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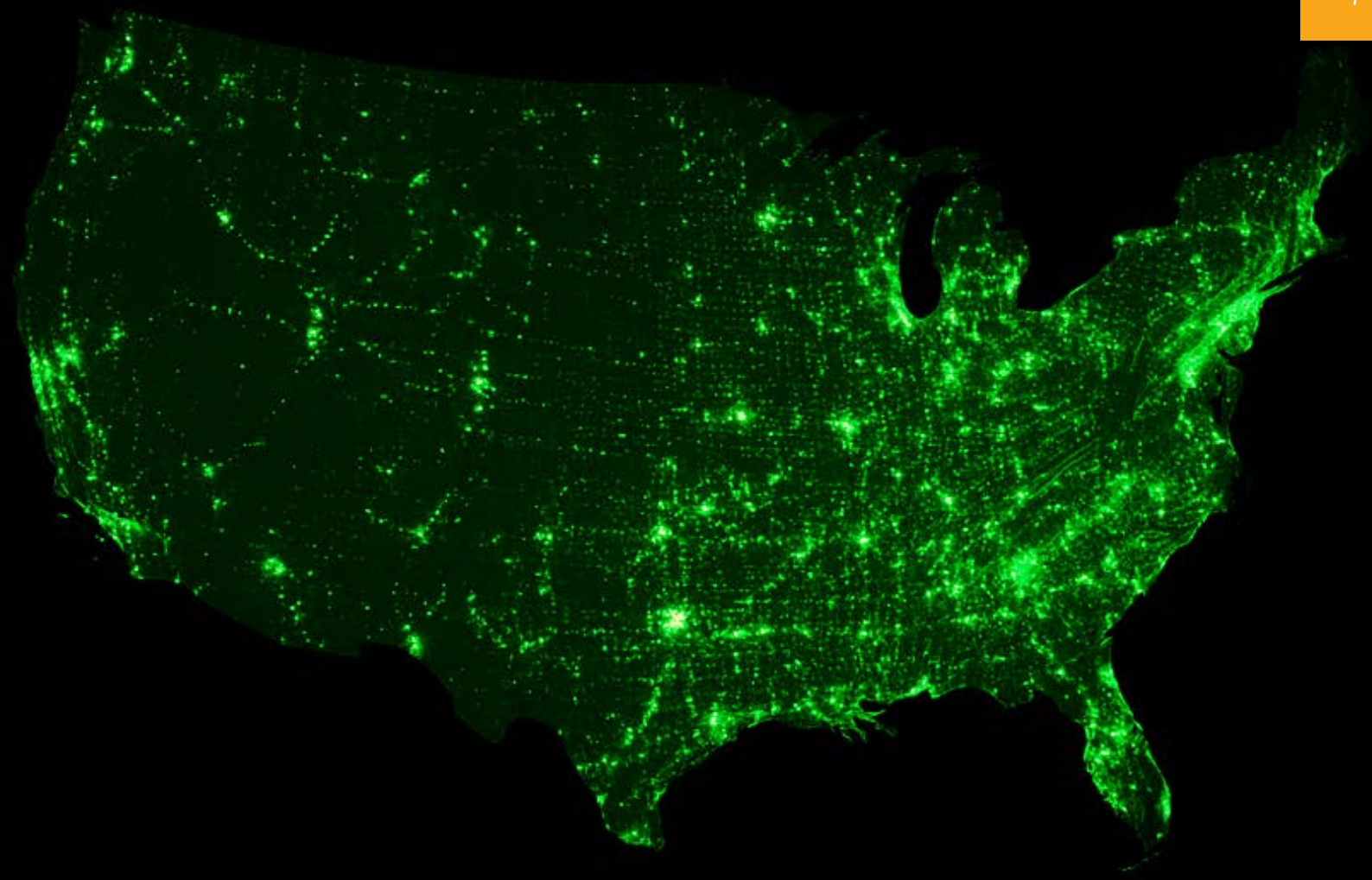

Expert Opinion Consensus Document

Recommendations to Inform National Coverage Determination Development for Skin Substitutes in Hard-to-Heal Wounds

The American Healthcare Accountability Alliance

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CONSENSUS DOCUMENT

Recommendations to inform National Coverage Determination development for skin substitutes in hard-to-heal wounds

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Abstract

Rapid growth in Medicare use of skin substitutes (CAMPs) has improved wound outcomes but raised concerns about fraud, waste, and rising costs. Recent reimbursement reforms appear to have caused disruptions in patient access and care delivery. An expert consensus panel recommends a wound-agnostic national coverage approach focused on clinical need, 30-day reassessment, and clear discontinuation criteria, while deferring detailed standards of care to local policies.

Key panel recommendations

These recommendations reflect the expert panel's consensus view on the appropriate scope, structure, and safeguards for a National Coverage Determination governing the use of skin substitutes in hard-to-heal wounds. They are designed to align with CMS's established NCD framework while addressing known limitations of prior etiology-based and utilization-cap approaches.

The recommendations are supported by detailed analysis and discussion in the consensus document, which is intended to contextualize and justify the policy principles articulated here.

1. The National Coverage Determination should use the term 'skin substitutes' consistently, aligned with existing CMS usage and accessible to non-specialist audiences.

2. The National Coverage Determination should apply to hard-to-heal wounds that have failed to demonstrate meaningful clinical progress after at least 30 days of appropriate standard wound care, regardless of etiology.

3. The National Coverage Determination should explicitly exclude acute wounds, including burns, traumatic wounds, and surgical wounds (that have not devolved to chronic), as their management occurs within established surgical and inpatient care pathways governed by separate coverage and payment policies and should not be regulated through a chronic wound National Coverage Determination.

4. Hard-to-heal is a preferred descriptor to chronic, and this should be defined as failure to demonstrate meaningful healing after 30 days, without reliance on percentage-based wound area reduction thresholds.

5. Standard of Care should be referenced at a high level as a prerequisite to coverage, with detailed requirements and documentation standards deferred to applicable Local Coverage Determinations.

