

Rethinking Regulatory Tiers: Medicare Real-World Evidence Shows CAMP Outcomes Are Independent of FDA Regulatory Classification

WH Tettelbach,^{1,2,3,4} DG Armstrong,⁵ Travis Tucker,⁶ TA Davenport,⁷ LA Morrison,⁸ DB Alper,⁹ J Johnson,¹⁰ LC Rogers,¹¹ JA Niezgoda,^{12,13} J Feight,¹⁴ K Nolan,^{8,15} D Kapp,¹⁶ N Wahab,^{17,18,19} MR Kelso,^{20,21,22,23}

INTRODUCTION

Cellular, acellular, and matrix-like products (CAMPs) are widely used in the management of hard-to-heal lower-extremity diabetic ulcers (LEDUs) and venous leg ulcers (VLUs). However, current reimbursement frameworks frequently assume that FDA regulatory pathways, section 361, 510(k), and premarket approval (PMA), reflect meaningful differences in clinical effectiveness. These categories, in reality, are primarily based on product origin, processing, and regulatory requirements rather than comparative clinical performance. This study evaluated whether FDA regulatory classification predicts real-world outcomes in Medicare beneficiaries and examines how CAMP-treated episodes compare with standard of care (SoC) alone. As shown in Figure 1, CAMPs are unevenly distributed across FDA regulatory pathways, with the majority classified under section 361, highlighting the need to evaluate whether these distinctions reflect meaningful differences in clinical outcomes.

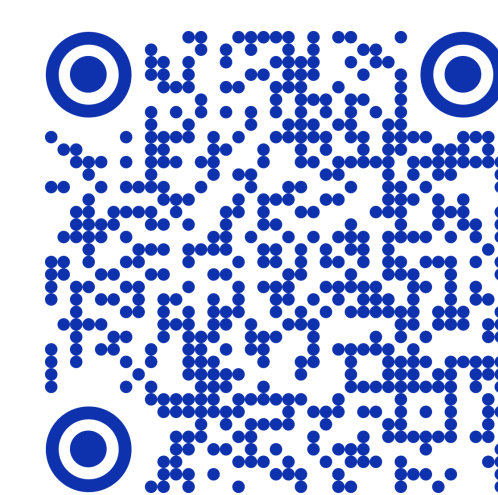
METHODS

A retrospective cohort study was conducted using the Centers for Medicare & Medicaid Services (CMS) 100% Limited Data Set (2016–2024), including 2.65 million lower-extremity diabetic ulcer (LEDU) and 745,411 venous leg ulcer (VLU) episodes of care. Episodes were defined as continuous periods of wound-related care separated by ≥ 90 -day clean intervals without wound-related claims. Eligible beneficiaries were identified using claims-based definitions for diabetes (LEDU) and chronic venous insufficiency (VLU), with comorbidity burden quantified using the Charlson Comorbidity Index.

Episodes receiving cellular, acellular, and matrix-like products (CAMPs) were identified using Q- and A-codes and stratified by FDA regulatory category (section 361, 510(k), and premarket approval [PMA]). SoC episodes included debridement and routine wound management without CAMP exposure.

