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The hidden costs of limiting access: clinical and economic risks of Medicare's future effective cellular, acellular and matrix-like products (CAMPs) Local Coverage Determination

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The hidden costs of limiting access: clinical and economic risks of Medicare's future effective cellular, acellular and matrix-like products (CAMPs) Local Coverage Determination

Objective: To evaluate the impact of Medicare's future effective Local Coverage Determination (LCD) for cellular, acellular and matrix-like products (CAMPs), which, while informed by a literature review and expert input, was finalised without incorporating a detailed statistical or cost analysis of its projected clinical and economic impact across diverse wound care delivery settings (e.g., hospital-affiliated, private practice, and post-acute care). This analysis focuses on the clinical consequences for Medicare beneficiaries with chronic or hard-to-heal lower extremity diabetic ulcers (LEDUs) and venous leg ulcers (VLUs). Additionally, it aims to assess the economic implications of implementing a capitated or fixed-fee schedule on CAMPs' use, Medicare expenditures and associated medical outcomes.

Method: A review of retrospective analyses of Medicare claims (2015–2020) was conducted, comparing treatment outcomes for LEDUs and VLUs using CAMPs plus medically accepted standard of care (SoC) versus SoC without CAMPs. Clinical endpoints included rates of hard-to-heal ulcer healing, amputation rates, hospitalisations and healthcare resource use. Cost-effectiveness models evaluated the impact of CAMP reimbursement structures on overall Medicare costs. Analysing the impact of a fixed-fee schedule involved evaluating Medicare claims data from 2016–2023 to determine the number of commercially available CAMPs, along with the most up-to-date average sales price (ASP). A comparative cost analysis model using an activity-based costing approach and a prospective payment system comparison was applied to evaluate two distinct reimbursement structures: an ASP fee-for-service model versus a fixed-fee schedule model.

Results: Medicare beneficiaries receiving SoC plus CAMPs for stalled wounds demonstrated significantly lower amputation rates, reduced hospitalisations and improved wound healing times compared with those receiving SoC without a CAMP during the episode of care. Beneficiaries receiving CAMPs also realised annual cost savings of $3670 USD per patient and a five-year net benefit of $5003 USD per patient. When evaluating over a 12-month window, restricting CAMPs to eight applications in the treatment of hard-to-heal VLUs and LEDUs resulted in estimated treatment failure rates of 10.9% and >30%, depending on the area of investigation. Moreover, the non-real-world restriction of a 16-week treatment episode in the future effective CAMP LCD, which fails to account for care delays (e.g., cellulitis, hospital admissions), will likely drive treatment failure rates even higher. Among failed LEDU cases receiving a CAMP, 1% require an amputation at a reimbursement rate of $23,435 USD per case, 37% are readmitted at a rate of $2079 USD per admission, and 30% seek emergency care at a reimbursement rate of $8292 USD per visit. These complications could result in hundreds of millions of dollars in additional annual Medicare expenditures, eroding any expected savings from the future effective CAMP LCD. Implementing a fixed CAMPs fee schedule instead of the traditional ASP reporting system could potentially reduce Medicare expenditures on CAMPs by >51% while still enabling wound care providers to determine medical necessity on evidence-based decision-making.

Conclusion: The proposed CAMPs LCD could negatively impact outcomes for Medicare beneficiaries who experience adverse outcomes when treatment is prematurely limited to eight applications over a fixed 16-week episode of care. While this subset of patients represents a relatively small proportion, they are at high risk of costly complications, which are likely to escalate when effective and medically necessary CAMPs treatment, ordered, selected and applied by their healthcare provider, is denied. Implementing a fixed-fee schedule for CAMPs without an absolute eight-application cap could enhance access by allowing healthcare providers to treat a greater proportion of hard-to-heal ulcers to closure with the goal of limb preservation, while maintaining cost controls. Policy adjustments should incorporate real-world evidence demonstrating the effectiveness of CAMPs rather than relying solely on randomised controlled trials.

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CAMPs • cellular, acellular and matrix-like products • local coverage determination • wound • wound care • wound dressing

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Hard-to-heal (chronic) wounds, particularly lower extremity diabetic ulcers (LEDUs) and venous leg ulcers (VLUs), pose a significant public health challenge, impacting millions of individuals and creating substantial economic and clinical burdens on healthcare systems. Between 2015–2019, >1.2 million Medicare beneficiaries were diagnosed with LEDUs.[1] An estimated 500,000–600,000 beneficiaries develop VLUs annually, with combined Medicare expenditures surpassing $1.1 billion USD.[2] These conditions are linked to prolonged healing times, recurrent

hospitalisations and an increased risk of complications, including limb loss. LEDUs alone account for >100,000 amputations annually in the US, with VLUs further complicating the healthcare landscape due to high recurrence rates and increased morbidity.[1–3]

Advanced wound care strategies, including cellular, acellular and matrix-like products (CAMPs), have emerged as critical tools for limb salvage by improving healing rates and reducing infection risks, ultimately lowering healthcare costs. Previous retrospective analyses of Medicare claims data have demonstrated that CAMPs, when applied according to established clinical parameters (following parameters for use (FPFU)), can significantly improve patient outcomes by decreasing the incidence of major amputations, reducing emergency department visits and facilitating wound closure.[1,2] These benefits underscore the importance of ensuring continued access to proven, effective treatments for hard-to-heal wounds.