6. Coverage should include explicit contraindications to coverage, including active cancer in the wound bed, untreated or uncontrolled infection, and unaddressed systemic conditions that impair wound healing. Coverage should require compliance with product Instructions for Use for selection, placement, fixation, and reapplication.

7. Clinicians applying skin substitutes should demonstrate competency in wound assessment, wound bed preparation, and post-application management, consistent with their training, scope of practice, and institutional credentialing. Additional structured education should be recommended when these competencies are not part of foundational training, and recommended to all clinicians utilizing these advanced technologies.

8. The treatment plan should be reassessed at least every 30 days, with continuation or discontinuation based on wound behavior and clinical response rather than rigid numeric caps. Qualitative indicators of progress should be permitted, and clear clinical off-ramps should be required when continued application is unlikely to provide benefit.

9. Measurement of wounds should support clinical decision-making and documentation of progress without reliance on rigid surface area calculations alone. Assessment should account for depth, undermining, tunneling, and overall wound behavior. Product selection and quantity should reflect the medically necessary amount required for appropriate application and fixation in accordance with product Instructions for Use, rather than simple length-by-width calculations.

Background

The rapid growth in the use of skin substitutes also referred to as cellular, acellular, and matrix-like products (CAMPs) has introduced both opportunity and controversy within Medicare policy. On one hand, these technologies are increasingly recognized as clinically valuable tools that improve healing, reduce amputations, and therefore potentially save lives. On the other, recent analyses have identified significant concerns regarding fraud, waste, and abuse (FWA), as utilization and spending have risen sharply. Between Q3 2022 and Q3 2024, the number of patients receiving skin substitutes increased by approximately 40%, while associated Medicare spending grew disproportionately, by an estimated 640% over the same period.[1] This divergence has prompted ongoing debate regarding the extent to which increased utilization reflects inappropriate use versus necessary expansion of access to effective therapies.

In response, the Centers for Medicare & Medicaid Services (CMS) implemented a revised unified national reimbursement model on January 1, 2026, for non-BLA skin substitutes (products not approved as biologics under a Biologics License Application).[2] Although broadly supported in concept to improve pricing consistency and program integrity, the unified national rate of approximately $127.14/cm² has been widely viewed by impacted wound care providers, manufacturers, and other policy stakeholders outside of CMS as insufficient to sustain real-world care delivery.

Early national provider data following implementation of the CY 2026 reimbursement policy suggest that these concerns are not theoretical. In a Wound and Hyperbaric Association (WHA) national clinician survey conducted

from February 4 to April 14, 2026, 130 respondents from 36 states and DC reported broad disruption in access to skin substitutes across diverse care settings and MAC jurisdictions.[3] Respondents collectively reported caring for approximately 12,000 wound patients per week. The most frequently reported impacts included authorization delays for clinically eligible patients, reduced ability to deliver timely advanced wound care, increased denials despite patients meeting coverage criteria, reductions in staffing or clinical capacity, and closure or planned closure of wound care practices or service lines. Notably, 59 respondents, or 45.4%, reported closure or planned closure of a wound care practice or service line. These findings remain observational and self-reported, but they provide an important early signal of access disruption that is consistent with the policy concerns raised in this consensus document.

At the same time, the need to preserve access does not eliminate the need for responsible utilization standards. Nearly all stakeholders agree that setting judicious utilization guidelines on skin substitutes should play a part in responsible usage and, most importantly, preserving patient access. Caught in the efforts to curtail overutilization, well-meaning providers who are trying to heal patients have been rocked by high-dollar audits that put practices at risk. With an eye to providing stabilization, providers need clear guidelines on skin substitutes that allow them to confidently and appropriately treat patients while exercising medical decision-making.

Instituting utilization guidelines via Local Coverage Determinations (LCDs) has been difficult. Policymakers delving into wound care find that the patient population is heterogeneous in presentation, with a large menu of potential comorbidities. Wound etiology and confounding factors are not always clear cut. Wound sizes vary considerably in area, depth, and involvement of underlying critical structures (such as tendon, joint capsule, muscle, and bone). "Wound care" itself does not have its own taxonomy or Accreditation Council for Graduate Medical Education (ACGME)-recognized specialty designation. Instead, it draws upon practitioners from multiple disciplines, reflecting the inherently diverse and multidisciplinary nature of wound management. Wound care could be seen as the Galápagos Islands of medicine, a micro ecosystem where various wound types drive rapid, adaptive innovation. Technologies evolve in response to the environment, and skin substitutes exemplify this through wide variation in composition and regulatory pathways.

Against this backdrop, Medicare Administrative Contractors (MACs) sought to expand their policy footprint in skin substitutes via two waves of multijurisdictional efforts.[4] CGS, First Coast Service Options (FCSO) and Novitas Solutions, LLC (Novitas) proposed to unify their skin substitute language in 2023 but ultimately withdrew the drafts in October of the same year. The second wave comprised all seven Part A/B MACs to also include National Government Services (NGS), Noridian, Palmetto and WPS. Identical proposed LCDs were unveiled in April 2024. The final-status draft versions were given longer notice time than required by regulation (90 days versus the traditional 45) to allow for significant adjustment. Nevertheless, the LCDS were delayed again and ultimately withdrawn in December 2025.

The withdrawn LCDs were widely criticized due to inflexible, arbitrary caps on the number of applications, and lack of clarity as to covered products. Stakeholders continue to request that CMS and the MACs work more closely with nationally recognized wound care Subject Matter Experts (SME) across the United States to develop guidelines.

Consensus panel composition and development process

To that end, an expert panel was convened on March 5, 2026, to compile best recommendations for future National Coverage Determination (NCD) development. Panel members were selected to ensure geographic diversity, representation across multidisciplinary clinical practice, academic contributions, and direct experience with CMS coverage policy.