Author Affiliations

1. Chief Medical Officer, RestorixHealth, Metairie, LA, US. 2. President, American Professional Wound Care Association (APWCA), Milwaukee, WI, US. 3. Adjunct Assistant Professor of Undersea & Hyperbaric Medicine, Duke University School of Medicine, Durham, NC, US. 4. Adjunct Professor of Podiatric Medicine & Surgery, Western University of Health Sciences, Pomona, CA, US. 5. Distinguished Professor of Surgery and Neurological Surgery, Keck School of Medicine of USC, US. 6. Owner, Principal Consultant, Woodside Analytics, LLC, St Petersburg, FL, US. 7. Plastic Surgeon, Partner, New York Plastic Surgical Group, New York, NY, US. 8. Regional Medical Director, RestorixHealth, Metairie, LA, US. 9. Board of Trustees, American Podiatric Medical Association, US. 10. Plastic Surgeon, Comprehensive Wound Care Services, Rockville, MD, US. 11. Chief of Podiatry, Professor of Podiatric Medicine and Surgery, UT Health San Antonio, TX, US. 12. President, WebCME, Milwaukee, WI, US, and RxOS Medical, Milwaukee, WI, US. 13. Chief Medical Officer, Kent Imaging, Calgary, Canada, and Auxilium Health, Milwaukee, WI, US. 14. Vice President of Health Policy, Kent Imaging, Calgary, AB, CA. 15. Clinical Professor of Vascular Surgery, Michigan State University College of Human Medicine, Grand Rapids, MI, US. 16. Plastic Surgeon, Jupiter Medical Center, Jupiter, FL, US. 17. CEO, Wound Care Experts, NV, US. 18. HCA Mountain View Hospital, Las Vegas, NV, US. 19. Roseman University College of Medicine, Henderson, NV, US. 20. Chief Executive Officer, Wound Care Plus, LLC, Kansas City, MO, US. 21. Board Member, APWCA, US. 22. Board Member, Post Acute Wound & Skin Integrity Council, US. 23. Head of Research, United Health Partners, Naperville, IL, US.



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METHODS

A unified four-way 1:1:1:1 matching strategy was applied to create balanced cohorts across CAMP categories and SoC using age, sex, comorbidity burden, time to treatment, debridement depth ($>20 \text{ cm}^2$), and episode year.

Outcomes were assessed at the episode level and included mortality, major and minor amputations, infection, length of treatment (LOT), and healthcare utilization (emergency department visits, inpatient admissions, ICU and CCU utilization). Statistical comparisons were performed using chi-square and t-tests, with Bonferroni-adjusted thresholds applied to control for multiple comparisons.

