# COMPARATIVE EFFECTIVENESS FOR MEDICARE BENEFICIARIES WITH DIABETIC FOOT ULCERS (DFUs) MANAGED WITH AND WITHOUT A PURIFIED NATIVE TYPE 1 COLLAGEN MATRIX PLUS POLYHEXAMETHYLENE BIGUANIDE (PHMB) ANTIMICROBIAL BARRIER (PCMP)

Urvi Desai, PhD;[1] J. Bradford Rice, PhD;[1] Jian-Yu E , ScD;[1] Serena Kongara, MPH;[1] Justin Chun, MHS;[1] Robert S. Kirsner, M.D., PhD[2]

[1]Analysis Group Inc., Boston, MA USA, [2]Director, University of Miami Hospital and Clinics Wound Center, University of Miami Miller School of Medicine, Miami, FL USA

## 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 alone[4]
- Currently, little is known about the characteristics and outcomes of patients receiving purified native Type I collagen ECM plus polyhexamethylene biguanide (PHMB) antimicrobial barrier (PCMP)[(a)] for the management of DFUs

[(a)]PuraPly®AM, Organogenesis Inc., Canton, MA

## OBJECTIVE

- To better understand the profiles of patients receiving PCMP versus those not receiving PCMP (non-PCMP) for the management of DFUs
- 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 receiving PCMP versus non-PCMP patients for the management of DFUs

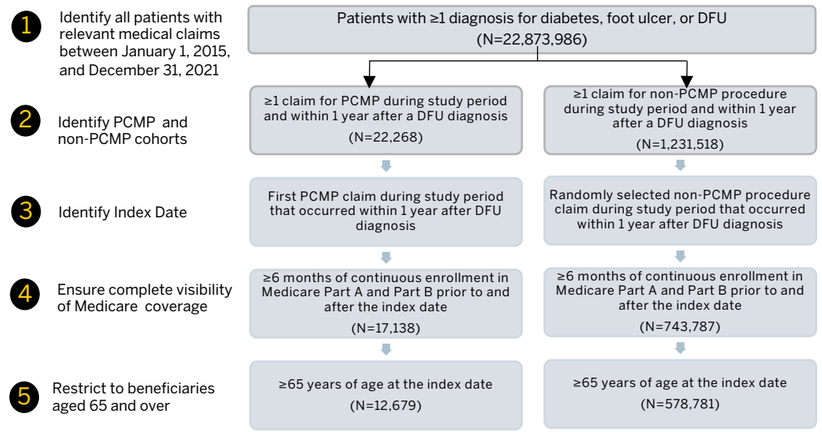
## DATA SOURCE AND STUDY DESIGN

- 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 PCMP in 2016 or later years
- The first observed claim for PCMP or a randomly selected non-PCMP procedure during the study period that occurred within 1-year after a DFU diagnosis was designated as the index date
- Beneficiaries receiving PCMP were matched 1:1 to those not receiving PCMP using propensity score matching algorithm which accounted for differences in baseline 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 HCRU 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



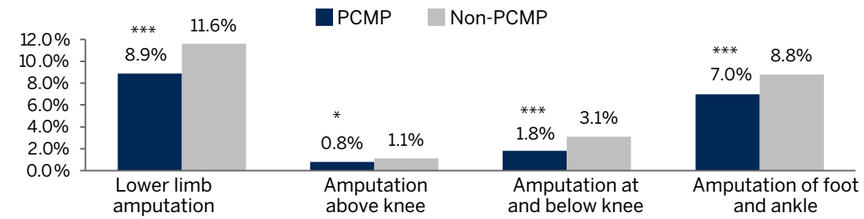

**Note:** Procedures qualifying for non-PCMP include debridement, negative pressure wound therapy, drainage, use of offloading devices, compression therapy, and hyperbaric oxygen therapy.

