# Skin substitutes at the Crossroads

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Currently, he serves as chair of the Real-World Evidence Group of the Wound Care Collaborative Community working with Key Opinion Leaders, clinical experts, product developers and manufacturers to accelerate innovation and access with policymakers at the Food & Drug Administration (FDA) and Centers for Medicare and Medicaid Services (CMS).

Skin substitutes have been a part of the wound treatment armamentarium of medical practitioners for over 20 years, yet widespread adoption of these products in the US and other countries did not take off until just a few years ago. The global market for skin substitutes is estimated to be $660M (USD) in 2019 and growing at a rate of 4.7% per year[1]. Six to ten new skin substitutes, and sometimes more, enter the market every year. Some new product introductions are simply design variations of existing products, but many new skin substitutes incorporate biosynthetic and synthetic materials and novel designs that push the boundaries of what is possible with this class of wound treatment products.

Today there are over 110 skin substitute brands in the US market. The large and growing market for these products reflects increasing need for effective treatments for difficult-to-heal chronic wounds such as diabetic foot ulcers treated in outpatient clinics and physician offices, and traumatic injuries and burns treated in hospitals. The market is also a reflection of the complex reimbursement environment created by government and commercial payers across the different sites of care where wounds are treated. For example, in the hospital setting, reimbursement for skin substitutes is included in a single, bundled DRG (Diagnosis Related Groupings) payment for the inpatient episode. In the Outpatient/Day Surgery setting, payment for skin substitutes is also bundled into a single payment called an APC (Ambulatory Payment Classification), but the payment is per visit, not per-episode and is a much smaller amount than inpatient DRG rates. In free-standing physician offices, bundled payment is not the case at all. Instead, skin substitutes are reimbursed separately and differently by brand. This situation presents financial opportunities for astute health care providers and manufacturers that has helped drive a flood of new products, and in some cases led to overconsumption and unnecessary costs. The "Wild West of Reimbursement" may soon be coming to an end, however.

Major changes recently proposed by the Centers of Medicare and Medicaid Services (CMS) would impact how skin substitutes are classified and paid under the Medicare program. CMS administers Medicare, a US national health insurance program covering 54 million people over the age of 65[2]. Because of its size and influence, Medicare policies serve as reference for many coverage policies issued by commercial/private insurers. At the center of CMS' proposed changes is something relatively innocuous, yet provides insight as to how CMS views this class of products: the name "skin substitutes" itself.

In its proposed payment rules for the Hospital Outpatient[3] and Physician Office[4] settings last year, CMS stated that it believed that the existing terminology of "skin substitutes" was an overly broad misnomer. They noted that skin substitute products are not a substitute for a skin graft as they do not actually function like

human skin that is grafted onto a wound. According to CMS, skin substitute products are actually wound coverings. For this reason, CMS proposed to replace the term “skin substitutes” with the term “wound care management” or “wound care management products.”
The proposed name was met with a lot of resistance by wound care stakeholders – so much so that CMS decided to delay the change until it could solicit more feedback on the issue. Most stakeholders resented the implication that skin substitutes were mere wound coverings similar to passive wound dressings. Stakeholders presented CMS with preclinical and human clinical studies to support their position that skin substitutes help stimulate the development of viable, healthy tissues when conservative treatment fails. Interestingly, there are many people who, like CMS, believe the term ‘skin substitute’ is no longer adequate to describe today’s wide array of technologies. Many stakeholders prefer the term ‘Human Cells, Tissues, and Cellular and Tissue-based Products, or HCT/Ps, for short. While HCT/P nomenclature is cited in regulations by the Food and Drug Administration (FDA), it represents more technologies than just skin substitutes and the term has received only moderate acceptance to date. Further, the term HCT/P does not actually include all skin substitute types. For example, human and animal-derived collagen matrices are reimbursed as skin substitutes, but regulated by FDA as medical devices and not HCT/Ps. To be regulated solely as an HCT/P, a cellular therapy product must meet all the criteria in the Code of Federal Regulation 21 CFR 1271.10(a) including 1) undergoing minimal manipulation during manufacture and 2) labelled for ‘homologous use’ only. “Homologous Use” means the goods perform the same basic function(s) in the recipient as they perform in the person from whom they were collected (donor).

A third name for skin substitutes has recently been proposed by an International Consensus Panel convened by the Journal of Wound Care. The Panel proposed the term ‘CAMPs’ which stands for Cellular, Acellular and Matrix-like Products. This is an interesting term because it is easy to remember and accurately represents the three main categories of skin substitutes. Time will tell if CAMPs eventually replaces ‘skin substitute’. More information on CAMPs can be found in the JWC International Consensus Document: Best Practice for Wound Repair and Regeneration, Use of Cellular, Acellular and Matrix-like Products (CAMPs)[5].
Since CMS made clear it believes skin substitutes are simply wound coverings, it also becomes clear to understand its rationale for other proposed changes involving skin substitutes. As mentioned earlier, skin substitutes applied in a physician office setting are reimbursed separately from the facility’s payment for the application procedure. That is because CMS has traditionally considered skin substitute products to be biologicals and qualified for separate (nonbundled) payment from the payment for the surgical procedure. With the introduction of synthetic skin substitute products over the past few years, however, CMS is proposing to recategorize all skin substitutes as ‘medical supplies and bundle reimbursement into a lump sum amount for both the product and procedure. If the proposal is finalized, it would represent a fundamental change in payment methodology in the physician office and eliminate the ability to differentiate skin substitutes on the basis of price and reimbursement. All skin substitute brands, and product sizes would essentially receive the same reimbursement amount. On the positive, product selection decisions may shift from being based on financial rewards to patient outcomes. However, the policy may also result in slowing innovation and limiting access to skin substitutes for larger size wounds when the payment amount is inadequate to cover the higher product cost.

Other changes proposed by CMS involve how skin substitutes are reimbursed in Outpatient/Day Surgery Clinic and the number of skin substitute applications allowed per treatment episode. Current policy allows for 10 applications over a 12-week treatment episode. The proposed policy would reduce the allowed number to 2 or 4 applications per 12-week episode unless a medical need for more is documented and appealed case-by-case.

Taken together, these proposed changes have the potential to lower and level the reimbursement playing field, but at a cost of reducing patient access, delaying healing, and increasing medical complications. CMS is scheduled to release a revised set of payment policy proposals in July of this year. To be sure, there will be a lot of discussion on this topic coming in the months ahead.