The finalized panel comprised clinicians, well-published researchers, representatives from medical societies and advocacy groups, reimbursement and policy experts, and manufacturing specialists. Panel members represented diverse specialties including podiatry, infectious diseases, plastic surgery, and states (as shown in Table 1). Providers

TABLE 1 | Panel composition

Specialty	Doctor of podiatry, plastic surgery, emergency medicine, vascular surgery, industry, mobile provider, infectious disease, health policy, certified coder and auditor, medical device industry, hyperbaric medicine
States represented	AL, AR, AZ, CA, CO, CT, DE, FL, GA, IA, IL, IN, KS, KY, LA, MA, MD, MI, MN, MO, MS, NC, NE, NJ, NY, OH, OK, OR, PA, SC, SD, TN, TX, UT, VA, VT, WA, WI, WV, WY. Nationwide.
Location of practice	Metropolitan, suburban, rural
Types of practice	Private practice, hospital based, academic, research

on the panel also practice in a variety of care settings such as the private office, hospital outpatient department, and nursing facility (Medicare Place of Service (POS) codes 11, 22, and 32), across both urban and rural settings. The combined experience of the 16 members represented over 150 years of wound care experience.

Consensus development methodology

The panel met for a single, moderated session. Prior to the meeting, participants were provided with limited background materials intended to frame the discussion rather than to serve as a comprehensive review of the evidence. Given the depth of subject matter expertise represented among the panelists, discussions were informed primarily by cumulative professional experience, familiarity with the published literature, and firsthand involvement with coverage policy development and implementation.

Given the panel's charge to inform national coverage policy rather than to issue clinical practice guidelines, a structured qualitative consensus approach grounded in policy expertise and real-world implementation experience was deemed most appropriate. Therefore, this consensus process was qualitative and discussion based, without formal systematic literature review, quantitative scoring system, structured consensus methodology (e.g., Delphi or RAND/UCLA), or predefined voting thresholds. Recommendations were developed through open, iterative discussion, during which panel members were encouraged to raise questions, identify areas of agreement or concern, and propose refinements to draft concepts. Statements were revised in real time until broad alignment was achieved. For the purposes of this panel, consensus was defined as the absence of sustained objection to the final recommendations.

Scope and focus of the panel

Several wound care consensus panels have been convened over the past two years to examine a range of issues related to the clinical use of skin substitutes, including evidentiary expectations for individual products, reimbursement structures, patient selection, and coverage criteria. In contrast, the focus of this current consensus panel was to develop recommendations to CMS specific to NCD development. Pricing and reimbursement issues are therefore not addressed.

Although this consensus document does not make reimbursement recommendations, it is important to note the early real-world access signals exhibited in the WHA national clinician survey, following the CY 2026 PFS policy, are relevant context because coverage criteria that are overly restrictive may compound existing access disruption.

Consensus findings and policy considerations

At times the panel distilled from previous publications, but with an eye toward coverage content that is most appropriate to a national coverage document. Historically, skin substitute policy has also attempted to define a Standard of Care (SoC) prior to graft placement.

Through iterative discussion, and in the context of emerging real-world reports of access disruption following the CY 2026 PFS reform, the panel reached consensus that the dual goals of maintaining appropriate patient access to skin substitutes while simultaneously strengthening safeguards against FWA are best achieved by:

- Creating a more etiology-agnostic policy
- With clearly defined decision points for reassessment and guidance for reapplications
- That is supported by separate, more granular wound care LCDs.

History and nomenclature

Skin substitutes have a rich medical history with documented use over 100 years. As with much of medicine, skin substitute options marched on slowly until certain punctuated inflection points allowed for rapid diversification. Panelists noted the use of human placental graft—harvested immediately after birth—placed directly on acute burn patients in the early 1900s. Porcine derived xenografts proliferated in the middle and later decades of the 20th century while the HIV/AIDS epidemic of the early 1980s halted the development of human derived tissue grafts of all types. During this hiatus, alternatives that reduced the risk of blood-borne pathogens advanced rapidly. This era led to the growth of a number of bioengineered options, with the first wave relying on the propagation of neonatal foreskin cells. Today, approximately 340 HCPCS codes capture a wide diversity of products including cadaveric, bioengineered, amniotic/placental, xenograft, hybrid placental xenograft, and fully synthetic matrices.[5] The scientific and regulatory evolution of these materials has outpaced the terminology historically used to describe them. The science and usages have moved from more exclusive use in the burn ward that makes skin substitutes seem outdated. Human Cellular Tissue Products (HCT/Ps) was well-adopted but does not adequately capture the most recent wave of fully synthetic products (with bioactive glass as a newest example).

The term CAMPs (Cellular, Acellular, and Matrix-like Products) emerged in 2023, represents the full range of product composition, is palatable across industry and preferred by wound care SME such as this convened panel.[6] However,

the panel acknowledges the need for plain speech that is easily understandable to audiences who do not closely follow the nomenclature debate. The panel continues to acknowledge CAMPs as the most clinically accurate terminology. However, because this document informs policy, the panel recommends continued use of the term skin substitutes within the NCD for clarity and accessibility.

The need for a unified definition of skin substitutes

The panel agrees with CMS that skin substitutes is easily understood on a broad level by stakeholders. However, the panel notes the reluctance of CMS to define these products through regulation has also created confusion amongst the provider audience as well. The panel maintains that any NCD or LCD regarding skin substitutes will always suffer from challenges until there is an agreed upon definition.

From a statutory standpoint the AMA CPT Coding manual is the national data coding set for services and procedures and thus its description of skin substitutes is merely an aid in selecting proper procedural codes, and consequently its descriptor is not widely accepted by the community of stakeholders.[7] For example, coding guidelines prohibit non-sheet skin substitutes, (primarily granulated but also flowable products) from using skin substitute application codes 15271-15278.[8] Stakeholders have long regarded what they view as a "wag the dog" type policy scenario, where Medicare policy will not consider alternate formats for skin substitutes because of this language. In reality, CPT codes should reflect and adapt to the realities of current practice and technology, rather than being used as a regulatory proxy.

