%	<0.01	38.2%	37.6%	0.617
COPD	23.0%	22.0%	0.129	23.1%	22.6%	0.619
Renal disease	46.0%	39.4%	<0.01	46.1%	44.7%	0.218
Myocardial infarction	15.1%	12.5%	<0.01	15.0%	16.5%	0.084
Number of unique DFU diagnosis, mean	21.0	6.0	<0.01	20.5	18.4	<0.01
Severity						
Months of active ulceration	7.0	3.7	<0.01	6.9	6.9	0.117
DFU related infections	67.8%	49.2%	<0.01	67.6%	64.9%	0.011
Non-traumatic lower limb amputation	11.7%	6.9%	<0.01	11.8%	11.4%	0.560

## RESULTS

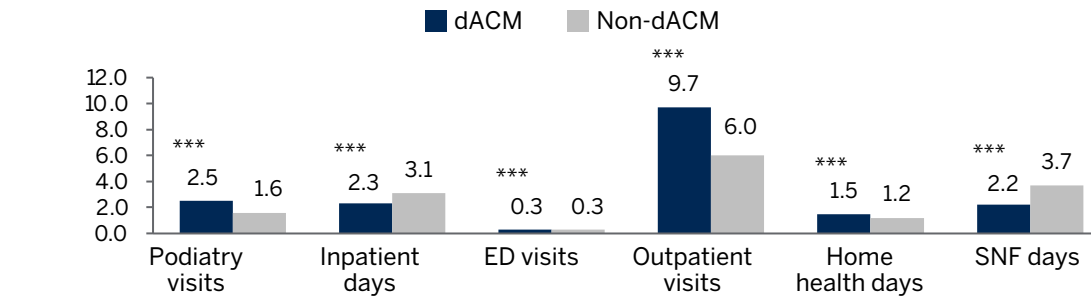
### Non-traumatic lower-limb amputations during 6-month follow-up period after matching



### 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 dACM and non-dACM: \*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
- dACM is disproportionately used in more complex patients, with more severe DFUs
- Despite this, use of dACM, 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 dACM in patients with DFUs

## REFERENCES

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- Rice JB et al. *Diabetes Care*. 2014;37(3):651-658.
- Frykberg RG et al. *J Foot Ankle Surg*. 2006;45(5):52-66.
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