To date, the Center for Medicare & Medicaid Services (CMS) has been managing two separate payment models within the outpatient wound care arena: a bundled payment system for claims submitted in the hospital outpatient department (HOPD) wound care settings, and an average sales price (ASP) reimbursement model for claims submitted in the private office and post-acute wound care settings. While the bundled model has long been criticised for underfunding care for larger or more complex wounds, the ASP model, though more reflective of actual product costs, has led to significant variability in reimbursement due to wide disparities in product pricing.

The recent proposals made by the seven Medicare Administrative Contractors (MACs) for 2024 and 2025 to implement an updated Local Coverage Determination (LCD) for CAMPs represent a pivotal shift in reimbursement policies that could significantly impact access to and use of these essential treatments. Notably, the policy limits CAMP applications to a maximum of eight within a 16-week episode of care, regardless of wound complexity or clinical response, and does so without addressing the shortcomings of the current ASP payment model. Advocates assert that a capitated or fixed-fee schedule may enhance access to CAMPs, enabling providers to address hard-to-heal wounds more efficiently, provide a solution to the flawed bundled payment methodology, and address the MACs' desire to limit CAMP applications unnecessarily. However, valid concerns exist about potential restrictions on treatment frequency and the implications these may have on patient outcomes. This analysis is crucial as it aims to evaluate the clinical and economic consequences of the future-effective CAMPs LCD for Medicare beneficiaries, particularly those with chronic or hard-to-heal LEDUs and VLUs. Specifically, we assess:

- The real-world impact of restricting CAMP applications to a fixed number, such as the proposed eight-application limit, on patient outcomes and healthcare use
- The projected economic burden of treatment failure resulting from premature cessation of therapy
- The cost-saving potential and clinical viability of replacing the ASP-based reimbursement system with a fixed-fee schedule model.

By integrating Medicare claims data with cost-effectiveness modelling, we seek to inform policy revisions that preserve clinical flexibility, reduce preventable complications and support value-based care.

Methods

A review of cohort analyses was conducted using Medicare Limited Data Standard Analytic Files (2015–2020). The claims data originated from inpatient hospitals and HOPDs. Propensity-matched groups that received CAMPs were compared to standard of care (SoC) patients who did not receive a CAMP during their episode of care. Statistical analyses included logistic regression models for assessing amputation risks and hospital use, as well as Markov models for evaluating cost-effectiveness up to a five-year horizon. Analysing the impact of a fixed-fee schedule model involved evaluating a limited 2016–2023 Medicare claims database to determine the number of commercially reimbursed CAMPs, along with the most up-to-date ASP. This dataset included claims from inpatient hospitals, HOPDs, and a 5% sample from private offices and post-acute care settings. A comparative cost analysis model using an activity-based costing approach and a prospective payment system comparison was applied to evaluate two distinct reimbursement structures: an ASP fee-for-service model versus a fixed-fee schedule model.

Ethical standards and patient consent

The Medicare Limited Data Set (LDS) files (2015–2023) were acquired under a data use agreement with CMS. Medicare LDS files do not contain specific direct identifiers, as defined in the Health Insurance Portability

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and Accountability Act Privacy Rule. All analysis and reporting of Medicare data was performed in compliance with relevant laws and institutional guidelines approved by the CMS. Patient consent was not required for this study.

Results

Lower extremity diabetic ulcers

A favourable impact was observed when comparing propensity-matched Medicare beneficiaries, from 2015–2018, with hard-to-heal LEDUs and who received CAMPs during their episodes of care to those who did not receive such intervention:

- Clinical effectiveness
  - Decreased major amputation rates ($p<0.0001$), fewer emergency department visits ($p<0.0001$), decrease in readmission rates ($p<0.0001$) (Table 1)[1]
  - Propensity-matched groups revealed that applying CAMPs in alignment with FPFU resulted in lower minor amputation rates ($p=0.002$).[1] (FPFU is defined as initiating treatment with CAMPs within 30–45 days of diagnosis and re-applying new CAMPs at regular intervals within the specified 7–14 day range)
- Cost-effectiveness
  - A retrospective cohort study analysing Medicare beneficiaries (2015–2019) with hard-to-heal LEDUs, using a hybrid economic model that combined a one-year decision tree and a four-year Markov model, demonstrated that placental-derived CAMPs provided an additional 0.013 quality-adjusted life years (QALYs) while saving $3670 USD per patient in the first year alone. Over a five-year horizon, the net monetary benefit (NMB) was estimated at $5003 USD per patient, based on a willingness-to-pay threshold of $100,000 USD per QALY (Table 1).[4]

Venous leg ulcers

Some 42% of Medicare beneficiaries with chronic venous insufficiency, evaluated from 2015–2019, developed at least one VLU, and 79% had their episode claim resolved within one year. However, 59% of patients developed another VLU during the 12-month study period.[2] A favourable impact was observed when comparing propensity-matched Medicare enrolees with a hard-to-heal VLU who received CAMPs during their episodes of care.

- Clinical effectiveness
  - Faster healing time (by 21 days; $p=0.0027$), lower infection rates ($p=0.034$), and reduced hospital resource use (Table 2)[5]
  - Timely initiation and routine application of CAMPs reduced VLU recurrence rates[6]
- Cost-effectiveness:
  - A Markov model-based cost-effectiveness study on

Table 1. Real-world outcomes and cost savings of CAMPs versus SoC in Medicare patients with a LEDU

Outcomes (2015–2018)	LEDUs
QALY gain (versus SoC)	+0.013 QALYs (5-year model)[4]
Net monetary benefit	$5003 USD per patient (5-year horizon)[4]
Cost savings per patient	$3670 USD (year 1); $p<0.05$[4]
Reduction in major amputations	↓ 50.0% (3.2% → 1.6%); $p<0.0001$[1]
Reduction in emergency department visits	↓ 21.0% (23.1% → 18.3%); $p<0.0001$[1]
Reduction in hospital readmissions	↓ 38.0% (6.4% → 4.0%); $p<0.0001$[1]

CAMPs—cellular, acellular and matrix-like products; LEDU–lower extremity diabetic ulcer; QALY—quality-adjusted life year; SoC—standard of care

Table 2. Real-world outcomes and cost savings of CAMPs versus SoC in Medicare patients with a VLU

Outcomes (2015–2018)	VLUs
QALY gain (versus SoC)	+0.010 QALYs (3-year model)[6]
Net monetary benefit	$1178 USD per patient (3-year horizon)[6]
Cost savings per patient	$170 USD (3 years); $p<0.05$[6]
Reduction in cellulitis	↓ 28.8% (17.0% → 12.1%); $p=0.00398$
Reduction in sepsis	↓ 51.1% (4.5% → 2.2%); $p=0.00038$[2]
Reduction in emergency department visits	↓ 18.2% (56% → 45.8%); $p<0.00012$[2]
Reduction in hospital readmissions	↓ 56.4% (11.7% → 5.1%); $p<0.0018$[2]

CAMPs—cellular, acellular and matrix-like products; QALY—quality-adjusted life year; SoC—standard of care; VLU—venous leg ulcer

VLUs in Medicare enrolees revealed that a placental-derived CAMP, when following clinical guidelines, yielded a lower per-patient cost of $170 USD and an increase of 0.010 QALYs over three years. The resulting NMB was $1178 USD per patient, favouring treatment episodes that included a CAMP. The analysis also demonstrated that early and regular application of CAMPs reduced hospital readmissions and overall healthcare expenditure (Table 2).[6]

Economic impact of CAMP application limitations

A retrospective observational cohort study using real-world evidence from a Medicare LDS between 2016–2020 demonstrated that treating LEDUs and VLUs with placental-derived CAMPs resulted in a 26% reduction in one-year mortality, a 91% lower recurrence rate, and 71% fewer adverse outcomes compared with SoC.[7] Limiting beneficiaries with hard-to-heal LEDUs and VLUs to eight CAMP applications over a static 16-week episode of care will lead to significant adverse events and economic losses. When evaluating 2023 Medicare claims data over a 12-month period, restricting CAMPs to eight applications in the treatment of hard-to-heal LEDUs led to estimated treatment failure rates of 10.9% in the HOPD setting, 22.3% in the private office and post-acute care settings, reaching ≥30% in published comparative trials.[8–10] The prospective randomised controlled trials (RCTs) that had a ≥30% failure rate were designed and strictly controlled to evaluate the frequency of complete wound closure at 12 and 16 weeks compared to SoC, but included a cohort of non-Medicare patients.[9,10] Our analysis of Medicare enrolees demonstrated that 10.9% of patients in the HOPD setting and 22.3% in the private office and post-acute care settings had claims that remained open after eight applications.