Accordingly, the panel endorses the following coverage-oriented working definition for skin substitutes which is: cellular, acellular and matrix products for the management of integumentary defects.

Regulatory development pathways and coverage relevant evidence in skin substitutes

It was not until April 2002 that the U.S. Food and Drug Administration (FDA) approved Integra Dermal Regeneration Template for scar contractures, representing the first indication outside the burn unit and permitting promotion to a broader physician audience.[9] That same year, Integra Bilayer Wound Matrix received 510(k) clearance for use across the full spectrum of hard-to-heal wounds, including diabetic foot ulcers, venous leg ulcers, and pressure injuries.[10] From laboratory concept to broad inclusion on the wound care formulary, this evolution spanned more than two decades.

This timeline is not exceptional. It is emblematic of the development pathway for many complex wound technologies, where iterative regulatory engagement, post market surveillance, and accumulated clinical experience precede widespread adoption. Products currently in routine clinical use therefore typically embody years, often decades, of review, refinement, and real-world evidence generation. Coverage frameworks that fail to account for this maturation pipeline risk obstructing patient access to therapies that required a generation to develop and validate.

Importantly, the panel recognizes that not all skin substitute products have followed identical regulatory or developmental timelines. In particular, some biologically derived and placental-based products entered clinical use through regulatory pathways distinct from those of earlier bioengineered matrices. This variability does not undermine the relevance of regulatory maturation and post market evidence accumulation; rather, it underscores why coverage policy should not rely on product class, origin, or chronology as proxies for clinical appropriateness.

A coverage framework anchored in wound physiology, documented response to treatment, Instructions for Use (IFU) compliant use, and defined clinical reassessment points is better suited to accommodate heterogeneous product lineages than one premised on static evidentiary thresholds or categorical assumptions. Such an approach allows effective, well established technologies to remain accessible while ensuring that newer or rapidly adopted products are subject to consistent expectations for demonstrated clinical benefit, appropriate duration of use, and principled discontinuation when progress is not observed.

In this regard, variability in regulatory pathways argues for—not against—a coverage structure that emphasizes auditable clinical decision-making over presumptive inclusion or exclusion based on product type. Aligning coverage with observable wound response and documented medical necessity provides a defensible mechanism to preserve access while supporting program integrity across an increasingly diverse therapeutic landscape.

Etiology-based policy has failed: the NCD must cover all hard-to-heal wounds

Panelists strongly agree that any new skin substitute policy should expand beyond diabetic foot ulcers (DFUs) and venous leg ulcers (VLUs) to consider all hard-to-heal wounds that:

1. Do not respond to 30 days of SoC
2. That are not contraindicated for skin substitute usage or for a particular product, and
3. Align with the indications or usages within the product IFU.

From a logistical perspective, clinical practice and research have expanded beyond DFUs and VLUs.[11,12] Continued policy focus on neatly defined etiologies creates MAC-by-MAC benefit parity issues in the face of clear, years-long efforts by the MACs to develop unified policy. Focus on DFUs and VLUs leaves providers less confident to treat patients and more susceptible to audit. Early WHA survey findings similarly suggest that access disruption is being reported across multiple states, care settings, and MAC jurisdictions,[3] reinforcing the need for a national framework that minimizes geographic and place-of-service (POS) variability.

More important than logistical considerations, a hyperfocus on DFUs and VLUs ignores the clinical and scientific reality of wound pathophysiology and healing within the integumentary system, which is explored below.

Wounds follow the same healing cascade regardless of etiology

The panel strongly agreed that all wounds and ulcers, irrespective of etiology, must pass through the healing cascade to achieve closure. The panelists aligned with parallels from other specialties, with one panelist noting: "Simply said, there are a plethora of causes for acute or chronic renal failure and regardless of etiology, the penultimate treatment is dialysis. The same holds true for wounds." The ability to fully treat hard-to-heal wounds regardless of causation, is important because all open wounds represent a portal for potential infection, hospitalization, amputation and death.

Regardless of etiology, all wounds heal through the same fundamental biological cascade, corresponding to the core, overlapping phases of tissue repair: platelet activation and hemostasis initiate the response, followed sequentially by neutrophil activation and infiltration, macrophage-mediated debridement and signaling, and fibroblast-driven matrix deposition and remodeling. Although wounds arise from different initiating etiologies, they require progression through hemostasis, inflammation, proliferation, and remodeling to heal. This cascade is not unique to chronic wounds—it is the same physiologic sequence that governs healing after surgical or traumatic wounding, myocardial infarction, bowel anastomosis, and fracture repair.[13]

What distinguishes hard-to-heal wounds is not a different biology, but a stalled or dysregulated one. As reflected in the framework cited by Schreml, Falanga, and Gottrup, chronicity develops when barriers such as ischemia, venous hypertension, neuropathy, infection, edema, pressure, malnutrition, or metabolic dysfunction disrupt these universal healing pathways.[14] In practice, healing trajectories are governed less by ICD-10 categorization than by the identification and correction of systematic and local comorbidities.

Because the cascade is universal, the clinical principles that support its progression—including adequate perfusion, infection control, moisture balance, and offloading—apply across wound etiologies. Wound etiology remains clinically relevant, but rigid etiology-based coverage frameworks may fail to reflect how wounds behave in real-world practice, where mixed-pathophysiology wounds are common. This is the scientific basis for an etiology-agnostic coverage framework.

Emerging data also document the high prevalence of mixed-etiology ulcers in real-world practice, further undermining the utility of etiology-defined policy silos. Published guidelines and cohort analyses demonstrate that mixed-pathophysiology wounds are common in clinical practice, with approximately 15–25% of patients with venous leg ulcers having concomitant arterial insufficiency, and additional populations demonstrating combined arterial–venous etiologies.[15,16]

Consistent with these principles, healing across wound etiologies proceeds through overlapping biological phases of inflammation, proliferation, and remodeling that reflect conserved cellular responses to tissue injury, including immune activation, matrix deposition, angiogenesis, and epithelialization. While the timing, intensity, and expression of these phases vary substantially based on factors such as perfusion, comorbidities, contamination, and wound geometry, the underlying biologic processes are shared. Accordingly, assessment of wound progress is most appropriately grounded in biologic behavior and healing trajectory rather than etiology alone, recognizing expected variability without assuming uniform or linear healing across all wounds.

