Navigating obstacles impacting the sustainability of Medicare-funded wound care pricing

Abstract: As the US population continues to age, costs for hard-to-heal wounds are expected to rise and negatively contribute to the long-term financial stability of Medicare, which is currently labelled a 'high-risk' program by the US Government Accountability Office. Within wound care, some skin substitutes, also known as cellular tissue products (CTPs), and now referred to as CAMPS (cellular, acellular, and matrix-like products), have demonstrated improved healing times and cost-effective usage. However, a dramatic increase in the number of CAMPs has led to controversy on reimbursement rates. For instance, in the third quarter of 2022, 30 of 68 CAMPs represented a disproportionate $256 million USD in costs, due to failures to report their average sales pricing. In its calendar year (CY) 2024 Proposed Rules, the Centers for Medicare and Medicaid Services (CMS) did not implement the proposal to package ('bundle') CAMPs products within the private office. Moreover, three Medicare Administrative Contractors (MACs) withdrew Local Coverage Determinations (LCDs) that sought to curb use of CAMPs with limitations on covered products and number of applications, all of which illustrates a continued lack of consensus in coverage and reimbursement of CAMPs. To stabilise Medicare wound care expenditures, the CMS should use tools already at its disposal, to enforce reporting of average sales prices (ASP) for Q-coded CTPs or CAMPs, and to suitably audit ASPs for all potential abuses. MACs should consider adopting more rigorous strategies that drive all manufacturers of CAMPs to adopt an ASP reporting model.
Conclusion: With more effective oversight, Medicare costs can be reduced, while stabilising a portion of its trust fund, disincentivising non-compliance and improving outcomes for the growing population of US beneficiaries with hard-to-heal wounds.
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CAMPs • costs • hard-to-heal wounds • Medicare • wound • wound care • wound dressing • wound healing

In 2021, the US Medicare program covered over 63.8 million lives, at a cost of $839 billion USD or 3.9% of US gross domestic product (GDP), and is projected to increase to 6.5% of GDP by 2096.[1] Hard-to-heal wounds affected an estimated 8.2 million US Medicare beneficiaries in 2018 and cost projections for all wounds ranged from $28.1–$96.8 billion USD.[2] It has been calculated that approximately 1–3% of the total healthcare expenditure in developed countries is devoted to hard-to-heal wounds while concomitantly increasing as populations age.[3] Thus the problem of paying for hard-to-heal wounds should be viewed as a global crisis with unique complications and impediments in the US. Within the Centers for Medicare and Medicaid Services (CMS) healthcare framework, reimbursement rates of CAMPs have become controversial.

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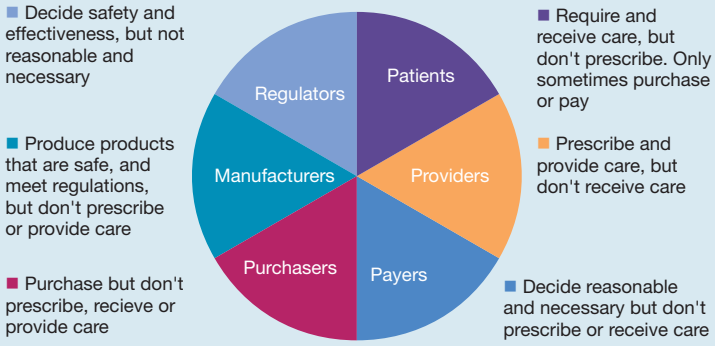
Background

Medicare benefits are a legal obligation to enrolled Americans. As such, adjustments to eligibility and benefits are guided by checks and balances to safeguard medical necessity-based access. To maintain Medicare enrollee health, continued improvements in healthcare must be accompanied by economies of scale, reductions in costs, and/or increases in taxes and fees. These issues are acutely evident in the wound care arena where new and innovative methods of wound care management have favourably impacted healthcare outcomes,[4,5] but concurrently resulted in an avoidable rise in product costs and reimbursement.[6]

Cellular, acellular, and matrix-like products (CAMPs) are 'a broad category of biomaterials, synthetic materials or biosynthetic matrices that support repair or regeneration of injured tissues through various mechanisms of action'.[7] Their use in hard-to-heal (chronic) wounds, particularly those that have stalled along the healing cascade, is considered best practice among consensus experts as well as in peer-reviewed published results retrospectively analysing Medicare claims data.[7–10] However, inappropriate use or poor integration of CAMPs into wound care practices may actually drive up costs without adding significant benefits.[4,11] Reimbursement practices need to acknowledge appropriate use of CAMPs among other cost control mechanisms.[11]

