The state of wound care in North America: Regulations, evidence and the march toward personalised, data-driven healing

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North American wound care, particularly the US, is in the midst of a regulatory and technological reset. In the US, the Centers for Medicare and Medicaid Services (CMS) finalised a 2026 payment overhaul for cellular/tissue-based products (CTPs), otherwise known as cellular acellular and matrix-like products (CAMPS), pivoting to a single national rate per cm² and classifying most products as "incident-to supplies" – changes that are aimed at curbing spending while preserving access. (Wallfisch, 2025) Simultaneously, CMS surprised the field by withdrawing planned Local Coverage Determinations (LCDs) for diabetic foot ulcer (DFU) and venous leg ulcer (VLU) products days before they were to take effect, creating a curious split: sweeping payment reform without the anticipated coverage restrictions. (CMS, 2025).

These changes are poised to fundamentally alter how clinicians in the US practise wound care. Under the new economic model, product selection will shift away from brand-driven decisions toward evidence-based, outcome-oriented care, compelling clinicians to more rigorously justify advanced therapy use through objective data, such as wound area reduction trajectories, biomarker-informed risk stratification and advanced imaging findings.

With uniform payment rates replacing high-margin products, clinicians may increasingly rely on diagnostic precision tools, such as fluorescence imaging, perfusion mapping, protease activity profiling and AI-enabled wound assessment, to identify which patients truly benefit from advanced interventions, ensuring that therapeutic decisions demonstrate clear medical necessity in a resource-constrained environment. As a result, care pathways are evolving toward standardised, measurable, tech-supported wound management, integrating objective assessment at each visit and reducing reliance on subjective observation alone.

The Food and Drug Administration (FDA) has proposed a first-of-its-kind classification framework for antimicrobial wound dressings and liquid wound washes potentially requiring pre-market approvals (PMAs) for products with higher antimicrobial resistance (AMR) concern and special controls for others (Califf, 2023). This shift is expected to significantly influence wound management by tightening evidentiary standards for antimicrobial-containing products, leading clinicians to rely more heavily on formulations with demonstrated safety, antimicrobial stewardship alignment and clearly defined mechanisms of action. As products are reclassified, wound care teams will need to adjust formularies, anticipate changes in product availability and integrate more rigorous decision-making around when and for whom antimicrobial dressings are truly indicated.

Meanwhile, the evidence base in wound management is expanding in support of precision wound care: point-of-care fluorescence/hyperspectral imaging improves objective infection screening and perfusion assessment; biomarkers, particularly protease activity and inflammatory cytokines, are guiding risk stratification and targeted treatments; and AI-enabled imaging platforms and other technologies are maturing, with early validations and growing real-world feasibility.

Policy reset in the US: CMS payment reform and coverage whiplash

Skin substitutes: The 2026 flat-rate era

In the CY 2026 Physician Fee Schedule (PFS) Final Rule, CMS fundamentally changed how Medicare pays for most skin substitutes (CTPs/CAMPs). Effective 1 January 2026, non-Biologics License Application products are treated as incident-to supplies with a unified national payment rate of ~$127/cm²; application procedures remain separately reimbursed. Products licensed as section 351 biologics continue under average sales price methodology. To justify the change, CMS cited an unprecedented rise in Part B spending from roughly $250m in 2019 to more than $10bn in 2024 (Wallfisch, 2025).

The policy applies consistently across settings (office, hospital outpatient departments and home) and CMS signalled its intent to differentiate rates in future years based on FDA regulatory categories (Wallfisch, 2025).

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A surprise twist on coverage

Just as programmes prepared for strict DFU/VLU LCDs that sorted hundreds of products by evidentiary thresholds, CMS announced on 24 December 2025 that its A/B Medicare Administrative Contractors would withdraw the finalised LCDs before their planned 1 January 2026 effective date. (CMS, 2025) Payment reform proceeded; coverage restrictions did not leave claims adjudicated under existing medical necessity standards while the field adapts to the new economics.

FDA: Clarifying the rules for dressings

Antimicrobial dressings and washes: Toward formal classification

For the first time, FDA proposed classifying certain antimicrobial-containing solid dressings, gel/cream/ointment dressings and liquid wound washes. Products with antimicrobials of high AMR concern would be Class III (PMA), while those with medium/low AMR concern and/or other chemicals would be Class II with special controls (plus 510(k); Califf, 2023). The goal is to align risk, evidence and labelling with antimicrobial stewardship principles and device performance. A final rule/order would set compliance timelines and product code updates.

Client alerts summarise scope/exclusions (e.g. products with topical analgesics or hydrocortisone are out of scope) and detail that antimicrobial functions must be preservative/barrier roles rather than therapeutic claims foreshadowing labelling and evidence shifts for many legacy products.