Acute and surgical wounds are not addressed by this NCD

The panel agrees that the need for national coverage guidance regarding skin substitutes is largely confined to the management of hard-to-heal integumentary wounds. Accordingly, the panel recommends that any future National Coverage Determination explicitly state that acute wounds, burns, traumatic wounds, and uncomplicated surgical wounds are not addressed by this NCD.

This exclusion is not a reflection of clinical efficacy or appropriateness in those settings. Rather, it reflects the fundamentally different clinical objectives, standards of care, and regulatory frameworks that govern acute and (acute) surgical wound management. Acute and surgical applications of skin substitutes are typically integrated into episode-

based surgical care, frequently involve intraoperative decision-making, and are evaluated within specialty specific clinical pathways that differ substantially from those applicable to non-healing wound management.

CMS has previously acknowledged that many products categorized as skin substitutes are used across a wide range of surgical specialties for indications unrelated to hard-to-heal wound care (see December 10, 2013 OPPS Final Rule). These products play essential roles in reconstructive surgery, neurosurgery, orthopedics, urology, gynecology, general surgery, and other surgical fields, where use is governed by distinct clinical objectives, surgical standards of practice, and existing Medicare payment and coverage policies.

Accordingly, the panel emphasizes that the purpose of this NCD is not to regulate or redefine the full spectrum of surgical or intraoperative applications of these products. Rather, the intent is to establish appropriate, auditable coverage parameters for their use as adjunctive therapies in the treatment of hard-to-heal integumentary wounds. A narrowly scoped NCD focused on hard-to-heal wound indications is essential to avoid unintended consequences that could disrupt established standards of care and access to necessary technologies in unrelated surgical contexts.

By clearly defining the scope of this NCD, CMS can preserve clinical flexibility and existing surgical practices while enabling consistent national coverage and program integrity within the hard-to-heal wound care space.

Definition of hard-to-heal (non-healing) wounds

For the reasons above, any Policy regarding skin substitutes should consider the needs of the patient rather than a rigid etiology-defined pronouncement. Therefore, the panelists defined chronicity in wounds as the presence of a non-healing (hard-to-heal) wound that has failed to demonstrate meaningful healing after 30 days of appropriate standard wound care.

This definition from the panel is agnostic to etiology and does not rely on a percentage reduction in size (e.g., 50%) as does previous policy. Instead, it focuses on failure to progress over a 30-day period after appropriate interventions have been applied and allows providers to exercise medical judgement. While acknowledging the value of the seminal works of Sheehan and Snyder in the early 2000s, who discovered 50% reduction at 4 weeks of SoC as a predictor of healing in DFUs,[17,18] the panelists agreed that skin substitute policy predicated on percent-reduction thresholds: 1) risks excluding clinically appropriate patients, 2) does not apply to wounds types that may not follow linear reduction curves (such as pressure injuries, traumatic and surgical site complications that devolve to become chronic wounds, mixed etiology, etc.), and 3) is impossible to apply uniformly across MAC regions.

Panelists agreed that hard-to-heal or non-healing is most appropriate nomenclature (as opposed to chronic) to align with policy. Key elements to the definition of hard-to-heal include:

1. Time-based: non-healing after 30 days
2. Behavior-based: wound is non-healing/hard-to-heal, regardless of etiology
3. SoC-dependent: Must have received appropriate standard of care during those 30 days.

Recommendations for standard of care

The failure to meaningfully progress after 30 days of appropriate care underpins the panel's definition of non-healing. However, to maintain appropriate scope, the panel recommended that SoC requirements be maintained through existing LCDs and guidelines rather than rewritten into the NCD. This bifurcation of wound care policy versus skin substitute policy allows flexibility for evolution in both. The panel emphasized that deferring detailed SoC requirements to LCDs does not diminish the obligation to provide and document comprehensive wound care.

However, the panel also agreed that skin substitute policy has previously tried to "boil the ocean" by directly addressing too many factors simultaneously. The requested NCD should remain narrowly focused on skin substitute-specific coverage parameters as an adjunct to optimized standard of care, rather than duplicating baseline wound care requirements. MACs may update existing wound and ulcer care LCDs or develop additional LCD guidance, as needed, to clarify baseline wound care expectations and documentation standards. Panelists reemphasized dialysis as a parallel to remark: "Again, this is essential as skin substitutes do not treat wound etiology, merely the wound itself, just as dialysis does not treat the causation of renal failure."

This scope-focused approach is consistent with existing CMS coverage policy across other wound-related National Coverage Determinations. For example, in NCD 270.1 (Electrical Stimulation and Electromagnetic Therapy for Wounds), CMS requires failure of "appropriate standard wound therapy" prior to coverage but articulates those expectations at a foundational level rather than as an exhaustive practice checklist. Similarly, NCD 20.29 (Hyperbaric Oxygen Therapy) and NCD 270.3 (Blood-Derived Products for Chronic Non-Healing Wounds) reference standard or "optimal usual" care as a prerequisite to coverage without redefining wound-care workflows at the national level, instead relying on established clinical practice and MAC-level guidance.

Maintaining SoC requirements at a high level within a skin substitute NCD while deferring granular operational detail to LCDs, therefore aligns with CMS's established use of NCDs as scope-setting instruments rather than comprehensive clinical manuals.

Role of LCDs in operationalizing standard of care

Several panelists cited the Noridian Wound and Ulcer Care LCD L38902 as a constructive model for SoC policy.[19] Panelists note that the policy was developed in 2021 with feedback from national SMEs, which yielded sensible evidence-based guidelines that foster good clinical practice. Panelists recommend any future NCD direct clinicians to existing policies for SoC.