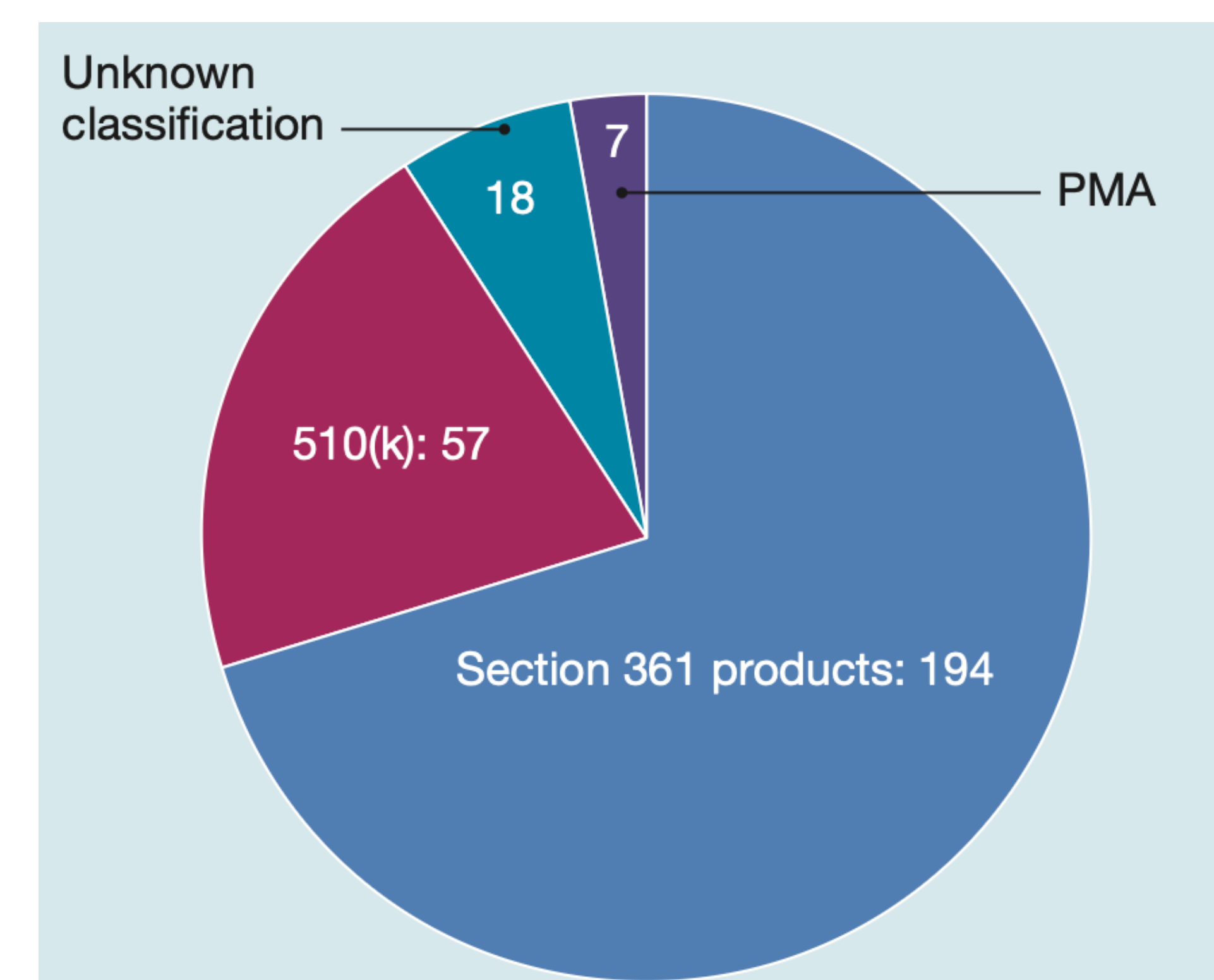


Figure 1. Regulatory classification of 276 Centers for Medicare and Medicaid Services-recognized CAMPs. There were >300 products as of July 2024 with an issued Q- or A-code. Included in this chart as 'unknown classification' are 18 products where a regulatory designation was not identified. Products that have since had their codes deleted or reissued ($n=6$) in addition to products which were sold by the milliliter ($n=23$) were removed from this chart. PMA = premarket approval