The future CAMP LCD further exacerbates this issue by imposing a rigid 16-week episode-of-care limit, which fails to account for real-world care delays (e.g., cellulitis or inpatient admission) and prematurely discontinues therapy in wounds that are responding but have not yet achieved closure. As highlighted in recent analyses, complex VLUs, which were defined as hard-to-heal VLUs that develop an infection, required significantly more healthcare resources and CAMP applications.[2,6] The study found that when adding one standard deviation to the mean number of CAMP applications, the total exceeded eight, demonstrating that many patients, particularly those with infections or other complications, need extended treatment beyond the imposed limits of the future effective CAMPs LCD. This arbitrary restriction not only increases the likelihood of treatment failure but also forces a shift toward more aggressive and expensive healthcare interventions throughout the patient's wound care continuum. Unfortunately, all CAMP-related expenditures in these failed treatment episodes are wasted, undermining both clinical outcomes and healthcare resource efficiency.

To calculate the total number of Medicare patients at risk after reaching application limitations without closure of their LEDU (Table 3), an extrapolation was made from the 2022–2023 population,[11] among which 31.8% of the Medicare beneficiaries were projected to

Table 3. Annual demographic at risk of not reaching LEDU closure at eight applications of cellular, acellular and matrix-like products in the HOPD setting

Parameter description	Factor	Population size, n
US population on 31 December 2022		335,453,105[14]
US Medicare population 2023		68,300,000[11]
US Medicare population with diabetes in 2022	31.8%[12]	21,719,400
Medicare patients who developed a LEDU	8.0%[13]	1,737,552
Patients with a LEDU which did not close after eight applications	10.9%[8]	189,393

HOPD—hospital outpatient department; LEDU—lower extremity diabetic ulcer

Table 4. Economic burden of non-healing LEDU episodes after eight applications of cellular, acellular and matrix-like products in the HOPD setting, 2022

Complication	% of LEDU population[4]	Projected cost per event, $ USD[4]	Projected total cost for patients with failed episodes care, $ USD
Major amputations	1.0	23,435	44,384,289
Hospitalisations	37.0	2097	146,948,265
Emergency department visits	30.0	8292	471,134,445
			662,466,999

HOPD—hospital outpatient department; LEDU—lower extremity diabetic ulcer

have diabetes.[12] An 8% subset was assumed to develop an LEDU,[13] and in the HOPD setting, 10.9% were expected to reach the eight application limit without ulcer closure, resulting in an annual at-risk Medicare population of 189,393.

Estimates were previously derived for patients whose ulcers may or may not close as part of a 2023 Markov model.[4] These values differed from clinical trial data and likely underestimated the number of patients who were slow responders to CAMP treatment (Table 4). Nearly 70% of patients are expected to have significant events if CAMP applications are halted at eight applications. The estimated cost of these events for 2022 is an astounding $662 million USD (Table 4).

For comparison, allowing medical necessity to determine whether additional applications are required, even two further applications for all 189,393 patients would cost $167 million USD less than the $662 million USD in complications at a reimbursement rate of $1307 USD per application.

This financial impact may be even more substantial if the estimates account for patients with VLUs, which are less prevalent but tend to require longer healing times. Medicare claims data from 2015–2020 indicate that approximately 20% of VLU episodes failed to close after eight CAMP applications.[6] Among those failed episodes that continued with the SoC alone, up to 2% underwent an amputation,[2] 12.2% were treated in the hospital setting,[7] and nearly 55% developed cellulitis.[2] When the costs associated with VLU-related complications are combined with the projected economic burden of LEDU complications, the financial impact of an eight-application limit is likely to exceed $1 billion USD annually.