Attempting to regulate SoC on a granular level in skin substitute-specific policy is problematic for several reasons:

- SoC checklists are often overly prescriptive and do not fit all wound types. This is especially problematic with wounds of mixed etiology
- Different specialties have different protocols for care, with management depending on whether the wound is acute or chronic and where it currently falls in the healing cascade
- Unrealistic expectations for wound bed characteristics mean that claims deny (via audit) for minor imperfections that may not be entirely correctable in hard-to-heal wounds
- LCDs imply wound-type pathways that are not reflective of practice
- More prescriptive lists lead to inconsistent MAC enforcement, which is at odds with the goal of unified national policy.

In short, SoC should define clinical strategy and goals, not prescriptive operational steps. The NCD should focus primarily on skin substitute-specific requirements such as wound selection, application and reapplication criteria, contraindications, measurements, and fixation, and should rely on IFU for product-specific rules.

At a high level, the NCD should state: "Standard of Care must be completed and documented over an adequate course of at least 30 days prior to skin substitute application and should consist of standard wound care interventions, as appropriate to the wound and as defined by applicable wound and ulcer care LCDs."

Exclusions and contraindications to skin substitute application

The panel recognized (unanimously) the need for explicit contraindications to skin substitute implementation, for the welfare of the patient, but also as a tool for auditors and enforcement arms to clamp down on FWA. Based on the 150+ years in wound care among the expert panel, the consensus was that skin substitutes should be withheld in cases of:

1. Active or non-resected cancer in the wound bed
2. Cardinal signs of infection (untreated or uncontrolled)
3. Uncontrolled or untreated systemic disease that is likely to impair wound healing and has not been addressed as part of the patient's plan of care (e.g., untreated diabetes, unmanaged inflammatory or metabolic disease)
4. Untreated hypoperfusion or progressive ischemia
5. Chronic, unaddressed malnutrition (untreated protein-energy malnutrition)
6. Large undermining/tunneling requiring surgery
7. Presence of necrotic material requiring debridement
8. Uses that are off label for that product (per IFU)
9. Inability to secure the graft appropriately.

These contraindications reflect clinical conditions that must be addressed as part of an appropriate SoC treatment plan and are not intended to function as absolute exclusions when active management is underway and documented.

Importantly, application of skin substitutes should be guided by the goals of care, expected clinical benefit, and alignment with patient and family preferences. In advanced illness or end-of-life contexts, documentation of patient-centered goals of care is particularly important in determining appropriateness of continued intervention. There are cases where wounds must be managed aggressively even when closure is not a realistic endpoint (e.g., exposed bone, infection risk) or the wound is causing severe pain, or suffering. Importantly, skin substitute use should not exceed the needs of the patient, and in general, should not be applied when wound closure is no longer a realistic objective or when the burden of treatment outweighs the anticipated benefit. The clinician has a fiduciary responsibility to society to provide effective and cost-effective care to the patient with realistic and defined goals of care. If wound closure is not a realistic clinical objective but skin substitute application as an intervention is consistent with patient-centered care goals, skin substitute use may be appropriate, and the supporting clinical rationale should be clearly documented.

Of special note, the panelists agreed that depth, undermining, or exposed critical structures (such as joint capsule, muscle, tendon or bone) should never be exclusion criteria on their own, but that skin substitute selection should be

based upon product IFU and labeling. Many product IFUs allow for direct application in deeper wounds, and these are often the patients most in need of advanced treatment to prevent infection, hospitalization, amputation and death. Rather, appropriateness of a deeper wound to receive skin substitute should hinge on: 1) has adjunctive surgery been considered as part of the future care plan for this wound, and 2) does the wound comport with the product IFU. Secondary dressing should be appropriate based upon the location of the wound. Concurrent use of Negative Pressure Wound Therapy (NPWT) with skin substitutes is an appropriate and clinically supported approach for many wound types, and the panel affirmatively endorses its use where IFU-compliant.

Qualified providers

Skin substitutes should be applied by clinicians with demonstrated competency in wound assessment, wound bed preparation, debridement, infection management, offloading, pressure redistribution, and post-application monitoring. Because wound care lacks an ACGME-recognized specialty or taxonomy code, competency may derive from training across multiple disciplines, including podiatry, surgical specialties, internal medicine, infectious disease, emergency medicine, and family medicine. This multidisciplinary framework aligns with findings from the recent WHA national survey, which identified access concerns across a diverse range of wound care practitioners rather than within a single specialty or care model.

Institutional credentialing and privileging may serve as evidence of competency. Accordingly, wound care policies should emphasize demonstrated proficiency, appropriate training, and scope-consistent practice, supported by credentialing processes and professional experience.

For clinicians without formal wound care training through primary specialty certification, the panel noted that competency could be supported through wound care-specific certification endorsed by a professional wound care society with appropriate subject matter expertise. At the same time, the panel recognized that many clinicians who routinely manage wounds already acquire foundational skills, such as wound bed preparation, through standard training and clinical practice. Therefore, the panel did not support a universal requirement for additional debridement certification.

The panel further acknowledged that the use of skin substitutes represents an advanced skill set. Additional education may be beneficial, particularly for those clinicians whose core training did not include these competencies. Relevant areas for advanced training may include:

- Pathophysiology of non-healing wounds
- Overview and appropriate use of CAMPs
- Demonstration of debridement proficiency
- Best practices in wound bed preparation, vascular assessment, infection control, and imaging
- Literature review, reimbursement considerations, and documentation standards

The panel referenced the American Board of Wound Healing (ABWH) Certificate of Added Qualification (CAQ) in CAMPs application as one model of advanced education. This approach preserves access and respects scope of practice, while ensuring that clinicians whose background falls outside the typical scope of wound care expertise receive appropriate training before applying skin substitutes.