The US healthcare system and the Medicare program in particular, are bureaucracies characterised by complex reimbursement mechanisms[12] and decentralised decision-making among multiple stakeholders which include: patients, providers, payers, purchasers, manufacturers and regulators (Fig 1). This article summarises where stakeholder needs, such as access to evidence-based medical care, administration of pre-existing pricing measures, and commercial sustainability, have created imbalances which reduce the effectiveness of coverage, especially for patients with hard-to-heal wounds.

Fig 1. Healthcare stakeholders represent decentralised and distributed authority for manufacturing, authorising, prescribing, purchasing, reimbursing, providing and receiving healthcare products and services



Regulation, pricing and reimbursement of CAMPs

CAMPs are regulated heterogeneously, as most are not biologic but have biologic components; they are not quite a drug, and yet not quite a device. They may include non-autologous human tissues (allografts), animal tissue-derived matrices (xenografts) and synthetic materials. CAMPs may be regulated by the US Food and Drug Administration (FDA) as medical devices (by the FDA's Center for Devices and Radiological Health; CDRH), as human cells, tissues, and cellular or tissue-based products (HCT/Ps) under section 361 of the Public Health Service (PHS) Act (or 361 HCT/Ps), or as biological products (by the FDA's Center for Biologics Evaluation and Research; CBER).

Despite the 21st Century Cures Act placing great emphasis on evidence-based programs, CAMPs brought to market as medical devices under 510(k) Premarket Notification or under Section 361 of the PHS Act, do not require clinical evidence of wound healing efficacy. Conversely, reimbursement by CMS typically does require evidence of efficacy for the first in class products for which peer-reviewed clinical work is expected, and randomised controlled trials (RCTs) or real-world evidence are the accepted standards. The initial innovative manufacturers should not be the only ones to be held to this standard. This is particularly the case when the Agency for Healthcare Research and Quality, a Federal agency within the Department of Health and Human Services charged with improving the safety and quality of healthcare for all Americans, clearly concluded in their 2020 technical brief on CAMPs that research results from one CAMP cannot be extrapolated to similar products due to differences in processing, composition and preservation methods.[13]

Average sales price in the private office

Under the current CMS system and passage of the Consolidation Appropriations Act 2021 (CAA),[14] in the private office, CAMPs fall under a Medicare Part B (outpatient drug) reimbursement methodology. On a quarterly basis, manufacturers are required to certify to CMS a report of the Average Sales Price (ASP) per unit for their outpatient products. The submitted ASP must account for any credits, chargebacks, discounts and rebates applied.

For the reporting structure to be efficacious, CMS publishes the ASP rate with a 6% markup, as the per unit reimbursement for the quarter in which the file is published. In general, providers practicing in the private office setting will not pay more for a CAMP than the set reimbursement rate, and thus the act of ASP publication sets the maximum reimbursement that providers can receive from Medicare. When published, there are a broad array of external pressures, such as discounted pricing offered and reported by the manufacturer each quarter that compels producers of CAMPs to consider lowering their pricing—which in turn lowers the subsequent reimbursement rate. The system as envisioned, is a cycle that exerts overall downward pressure on pricing and reimbursement. In the absence of centralised rates, the individual Medicare Administrative Contractors (MACs) will pay based on invoice or Wholesale Acquisition Cost (WAC) plus a modest margin, a practical workaround for new and desirable products until their ASP is established.

Bundling of Q-coded CAMPs in the private office, hospital outpatient departments (HOPDs) and provider-based departments/clinics (PBDs)

Presently, the private office operates on a fee-for-service model. Fee-for-service calculations theoretically capture the provider's expertise and medically necessary procedures, with lesser emphasis on resource costs. Alternatively, CMS supports packaging as a supply in the private office (also referred to as bundling) as the best accommodation for the heterogeneous CAMPs therapeutic class. Bundling moves a product or service from separately reimbursed, to payment under the umbrella of a different code. In this case, CMS proposes to take Q-coded CAMPs and bundle them under the CAMPs application code series, 15271–15278. The proposed Physician Fee Schedule rule for 2024 does not include a packaging reimbursement methodology at this time. However, CMS is currently requesting provider feedback on how to achieve private office packaging, including 'sources of pricing information' and 'approaches to billing'.