## TABLE 1. BASELINE SAMPLE CHARACTERISTICS

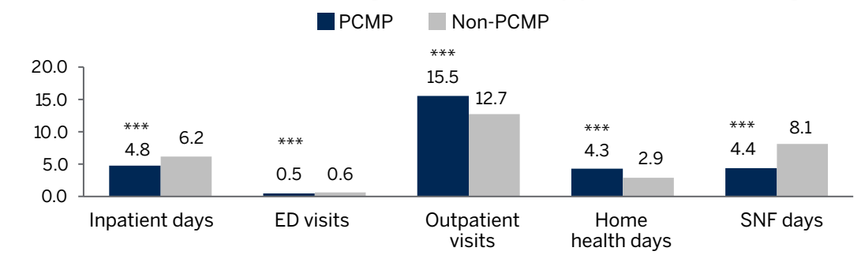
| Selected characteristics | Pre-match PCMP (N=12,679) | Pre-match Non-PCMP (N=578,781) | Pre-match P-value | Post-match PCMP (N = 12,587) | Post-match Non-PCMP (N= 12,587) | Post-match P-value |
|---|---|---|---|---|---|---|
| **Patient Demographics/Comorbidities** | | | | | | |
| Age, mean | 76.2 | 77.3 | <0.01 | 76.2 | 76.2 | 0.864 |
| Male | 61.0% | 54.5% | <0.01 | 61.0% | 61.5% | 0.393 |
| Charlson comorbidity index, mean | 3.17 | 2.95 | <0.01 | 3.2 | 3.2 | 0.164 |
| Select comorbid conditions, % | | | | | | |
| Diabetes with complications | 74.8% | 67.1% | <0.01 | 74.7% | 76.5% | <0.01 |
| Peripheral vascular disease | 71.5% | 53.5% | <0.01 | 71.4% | 64.8% | <0.01 |
| Cerebrovascular disease | 21.6% | 21.9% | 0.427 | 21.6% | 23.0% | <0.01 |
| Congestive heart failure | 40.4% | 34.8% | <0.01 | 40.4% | 40.2% | 0.806 |
| COPD | 24.6% | 21.9% | <0.01 | 24.6% | 23.9% | 0.216 |
| Renal disease | 46.3% | 39.2% | <0.01 | 46.2% | 46.1% | 0.869 |
| Myocardial infarction | 16.0% | 12.4% | <0.01 | 16.0% | 15.7% | 0.577 |
| Number of unique DFU diagnosis, mean | 18.1 | 5.8 | <0.01 | 17.5 | 15.5 | <0.01 |
| **Severity** | | | | | | |
| Months of active ulceration | 6.2 | 3.6 | <0.01 | 6.1 | 6.5 | <0.01 |
| DFU related infections | 68.2% | 48.9% | <0.01 | 68.1% | 67.5% | 0.298 |
| Non-traumatic lower limb amputation | 10.5% | 6.8% | <0.01 | 10.5% | 11.1% | 0.154 |

## RESULTS

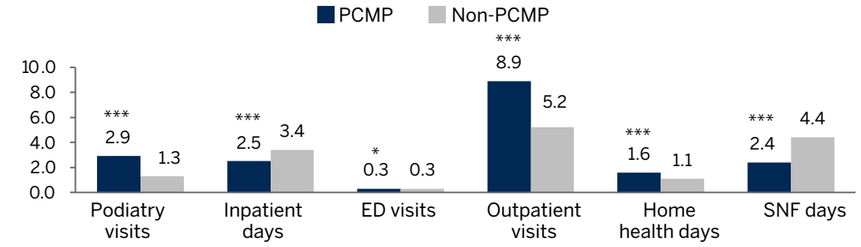
### Non-traumatic lower-limb amputations during 6-month follow-up period after matching




### 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 PCMP and non-PCMP: *$P$<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
- PCMP is disproportionately used in more complex patients, with more severe DFUs
- Despite this, use of PCMP for the management of DFUs 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 PCMP

## REFERENCES

**1.** Margolis D et al. AHRQ Publication No. 10(11)-EHC009-1-EF [online] January 2011. **2.** Rice JB et al. *Diabetes Care.* 2014;37(3):651-658. **3.** Frykberg RG et al. *J Foot Ankle Surg*. 2006;45(5):52-66. **4.** Rice JB et al. *J Med Econ.* 2015;18(8):586-595.

ORGANOGENESIS

Presented at Symposium on Advanced Wound Care Spring, April 26-30, 2023.

Acknowledgements and Financial Disclosures
Research funding provided by Organogenesis, Inc.
Dr. Kirsner serves as a scientific adviser for Organogenesis.