Impact of the current CAMPs ASP reimbursement model versus a fixed-fee schedule

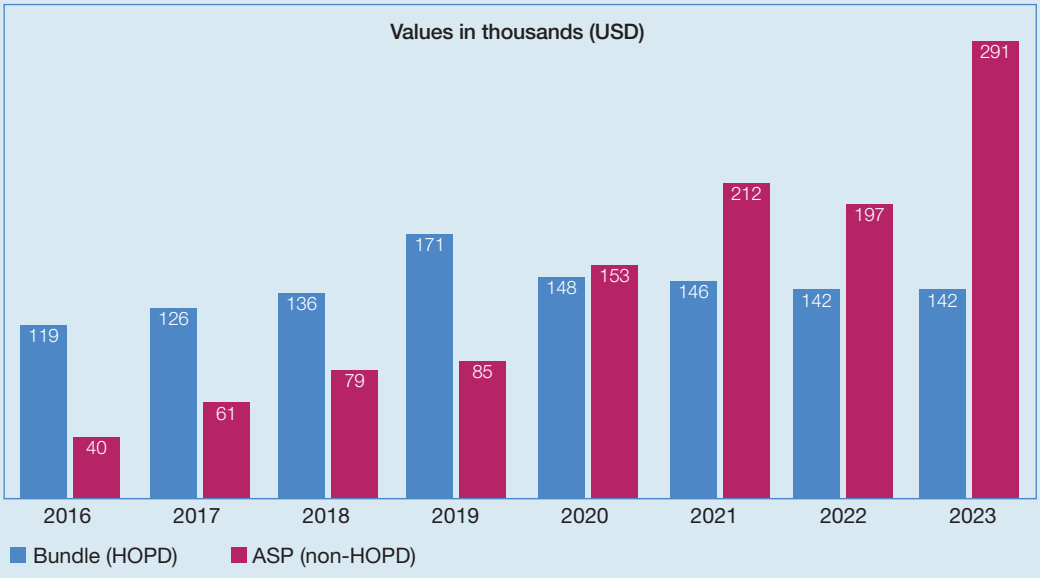
In 2025, there were calculated to be 221 CAMPs with Healthcare Common Procedure Coding System codes assigned by CMS: 23 with an A code; and 198 with a Q code. CAMPs scheduled for reimbursement by CMS can be found in CMS's ASP pricing file (https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files).

Based on 2023 Medicare claims data, 432,450 CAMP applications, excluding powders and flowables, were performed on hard-to-heal wounds, with 67.3% occurring outside the HOPD setting (Fig 1). Once the future effective CAMPs LCD is fully implemented in its current form, approximately 64% of CAMP technologies (275,471 applications based on 2023 HOPD, private office and post-acute care Medicare claims data) will be eliminated as a treatment option. This includes the loss of 72% of CAMP applications in private office and post-acute care settings (non-HOPD) and 28% in the HOPD setting, resulting in a significantly skewed delivery of care (Fig 2).

In the short-term, a reduction in reimbursed CAMPS will lead to product shortages, primarily due to the need to scale up manufacturing capacity for the remaining 17 of the 221 commercially available CAMPs listed as covered in the future effective CAMPs LCD. These shortages are yet another example of the unintended consequences of a poorly designed future effective CAMPS LCD, which is likely to create additional barriers to patient access and negatively affect outcomes for this at-risk population.

Given the current concerns of wound care providers in private offices and post-acute care settings that use

Fig 1. Cellular, acellular and matrix-like product (CAMP) applications by place of service and year, derived from 2016–2023 Medicare claims data. ASP—average sales price; Bundle—reimbursement is provided as a lump sum to the HOPD for a particular procedure, rather than a separate reimbursement for the CAMP product itself. HOPD—hospital outpatient departments



CAMPs with high ASPs, a comparison was performed using a weighted average ASP based on the 2023 Medicare claims data. The average weighted reported ASP in the non-HOPD setting for 2023 was \$828 USD/cm^2, ranging from an ASP of \$7.39 USD/cm^2 to \$13,116.92 USD/cm^2. This represents a total spend of \$3,883,091,207 USD on CAMPs by CMS in 2023.

Reimbursement for CAMPS should be guided by a multifactorial approach that encourages innovation while ensuring cost containment across the industry. A tiered reimbursement system may be necessary to balance these goals. For example, adopting a fixed-fee schedule model at \$828 USD/cm^2 would represent a break-even point in expenditures relative to CMS's total spending on CAMPs in 2023. While setting an ASP of \$400 USD/cm^2 may be considered a reasonable benchmark, as approximately 50% of CAMPs reimbursed by CMS in 2023 were priced close to or below this level. At this rate, a \$400 USD/cm^2 capitated cost would lead to substantial savings for CMS, with an estimated annual saving of \$2.01 billion USD in Medicare expenditures, representing a reduction of >51% in Medicare spending on CAMPs (Fig 3).

Compared to the reported ASP system, bundled payment models, which assign a fixed cost regardless of wound size or complexity, have faced criticism, including from CMS (calendar year 2023 payment rules). These models have been found to discourage HOPD-based providers from treating more extensive wounds (≥26cm^2, especially those exceeding 100cm^2) due to financial losses. Expressly, when the cost of CAMPs required for adequate surface area coverage exceeds the fixed bundled reimbursement, the HOPD wound clinic itself incurs a financial loss, leading to reluctance to treat such cases.