In contrast, CMS does package CAMPs reimbursement for hospital outpatient departments (HOPDs) and provider-based departments/clinics (PBDs). Hospital outpatient is paid using a prospective payment system

that reflects a high volume of procedures performed along with heavy resource costs. A prospective (bundled) model assumes that some episodes of care will come out ahead on reimbursement, and others will not. However, this payment structure does not adequately meet the needs of patients with more complicated larger ulcers, as bundled payments are typically undifferentiated by ulcer size. Stakeholder testimony at the January 2023 CMS Town Hall included providers who testified that the private office currently functions as the last practical option for treatment of large complex ulcers, since the current per-unit rate available in the private office setting allows providers to tailor the purchase of the product to the size of the ulcer. For example, the 2023 national rate of $1726 USD is paid in the HOPD or PBDs for application codes 15271 and 15275, regardless of size of the ulcer or cost of the product. Many products cost over $150 USD per cm^2, resulting in a net loss to any wound clinic treating ulcers greater than about $12cm^2$. Furthermore, CMS is disinclined to approve separate reimbursement for add-on codes under prospective payment systems. This further prevents hospital-affiliated outpatient departments from applying CAMPs to larger wounds. Codes such as 15272 and 15276 (within the current procedural terminology application code series) are designed to capture additional work and resources yet garner no additional reimbursement. This system is perceived by all stakeholders (patients, treating clinicians, healthcare institutions, manufacturers) to be an inadequate, flawed payment methodology.

Assignment of A-codes in the A2XXX series for CAMPs was initiated in 2021 to more accurately describe supplies and was intended as the first step toward a bundling methodology in the private office (the thinking is that supplies are meant to be bundled; advanced treatments are not). CAMPs coded in this manner fall under 'contractor pricing' (invoice or WAC+ a margin) rather than ASP+6%. This creates an incentive to register a CAMP as an A-code, resulting in the proliferation of such products since 2021 (Fig 2). A parallel track is emerging for A-code CAMPs, which are not provided the same transparency and oversight that results from the ASP system.

Local coverage determinations for use management and cost reduction

CMS has the authority to shape reimbursement methodology via annual rule-making or National Coverage Determinations. On a regional level, MACs have far fewer tools to affect reimbursement itself; their primary mechanisms to control costs are coverage decisions, often in the form of LCDs, Local Coverage Articles, and accompanying Billing and Coding Articles. These documents guide not only what services and products are covered, but also under what clinical thresholds and with what frequency they are considered to be medically necessary. In total, three MACs, covering 15 states, proposed LCDs for enactment on 17 September 2023 with a long list of non-covered products, as well as hard limits on the number of applications. For two of the MACs, this process spanned a year and a half, and two draft policies. Despite multiple open meetings—with heated feedback from stakeholders—the effective date was pushed back once before the documents were ultimately fully withdrawn, further illustrating a continued lack of consensus in coverage and reimbursement of CAMPs.

Issues regarding regulation and reimbursement of CAMPs

The current challenges in marketplace guidance are illustrative of:

1. The struggle of healthcare to adapt to emerging technologies
2. Noncompliance to the requested ASP reporting methodology,
3. Passive CMS oversight.

Emerging skin substitute technologies have resulted in industry leaders coining the term 'CAMPs' instead of inexact terms such as 'skin substitutes' or 'CTPs' to account for cellular, acellular and matrix-like products. For example, labelling a purely synthetic Cellular Tissue Product which is completely acellular is in itself an oxymoron. CMS acknowledges the placement of new CAMPs within the ASP taxonomy went unquestioned until the recent advent of purely synthetic CAMPs being introduced into this category. CMS and regulatory agencies continually struggle to treat all advanced products the same.

Similar classification issues are created with varied paths to CAMP regulatory approval and coding. Ultimately, manufacturers will seek the least expensive route to market. As previously noted, once an initial innovative CAMP is cleared under 510(k) Premarket Notification or under Section 361 of the PHS Act, based on safety and efficacy, all follow-on products can save costs by performing little-to-no efficacy research. Thus, market price advantages are provided to products with less rigour; cost-conscious procurers race to the bottom, encouraging the proliferation of a high number of skin substitute products on the market today (Fig 2). Products should show efficacy to be granted reimbursement, an appropriate but expensive requirement of only the initial innovative manufacturer.