Evidence updates: Biomarkers, imaging and AI for personalised wound care

Biomarkers: From bench to bedside triage

A growing body of current US literature supports biomarker-guided stratification of chronic wounds. Elevated protease activity, notably neutrophil elastase and matrix metalloproteinases, is consistently associated with non healing status and destructive extracellular matrix imbalance (Caton et al, 2025).

Bedside point-of-care diagnostic testing and exudate profiling are increasingly used to flag patients who may benefit from wound environment optimising dressings and aggressive debridement schedules.

Recent scholarly articles and scoping reviews synthesise exudate-derived cytokines and pain-linked mediators, underscoring the promise of multiplex panels to complement clinical signs and photography and to objectify pain trajectories in DFUs/VLUs (Goto and Saligan, 2020; Beraja et al, 2025).

Advanced imaging: Objective infection and perfusion insights

Point-of-care bacterial fluorescence, near-infrared spectroscopy, hyperspectral/multispectral imaging and thermal imaging now provide non-invasive data on bacterial burden, tissue oxygenation/perfusion, local inflammation and temperature asymmetry.

A multicentre study combining visible light, thermography and fluorescence imaging achieved 100% sensitivity and 91% specificity for identifying infected wounds and strong performance for distinguishing inflamed and non infected wounds demonstrating the power of objective, multimodal screening beyond clinician-dependent signs and symptoms (Ramirez Garcia-Luna et al, 2023).

Systematic reviews further support the capacity of hyperspectral imaging to quantify real-time tissue oxygenation and predict delayed healing, with no reported safety concerns, although widespread workflow integration remains a challenge (Saiko et al, 2020).

Increasing evidence has now led to the adoption of these advanced imaging devices across the continuum of wound care, from outpatient clinics to hospital-based wound centres and home-based digital wound monitoring programmes. The expanding data supporting fluorescence guided infection assessment, oxygenation-based perfusion evaluation and thermal/AI-augmented analytics are accelerating clinical uptake, embedding these technologies into triage, risk stratification and ongoing healing trajectory monitoring algorithms across North America.

AI-enabled assessment: Segmentation, trajectory and remote care

The AI literature is maturing. Artificial intelligence is rapidly transforming wound care across North America by improving access, accuracy and workflow efficiency especially in rural and under-served regions. AI-enabled platforms provide standardised wound imaging, automated measurements and consistent documentation, offering measurement reliability regardless of clinician experience or skin tone. These tools address longstanding challenges with manual assessment variability and fragmented charting.

In real-world evaluations, AI-driven wound care has reduced provider workload, saving home care clinicians over 400 hours of visit time, while simultaneously supporting earlier detection of wound deterioration and more timely interventions (Freeman et al, 2025). AI systems also have helped to facilitate

interdisciplinary communication by centralising wound data, enhancing coordination between nurses, physicians and care aides across geographically remote teams where staffing shortages and limited specialist access impede timely wound management.

AI supports the move towards more equitable care and strengthens adherence to evidence-based practices. Implementation challenges remain (e.g. digital literacy, electronic medical record compatibility and privacy concerns), but structured training, gradual adoption and leadership support are helping health systems to integrate these technologies sustainably (Saiko et al, 2020).

The net effect: AI is evolving from a helpful add on to a core enabler of standardised, data-driven and geographically equitable wound care across North America.

Conclusion

Wound care in North America is entering a period of accelerated transformation, driven by regulatory realignment, technological maturation and increasing pressure to demonstrate measurable patient benefit. The shift by CMS shift to flat per cm² reimbursement for CTPs/CAMPs places new emphasis on healing efficiency, documentation rigour and indication-driven product use, rewarding programmes that can demonstrate early wound improvement and operational discipline. Simultaneously, the FDA's proposed antimicrobial dressing classification will compel formularies and manufacturers to reassess product portfolios, aligning selection with clearer labelling, AMR-aware risk stratification and higher evidentiary standards.

Advanced diagnostics including bacterial fluorescence and hyperspectral imaging are becoming essential tools for reducing subjective variation and enabling targeted, defensible treatment decisions that withstand medical necessity review. Parallel advances in biomarker-based risk stratification offer the potential to identify stalled or high risk wounds earlier and guide more precise intervention pathways.

Together, these forces are moving the field away from product-centric wound care toward a phenotype-centric, precision-first model, characterised by multimodal assessment, adaptive care planning, continuous monitoring and transparent outcomes tracking. If systems can operationalise these changes triaging patients by risk, directing advanced therapies where they deliver the greatest benefit and eliminating low-value care the turbulence of 2026 may ultimately yield stronger equity, improved healing outcomes and a more accountable, data-driven wound care ecosystem across North America. ●

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