One consideration is that a fixed-fee solution could be implemented by generating temporary per cm^2 G-codes to replace the current procedural terminology (CPT) codes for CAMPs application procedures. The 'G' in

Fig 2. Total cellular, acellular and matrix-like products (CAMPs) applications in 2023 subjected to proposed Local Coverage Determination restrictions. CAMPs that remain covered (red) represent only 36% of ASP in the non-hospital outpatient department (HOPD) setting for 2023. CAMPs that are proposed to be eliminated (blue) represent 64% of all 2023 applications, of which 72% were provided in non-HOPDs. Non-HOPD settings include Medicare private office and post-acute care settings

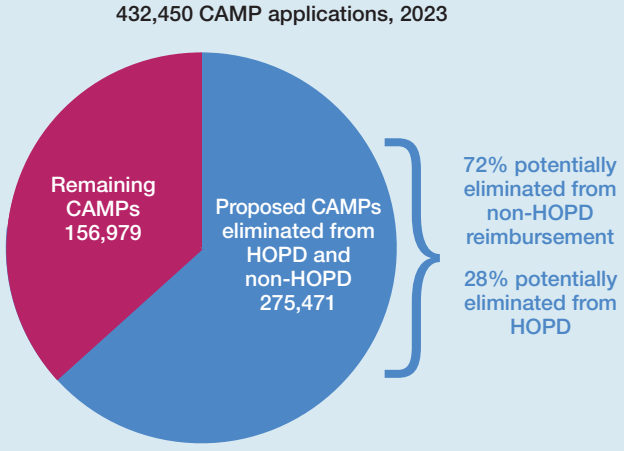
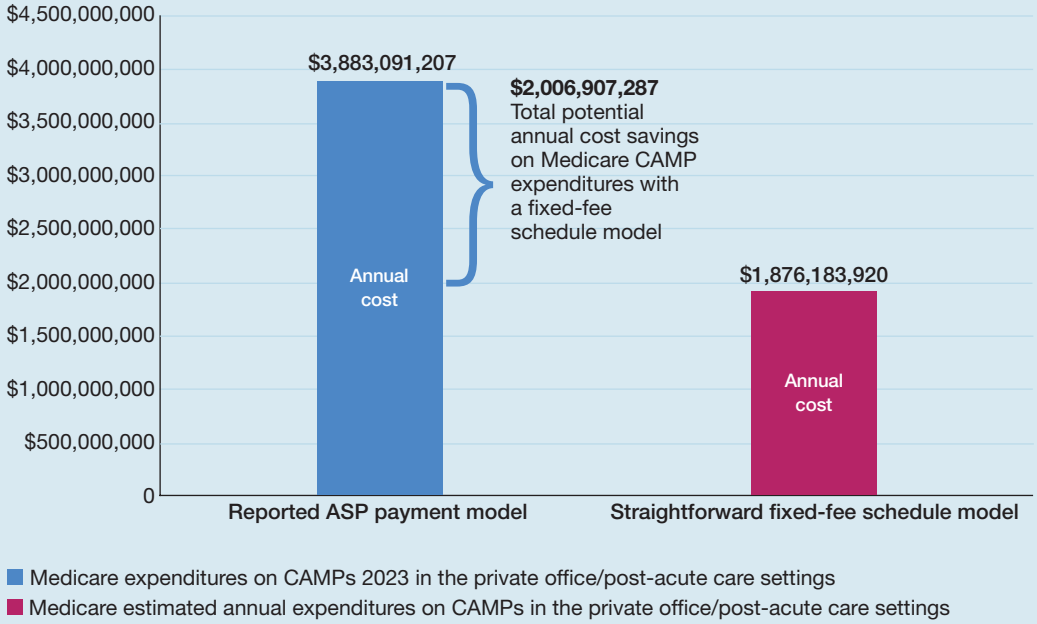


Fig 3. Cost comparison of Medicare cellular, acellular and matrix-like product (CAMP) expenditures (in USD): reported average sales price versus fixed-fee schedule model (2023 Medicare claim data). ASP—average sales price



G-codes, part of the Healthcare Common Procedure Coding System, signifies temporary codes used by Medicare to report and reimburse specific procedures, services and quality measures that do not have equivalent CPT codes. Q-codes for individual products would remain for data tracking purposes but would be billed at a zero-dollar amount. G-codes could be billed in 1cm² increments to match the wound size, ensuring appropriate reimbursement.[15] This approach would enable CAMPs to be categorised into specific classifications, allowing products to be compared to similar ones and priced accordingly. Compared to the current ASP fee structure, a fixed reimbursement per cm² for each G-code, calculated based on the average of all reported ASPs within comparable classifications, could save CMS hundreds of millions of dollars annually, and eliminate the inefficiencies of both the ASP and bundled payment processes, yet allowing access to CAMPs to beneficiaries requiring this advanced modality.

These approaches highlight the dramatic potential for cost containment in Medicare CAMP-related expenditures by transitioning to a fixed-fee schedule model without having to implement restrictive policies that have the potential to impact Medicare beneficiaries unfavourably.