Reapplications and the role of defined "off ramps" to combat fraud, waste, and abuse

The panel reached its strongest consensus on the issue of medical necessity related to reapplications of skin substitutes, concluding that alignment with the Medicare standard of "reasonable and necessary" was essential. This standard is established in Section 1862(a)(1)(A) of the Social Security Act and is operationalized through CMS guidance, including Chapter 13 of the Medicare Program Integrity Manual (Pub. 100 08, Ch. 13, §13.5.4) and Chapter 15 of the Medicare Benefit Policy Manual (Pub. 100 02, Ch. 15).[20-22] The panel viewed this alignment as the most meaningful way to ensure clinical appropriateness while mitigating the risk of FWA.

Much discussion was devoted to overuse in the form of reapplications that exceed the needs of the patient. Examples of these include high numbers of reapplications:

- On small or superficial wounds
- In the face of wound stagnation (no improvement after several applications)
- Despite wounds enlarging or exhibiting increased undermining
- With signs of clinical worsening such as increased drainage or bioburden
- Without addressing underlying barriers such as uncontrolled edema or patient non-adherence with offloading or appointments
- In the face of sequential product changes (change of brand or clinical formulation) with no clinical rationale
- At the same time, safeguards against overuse should be designed to avoid creating de facto access restrictions for

clinically appropriate patients, particularly in settings already reporting authorization delays, denials, and service-line contraction following the CY 2026 payment transition.

The panel emphasized that discontinuation criteria must avoid rigid, numerical triggers that lead to inappropriate denials or misuse in audits. Lack of linear surface area reduction should not be interpreted as treatment failure in isolation, as this is a common misapplication in audit contexts. Reinforcing that clinical progress must be assessed based on overall wound behavior, not solely surface area metrics, would help support consistent and appropriate interpretation. Instead, qualitative clinical improvement, wound behavior, and SoC adherence should serve as the foundation for continuation decisions. Panelists noted the misperception that SoC is only used in the 30-day run up prior to skin substitute application.

Rather, SoC is important throughout any good treatment plan, with frequent reassessment of effectiveness and progress. Noridian's LCD was referenced again as a standard for structured but flexible SoC-related timeframes without imposing percentage-based healing requirements.[19] The panelists liked Noridian's emphasis on 30-day reassessment of any treatment plan and recommend this be included as a requirement for plans of care with skin substitutes.

30-day reassessments would be the best, agreed upon metric to combat FWA. Panelists also noted that in their extensive clinical experience, hard-to-heal wounds do not progress linearly. Often there will be two or three applications where wound metrics worsen before a beneficial response is observable. Wounds do not always contract in measurement following the first one or two skin substitute applications before going on to demonstrate measurable improvement. Every wound has an initiation phase with the skin substitute, and this is a known phenomenon which makes size-based criteria at the point of initiation particularly problematic.

Reassessment at 30-day intervals would also prevent premature stoppage of treatments. The panel therefore strongly recommends a requirement for reassessment every 30 days, and discontinuation of skin substitutes when the:

- Wound demonstrates no meaningful clinical progress after 30 days
- Wound bed cannot be adequately prepared to receive a graft
- Patient's goals of care and reasonable clinical expectations for improvement can no longer be met
- Placement of the skin substitute is unlikely to change the outcome
- New modifiable barriers to healing arise, such as new infection, ischemia or patient non-adherence with offloading
- If the new issues cannot be addressed, it is imperative that skin substitute reapplications cease.

Medical necessity to continue applications

Conversely, providers and auditors need clear signs for continued use of products. Measurements will be discussed in subsequent sections of the consensus document, both in terms of progress and related to skin substitute wastage. All panelists agreed that rigid caps on the number of applications accompanied by Wound Area Reduction (WAR) as the sole metric for progress is outdated. Clear continuation criteria are important not only for program integrity but also for provider confidence, because ambiguity in coverage standards may amplify denials, delays, and treatment interruption for patients who are otherwise clinically appropriate candidates. Panelists gave the following examples of hard-to-heal wounds that may warrant many medically necessary applications:

- Large wounds may show good progress, including area reduction, but need additional applications by virtue of their size
- Complex wounds with slow but meaningful progress may need extended skin substitute therapy
- Depth, undermining, or exposed critical structures may justify more applications
- Pressure injuries and surgical site complications (that stall in inflammatory phase) often heal non-linearly, so counting applications alone is inappropriate

Any hard-to-heal wound receiving skin substitutes may show meaningful progress with one or more of the following:

- A reduction in WAR or internal wound surface area
- The development of granulation
- Improved quality of wound edges (i.e., less maceration, advancement of epithelium, resolving epibole)
- A reduction in bioburden, infection or inflammation (i.e., reduced slough, decrease in exudate, odor, erythema or edema)
- Improved oxygenation or enhanced perfusion (micro-vascular), (i.e., better measurements of perfusion by Near-Infrared Spectroscopy, capillary response or improved bleeding at wound edges after debridement, improved oxygen delivery into tissue after edema control).

The 30-day reassessment period was selected because it reflects longstanding SoC and aligns with prior LCD structures, especially those developed by Noridian. It provides sufficient time for SoC to impact wound trajectory while remaining policy-defensible and clinically appropriate.

Measurements as a determinant of progress and appropriate units of product

As a determinant of progress

As noted above, traditional WAR (based on surface area calculated as length × width) is not always indicative of progress or lack of progress. It remains a valuable metric but does not capture the three-dimensional behavior of all wounds.

Providers practice in varied care settings with differing resources; regardless of measurement method, documentation should include depth, undermining, and tunneling at each assessment. Panelists noted that wounds often improve from the "base up", with reductions in depth and internal wound surface area preceding visible changes in external dimensions.

Wound measurements used for clinical decision-making, documentation, and product sizing should accurately reflect viable tissue and true wound dimensions. Appropriate debridement is part of wound bed preparation and precedes meaningful measurement.

When documented, reviewers must give appropriate weight to improvement in depth or internal cavity surface area, even when external dimensions and surface area remain unchanged.