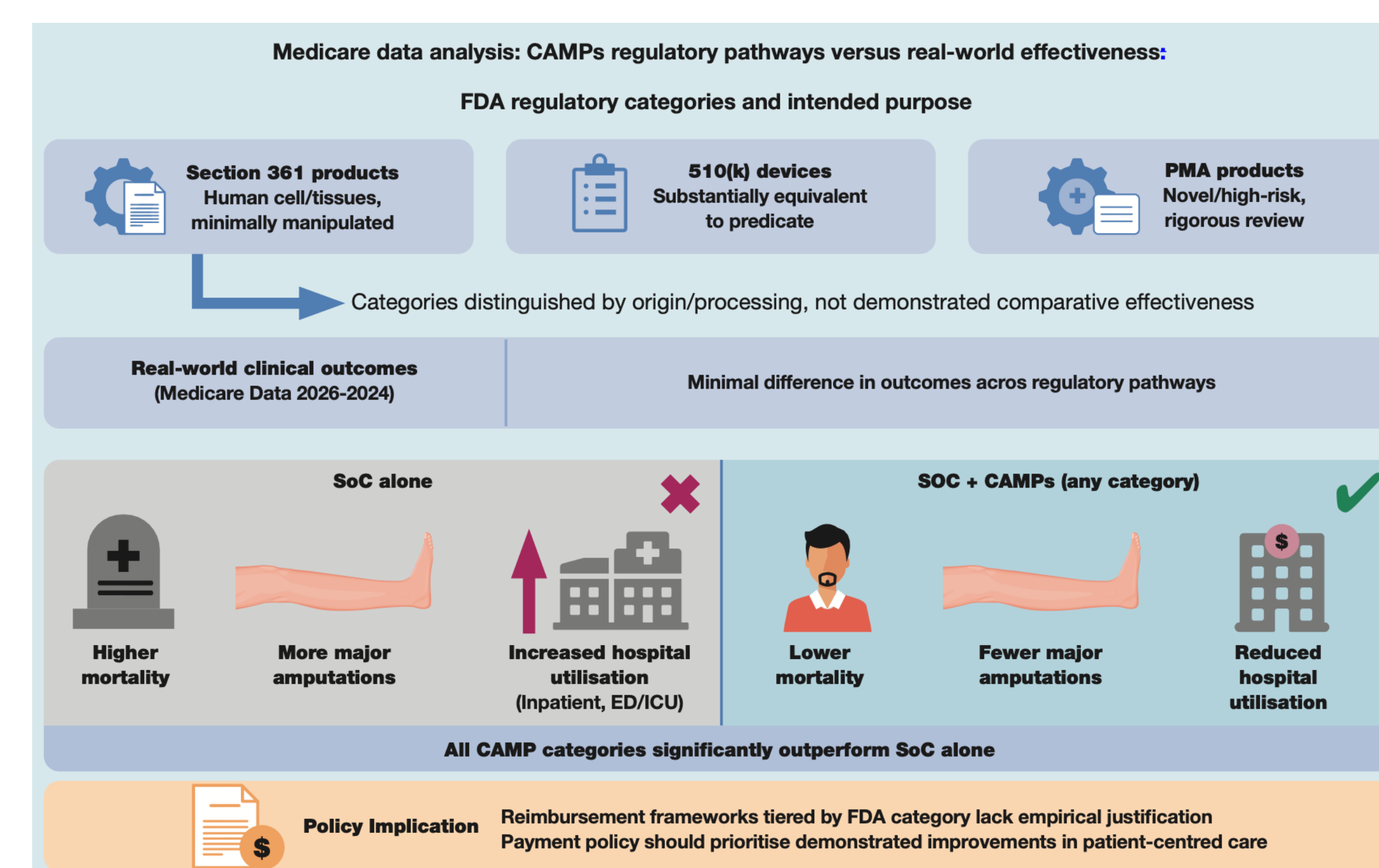


Figure 2. Although cellular, acellular and matrix-like products (CAMPs) enter the market via different US Food and Drug Administration (FDA) pathways, real-world data show minimal outcome variation across categories. All CAMP types used with SoC demonstrate improvement in mortality, amputation rates and hospital utilization compared with SoC alone, supporting performance-based rather than category-based reimbursement frameworks. ED = emergency department; ICU = intensive care unit; PMA = premarket approval

RESULTS

Across matched cohorts (LEDU: $n=3,585$ /group; VLU: $n=2,492$ /group), clinical outcomes were similar across FDA regulatory categories (section 361, 510(k), PMA), with no meaningful differences in mortality, amputation, infection, or healthcare utilization (Figure 2).

In contrast, CAMP-treated episodes consistently outperformed SoC alone across all major outcomes. Compared with SoC, CAMP use was associated with:

- Lower mortality (LEDUs: 9.5–11.1% vs 12.7%; VLUs: 10.0–12.2% vs 13.2%),
- Fewer major amputations,
- Reduced healthcare utilization, including fewer ED visits, inpatient admissions, ICU, and CCU use,
- Lower infection burden, including reduced cellulitis and sepsis in VLUs.

Although SoC episodes demonstrated slightly shorter length of treatment, this was accompanied by substantially higher complication rates and greater resource utilization.

These findings were consistent across wound sizes and ulcer types, reinforcing that outcomes are comparable across regulatory pathways while all CAMP categories demonstrate improved outcomes compared with SoC alone.

CONCLUSION

In this large Medicare real-world analysis, FDA regulatory classification (section 361, 510(k), PMA) did not meaningfully predict clinical outcomes for CAMPs. Across wound types and sizes, outcomes were comparable between regulatory categories, while all CAMP-treated episodes demonstrated consistent improvements in mortality, amputation, infection, and healthcare utilization compared with SoC alone.

These findings challenge reimbursement models tiered by regulatory classification, as such frameworks are not supported by real-world clinical effectiveness. Instead, payment policy should prioritize demonstrated improvements in patient-centered outcomes, supporting an outcomes-based rather than category-based approach to CAMP reimbursement.

Corresponding author email: tarpon@xmission.com

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