Likewise, with the institution of A-coded skin substitutes that are not reimbursed based on ASP, but rather WAC+ margin, CMS has created a bifurcated and inconsistent system. The Medicare Part B Drug ASP files are not designed to house A-coded supplies. CMS could explore moving the A-codes back to the Q-coded series. As an alternative, CMS could explore options for publishing and setting rates for these codes on a parallel file or via other commensurate oversight. In the meantime, manufacturers proliferate A-code CAMPs to ensure a lower cost to market and less regulated pricing on the market (Fig 2).

CMS stated that it 'considered skin substitute products to be biologicals in our initial implementation of the ASP

Fig 2. Cumulative annual registration of cellular, acellular and matrix-like products (CAMPs) or skin substitutes beginning in 2007 by Q-code and A-code. Registration for 2023 only includes the first quarter. Five Q-codes have been removed after subsequent registration in the 2009, 2011, 2012, 2017 and 2020 calendar years

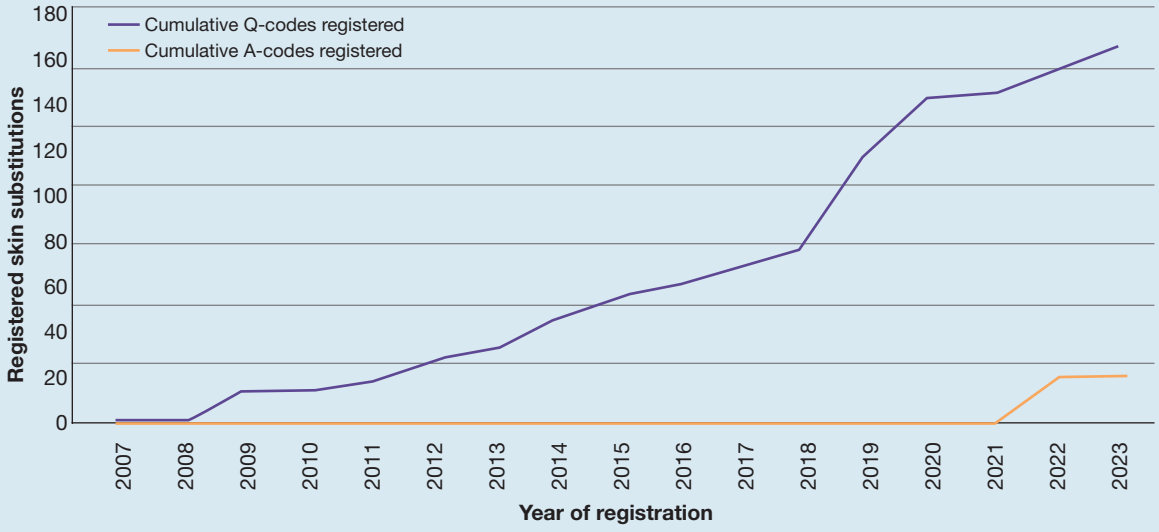
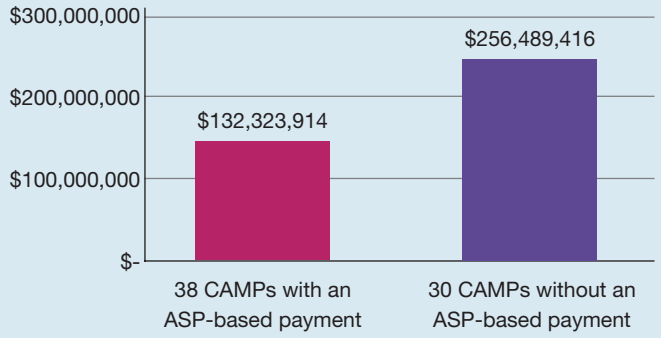


Table 1.[16] Number of CAMPs listed quarterly. ASP–average sales prices; CAMPs–cellular, acellular and matrix-like products

Quarter	CAMPs listed on National Part B ASP drug files
Q4 2023	74
Q3 2023	65
Q2 2023	58
Q1 2023	52
Q4 2022	16
Q3 2022	16
Q2 2022	16
Q1 2022	17