Discussion

The economic impact of limiting CAMPs applications to eight per 16-week episode of care for patients with either a LEDU or VLU is substantial.[16,17] With up to 30% of patients experiencing treatment failure due to these restrictions, additional healthcare interventions, including costly amputations and hospitalisations, will become necessary. A comparative analysis of the current reported ASP reimbursement system versus a fixed-fee schedule model demonstrates the need for policy adjustments. Under the current ASP reporting structure, Medicare expenditures for CAMPs in 2023 totalled >$3.8 billion USD, which was further exacerbated by inconsistent manufacturer-reported pricing. In contrast, a fixed-fee schedule model (i.e., $400 USD/cm²) would have reduced these expenditures to $1.9 billion USD, achieving an annual cost saving of >$2.0 billion USD, an overall 51.7% reduction. A fixed-fee schedule model offers predictable, controlled costs while preserving access to essential wound care treatments. Moreover, it would enable providers to treat multiple ulcers and more extensive wounds concurrently rather than adhering to a rigid and inflexible 'one-size-fits-all' reimbursement policy. Expanding coverage to permit ongoing CAMP applications based on clinical response and medical necessity is a logical step towards balancing cost containment with effective patient care.

Treatment limitations invariably induce disparities, particularly for high-risk populations. For example, a retrospective analysis of VLU outcomes revealed that Medicare/Medicaid dual enrolees frequently encounter more substantial socioeconomic barriers and experience significantly poorer clinical outcomes, including lower ulcer healing rates, higher infection rates and increased overall healthcare use.[5] Restricting the number of CAMPs applications under the future effective CAMPs LCD will disproportionately impact vulnerable patients, leading to increased numbers of amputations, hospitalisations and emergency department visits. Given that those dual enrolees required an average of 21 additional days for VLU closure and experienced higher complication rates,[5] similar adverse outcomes can be anticipated under the proposed CAMPs restrictions. The financial burden of delayed healing and increased complications would likely offset any intended cost savings of the LCD, ultimately driving up overall Medicare expenditures.

The proposed LCD's restrictions also fail to align with evidence-based best practices and create avoidable complications by prematurely terminating treatment, solely in the name of cost savings, for patients whose wounds are responding but not yet fully healed.[16,17] The policy allows for up to eight applications within the 16-week episode of care, with a KX modifier (a claim description indicating medical necessity and the justification for continued care) after the fourth application. However, it provides no option to continue treatment beyond the specified eight applications, even for complex wounds that demonstrate slow but progressive healing or when a healthcare provider determines it is medically necessary to avoid further complications. Wound care experts widely support an individualised approach, as highlighted during a townhall session at the CAMPs Wound Care Summit 2025 (28 February–2 March, 2025, Fort Lauderdale, FL, US) where both wound care providers and industry leaders advocated for the removal of rigid application limits in favour of evidence-based, patient-specific treatment pathways. Moreover, the proposed fixed-fee schedule model would eliminate the administrative burden associated with calculating and enforcing a rigid 16-week episode of care. This change would streamline reimbursement processes, reduce provider confusion and align payment models more closely with real-world clinical care timelines.

Achieving optimal clinical outcomes with CAMP therapy will not be possible unless the CAMPs LCD, entitled *Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers*,[18] is rescinded. In concert, CMS should convene a panel of clinically active wound care experts who have produced peer-reviewed publications in advanced wound care to develop a new National Coverage Determination (NCD) focused exclusively on CAMPs, accompanied by a separate coverage determination addressing general wound and ulcer care. A model similar to the LCD published by Medicare Administrator Contractor, Noridian, *Wound and Ulcer Care* (L38904), should be considered.[18] The revised framework for wound and ulcer care should prioritise evidence-based best practices to drive wound bed preparation, including the incorporation of endorsed screening techniques for haemodynamic and tissue

perfusion assessments. In parallel, the CAMPs coverage determination should focus more specifically on contraindications for CAMPs use, treatment initiation criteria, timely initiation of CAMPs,[19] routine application following initiation[19] and clear parameters for discontinuing CAMPs in non-responsive cases.