To determine appropriate quantity of product or tissue

The panel noted that under the historical ASP-based drug/biologic payment system, perpetrators of FWA benefited from reimbursement structures which paid for unused quantities of skin substitutes, encouraging the use of oversized sheets and amplified by manufacturers reporting inflated average sales price (ASP). Under this single use framework, auditors naturally scrutinized wound area relative to skin substitute size.

This, in turn, caused many good faith clinicians to be unfairly targeted when product sizes available through formularies, mobile kits, or purchasing constraints did not match wound dimensions, or when nonlinear wound progression caused a pre ordered SKU to be mismatched by the time of application. Skin substitutes continue to be buy and bill, whereby practices must front acquisition costs. Maintaining comprehensive inventories is often unrealistic and makes perfect size matching impractical in nearly all routine care. These operational realities are particularly relevant in non-facility, mobile, home-based, assisted-living, and skilled-nursing settings, where the early post-PFS survey data suggest reimbursement pressure, authorization delays, and audit concerns are contributing to reductions in clinical capacity and service-line instability.

The 2026 pricing reforms moved skin substitutes to an incident to supply framework—under which only administered units are payable and discarded portions are not. Both this consensus panel and the 2026 Wastage Consensus Panel[23] agreed that wastage is a legacy drug/biologic term and does not apply under current skin substitute rules. Most importantly, the panel emphasized that decisions about discarded product must center on patient well being. Appropriate use is defined not by surface geometry but by clinical judgment, wound biology, IFU compliant application, and documentation that the amount used represents the medically necessary quantity required to treat the wound safely and effectively.

When possible, providers are encouraged to calculate and document the Therapeutic Treatment Area (TTA)—the three dimensional internal wound surface area plus the medically necessary fixation edge (typically 0.5–1.0 cm unless otherwise specified by IFU). Traditional wound area measurements as defined by length times width may significantly overestimate or underestimate necessary product for wounds with depth, undermining, tunneling, or irregular contours and may falsely result in clinically appropriate sizing deemed as "excessive". Accurate post debridement assessment, documentation of depth and internal geometry, and justification for product size are essential for demonstrating medical necessity and avoiding clawbacks. In turn, reviewers and auditors must acknowledge the importance of depth, internal wound topography, and fixation requirements when evaluating claims.

Choice of fixation compliant with product Instructions for Use

Proper fixation is essential to successful skin substitute application and must ensure direct, stable contact between the skin substitute and a viable wound bed. The panel agreed that fixation techniques should be selected based on wound depth, location, surface irregularity, tissue quality, and patient mobility rather than any single mandated approach. In contrast to frequent audit assumptions, the panel emphasized that surgical anchoring is not universally required. Taber's Medical Dictionary defines fixation as meaning to hold in place,[24] and the medical community broadly agrees with this usage. Accordingly, acceptable fixation methods include sutures, staples, adhesive strips, bolsters, tacky non-adherent layers, and negative-pressure wound therapy (NPWT), provided they are consistent with the product IFU.

What is not in dispute is that most often fixation requires a secure margin of overlap, which is discussed as part of the TTA described in the preceding section. The fixation edge—often 0.5–1.0 cm unless otherwise specified by the IFU—should be treated as a medically necessary component of application, not as "excess product" as it is clinically necessary to achieve proper product apposition to the wound bed. Providers should document their choice of fixation method, particularly when wound geometry, tissue pliability, or the bolstering method requires a greater fixation margin than the typical range. This documentation, rather than rigid dimensional expectations, should guide determinations of medical necessity and appropriate utilization.

The panel also highlighted fixation practices that may be inappropriate and could lead to denials, particularly attempts to roll, fold, stuff, quilt, micrograft or pack, sheet-based grafts into tunnels or undermined spaces, which is often off-label and prevents true graft-to-bed contact. When undermining or tunneling is present, wound bed preparation may require unroofing or surgical site preparation to allow flat placement into the internal wound bed, or the clinician should select a skin substitute configuration designed for cavities (e.g., conformable, particulate or flowable forms). Ultimately, fixation appropriateness hinges on IFU compliance, adequate wound-bed contact, and documented clinical reasoning, rather than any single mandated technique.

Conclusion

Current coverage approaches for skin substitutes have struggled because they rely on rigid, etiology-specific frameworks, prescriptive utilization caps, and percentage-based healing metrics that do not reflect the biological variability of hard-to-heal wounds or real-world clinical practice. These constructs have inadvertently undermined patient access, created significant regional and site-of-care inequities, and exposed well-intentioned providers to punitive audits, without reliably distinguishing appropriate care from fraud, waste, and abuse. Early national clinician survey data following the CY 2026 PFS transition further suggest that access disruption is already being reported across diverse practice settings, states, and MAC jurisdictions, including authorization delays, increased denials, reduced clinical capacity, and closure or planned closure of wound care practices or service lines. By attempting to solve utilization, standard of care, and product-specific issues within a single policy construct, prior efforts have overextended coverage policy beyond its most effective scope.

The panel recognizes significant FWA and the very reasonable concerns on the part or regulatory bodies. We the consensus panel are striving to provide an outline that provides both fiduciary responsibility and improved patient outcomes.

Therefore, this framework proposed by this consensus panel offers a scalable and defensible alternative that directly supports CMS's dual mandate of preserving access while safeguarding the Medicare Trust Fund. By adopting a wound-agnostic NCD focused on eligibility, reassessment, and clear clinical "off ramps" and deferring granular standard-of-care requirements to LCDs, CMS can enable consistent national coverage while preserving local clinical flexibility and audit integrity. The panel's recommendations are immediately implementable, grounded in existing clinical practice, and designed to integrate seamlessly with current MAC infrastructure.

Finally, sustained collaboration between CMS, MACs, and wound care SMEs will be essential to ensure policy evolves alongside science, technology, and patient needs, fostering a shared commitment to evidence-based access and responsible stewardship.

Conflicts of interest

No compensation was received to participate in this consensus meeting. NW, DK, JAN, and WHT are on the editorial board of IJTR, but were not involved in the review process of this document.

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