Fig 3. 30 skin substitutes (CAMPs) for which manufacturers did not report Average Sales Price (ASP) (purple bar) represented a disproportionate share of payments compared to 38 skin substitute codes which did report ASP (pink bar)



methodology.'[15] This sets a significant precedent as the ASP framework was initiated in 2005, with product-specific Q-codes beginning as early as 2009. Although CAMP ASP reporting has been a longstanding expectation, reporting prior to the CAA 2021 was on a voluntary basis.[6]

ASP reporting (by manufacturers) and publication (by CMS) is necessary; either step without the other can foster an environment of rising charges and abuse. Unfortunately, there have been deficiencies in this process on both the commercial and government sides. For instance, until recently, CMS has not published all rates, making it nearly impossible to quantify how many manufacturers have reported or not. A recent report from the Office of Inspector General (OIG) highlighted that despite new legislative requirements, CMS was unable to calculate ASP-based payment amounts in the first quarter of 2023. In the third quarter of 2022, Medicare Part B paid almost $400 million USD for 68 unique CAMP Q codes. Thirty codes (of 68) which did not report the required ASP data represented a disproportionate $256 million USD of Part B spending, accounting for nearly two-thirds of all CAMP payments (Fig 3).[6] According to the OIG analysis, Part B payment amounts would be significantly mitigated if ASPs were consistently reported and used, theoretically leading to tens of millions of dollars in savings each quarter.[6]

An analysis of the national Medicare Part B Drug Average Sales Price ASP pricing files shows that only 16 CAMPs were published on the file for the majority of 2022 (Table 1).[16] Fortunately, the Q4 2023 file was released with 74 published rates (Table 1).[16] Given the short timeline of the release and lack of analysis of the more complete published data, the existing ASP model needs more time and enforcement to realise cost-savings while preserving patient access, particularly among socioeconomically disadvantaged regions and populations.

The lack of reporting ASP after 1 January 2022, should require accountability, since the CAA 2021 requires CAMP manufacturers to report ASP, is subject to audit by the OIG, and verification with potential penalties imposed by the secretary.[14] A simple solution could be to halt reimbursement of manufacturer products which do not report ASP. Note that Congress could have, but did not, exclude CAMPs from the new legislative requirements. Some have suggested that the CAA does not apply to CAMPs since these products are generally not regulated by the FDA as drugs or biologics. However, this was rebutted by the OIG report, which confirmed the CAA newly designates CAMPs as 'item, service, supplies, and products that are payable under Part B as a drug or biological'.[6] This statement implies that ASP reporting is not dependent on whether the product is actually regulated as a drug or biological, but rather whether it is paid like one.

Issues with bundling

Bundling CAMPs in the private office without addressing the need for increased reimbursement for larger wounds will undoubtedly lead to costly inpatient hospital admissions if hospital outpatient or physician offices are not offered sufficient reimbursement. The envisioned changes are almost certain to have greater impacts in areas of low healthcare access and poor socioeconomic metrics. A better approach would be to provide greater flexibility in an office setting, with broader product options, in order to handle large, complicated wounds, which tend to be more prone to infection or amputation, with appropriate cost-effective treatment options.

CMS must recognise that bundling across private office and HOPD would actually create an inconsistency in reimbursement between these two systems. Additionally, by implementing changes to the current payment methodology, there will be further restrictions on patient access to beneficial care. CMS is proposing one of these fee-for-service components—the Practice Expense—as the best methodology to bundle CAMPs in the private office. However, because of the lesser focus on resource costs within the private office, it is not equivalent to the hospital outpatient methodologies. The Practice Expense is a poor alternative and likely to cause budgetary issues outside of the wound care space, as these allocations require budget neutrality. The prospect of ballooning costs to wound care would necessitate cuts across the board.