A strong foundation in wound bed preparation is essential for optimising treatment outcomes with CAMPs. A retrospective study analysing Medicare claims data (2015–2019) and multicentre prospective RCTs found that ulcers receiving frequent debridement at intervals of ≤7 days had significantly improved healing rates, lowered amputation risks and reduced hospital resource use.[20] Among LEDUs, routine debridement combined with CAMP therapy resulted in 65% fewer major amputations ($p<0.0001$) and 42% fewer emergency department visits ($p<0.0001$).[21] Additionally, a standardised, evidence-based debridement protocol increased wound closure rates to 74%, compared to only 21% in ulcers with inadequate debridement.[20] Advanced imaging technologies can further enhance wound bed preparation by guiding clinicians in optimising bioburden removal and ensuring adequate perfusion.[20] Standardising debridement practices as a prerequisite to CAMPs therapy could improve healing outcomes and reduce overall Medicare expenditures by preventing complications. The widely accepted principle that clinical outcomes improve with provider education and training is particularly relevant to the use of CAMPs. Demonstrating competency in CAMPs-specific knowledge and skills can be achieved through certification, such as a Certificate of Added Qualification offered by a recognised certifying organisation.

Despite the critical role that CAMPs play in treating complex wounds, the current future effective CAMPs LCD neglects to address a significant patient population, those with hard-to-heal pressure injury ulcers. Each year, an estimated 2.5 million individuals in the US develop pressure injury ulcers, leading to substantial morbidity and healthcare costs.[22] The potential exclusion of credentialled wound care professionals from determining the medical necessity of CAMPs for hard-to-heal pressure injury ulcers is especially troubling. Without a clear medical necessity provision, clinicians lack the guidance needed to determine appropriate use beyond non-LEDUs and VLUs. This ambiguity, coupled with uncertainty about future CMS audits, effectively restricts access for the patients who need treatment the most. In post-acute care settings, where hard-to-heal pressure injury ulcers are frequently encountered, the absence of policy guidance is likely to delay healing, increase hospital readmissions and drive up overall healthcare costs.

A comprehensive, evidence-based approach to wound care should drive Medicare policy. Policy development should incorporate the findings of large retrospective analysis of Medicare enrolees and real-world registries in addition to RCTs. Real-world data provides important perspectives on patient outcomes, costs and point-of-service issues that are often overlooked in an RCT. Establishing a separate, revised NCD for CAMPs, distinct from a broader wound and ulcer coverage determination, would provide a framework for determining when CAMP therapy is appropriate, when it should be discontinued, and how to ensure just access for complex, non-healing wounds. The establishment of an NCD, rather than multiple LCDs, will promote socially equitable, uniform coverage across the US. An example occurred previously with hyperbaric access under an NCD implemented on 18 December 2017.[23] Without these critical updates, the future effective CAMPs LCD will fail to achieve cost savings and worsen clinical outcomes for some of the most vulnerable patient populations.

Conclusion

The future effective CAMPs LCD represents a fundamental shift in Medicare reimbursement that could significantly undermine patient care and increase long-term healthcare costs. By limiting CAMPs applications to eight per 16-week episode of care, the policy eliminates the ability of treating providers to determine medical necessity for patients who require continued treatment. The present one-size-fits-all approach disregards clinical evidence demonstrating that many hard-to-heal wounds require extended therapy to achieve closure, prevent complications, and reduce costly interventions, such as amputations and hospitalisations.

Policy adjustments should prioritise real-world clinical evidence supporting the effectiveness of CAMPs in improving patient outcomes. Implementing a fixed-fee schedule model, rather than restricting treatment options, would allow for cost control while maintaining access to necessary interventions. This framework would empower providers to tailor treatment plans based on patient-specific needs, ensuring optimal healing trajectories and reducing the economic burden of wound care on the Medicare system. Ultimately, the forthcoming CAMPs LCD does not offer a long-term solution to the issue of high-ASP CAMPs. A solution is necessary since a new wave of 'me-too' products will enter the market as manufacturers complete required RCTs for CAMPs projected as non-covered CAMPs. Thus, CMS may see a resurgence in elevated ASPs in the coming 2–4 years, recreating the cost challenges we currently face.

Another consideration regarding the future effective CAMPS LCD is the exclusion of allowing frontline wound care providers to determine 'medical necessity'. This will most likely create a critical gap in the treatment of pressure injury ulcers due to uncertainty in the proposed policy and stance on future audits. With 2.5 million patients developing pressure injury ulcers annually,[22] failure to provide access to a clinically proven therapy, particularly in the post-acute care settings, will likely result in delayed healing, increased hospital readmissions and higher Medicare expenditures. The policy should be revised to reflect the

medical necessity of CAMPs for pressure injury ulcers and other hard-to-heal wounds that extend beyond LEDUs and VLUs.

To ensure an effective, evidence-based wound care policy, CMS must retire the current CAMPs LCD and engage wound care experts with clinical and research expertise in developing an NCD that aligns with best practices. A comprehensive, patient-centred approach will preserve limb function, prevent unnecessary hospitalisations, and ultimately reduce overall healthcare costs, while ensuring that Medicare beneficiaries receive the highest standard of wound care available. **JWC**

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