Cost-effectiveness

A series of studies on Medicare patients with lower extremity diabetic ulcers (LEDUs), reported on outcomes and cost-effective practices associated with reduced amputation rates.[4,5,10] The studies directly addressed criticisms by the Agency for Healthcare and Research Quality (AHRQ) by retrospectively analysing cohorts of 9,738,760 and 10,900,127 patients with diabetes with real-world comorbidities, and tracking wound chronicity for up to 4 years.[5,10] Only 61% of Medicare patients with hard-to-heal LEDUs received debridement at intervals of 14 days or less,[4] despite prospective RCTs showing significant benefits of frequent debridement with adjunctive placental-derived allografts,[4,17,18] or conservative care only.[19] Furthermore, only 9.2% of providers applied a CAMP on stalled wounds beginning at 30–45 days followed with weekly or biweekly applications.[5,10] The inescapable conclusion is that nearly 40% of Medicare patients, when indicated, are not getting adequate sharp debridement and that approximately 91% of patients do not receive appropriate CAMP applications. An analysis of patients receiving just one type of CAMP, dehydrated human amnion chorion membrane (DHACM, MiMedx Group, Inc., US) for stalled LEDUs beginning at 30–45 days and re-applied at weekly/bi-weekly intervals demonstrated statistically improved outcomes and savings of $3670 USD per affected patient in the first year.[10] Based on published prevalence rates, a one-million-enrolee plan can be calculated to have 5980 patients with diabetes who will develop an LEDU (13% diabetes prevalence, with a 4.6% annual risk of an LEDU). Thus the plan will save nearly $22 million USD annually (=5980*$3670).[10] This research exemplifies a clear opportunity to improve outcomes and reduce costs, based on best practices observed in Medicare's own existing data.

Conclusion

Wound care is a maturing discipline where clinicians, academics, federal agencies and industry are still in the process of developing standards.[20] While marketplace oversight continues to advance, the CAMPs market currently contains well over 60 products (as identified by the OIG) and continues to expand.[6] While a competitive marketplace encourages innovative technology, the current wound care marketplace is cluttered with copy-cat products, using inappropriate pricing strategies with little evidence of their utility. When true efficacy and price are accurately provided to a competitive marketplace, non-differentiated products are unlikely to make the investment to enter the market unless they offer real innovation and would certainly be competitively squeezed out if they did not offer value along with favourable clinical results.

The OIG is sympathetic to the administrative difficulties CMS cites in tracking these disparate products—the typical methodologies used to track prescription drugs do not apply—as well as the need to explore different payment methodologies.[6] However, the OIG also touts the inherent strength of the ASP system, and calculates a potential savings of up to $84 million USD per quarter. Stakeholders hope that the OIG report, combined with the uniform responses at both the CMS Town Hall and written comment periods, are enough to tip the decision-making back to ASP methodology.

Part of pricing implementation should be performance, and CMS will need quality measures that

encourage good wound care,[11] including metrics for CAMP usage[5,10] across all demographic and socioeconomic populations.[5] Evidence-supported practices will reduce the use of healthcare resources, provide better patient outcomes, and lower amputation rates while minimising costs.

In the short term, Center for Medicare Services has the opportunity to consider the following five measures:

1. Requiring all manufacturers to report the ASP of all CAMPs and include actual paid invoices
2. Not allowing MACs to pay for any CAMP that has not reported an ASP
3. Publish ASP for both 'Q' and 'A' codes
4. Encourage the appropriate authority to perform audits to identify abuses
5. Rigorously implementing and overseeing the ASP payment program for physician offices.

The Government Accountability Office lists Medicare as a 'high-risk' program, due to long-term financial stability, and fraud vulnerability (an estimated $46.8 billion USD in improper payments, in fiscal year 2022).[21] To overcome this financial stress: manufacturers must comply with pricing regulations; and stakeholders must demonstrate cost-effective outcomes for patients. The integration of regulatory approval with reimbursement standards would reduce the fractured landscape and provide a more uniform path for emerging innovative technologies. Innovation could still occur within the same category of CAMPs, for instance by being the first to demonstrate efficacy in an otherwise disparate population. CAMP manufacturers must be part of the Medicare solvency solution, and not subvert oversight.

As in any competitive market, inadequate oversight of regulations and bad actors create barriers to innovation, penalise stakeholders who play by the rules, and distort fair pricing, while leaving many consumers victimised by a system that is beyond their control though intended for their benefit. Despite the perceived complexity of this landscape, at this moment CMS with a balanced collaboration of all involved stakeholders truly has the opportunity to reduce costs, stabilise a portion of the Medicare trust fund, disincentivise non-compliance and improve outcomes for the growing population of patients with hard-to-heal wounds within the US. **JWC**

Reflective questions

- How would both patients and Medicare benefit from Medicare Administrative Contractors (MACs) adopting more rigorous strategies that would drive all manufacturers of cellular, acellular, and matrix-like products (CAMPs) to adopt an average sales price (ASP) reporting model?
- What does the acronym CAMPs stand for and why is the term more encompassing than CTPs?
- How will the bundling of Q-coded CAMPs in the private office unfavourably impact outpatient wound care outcomes?

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