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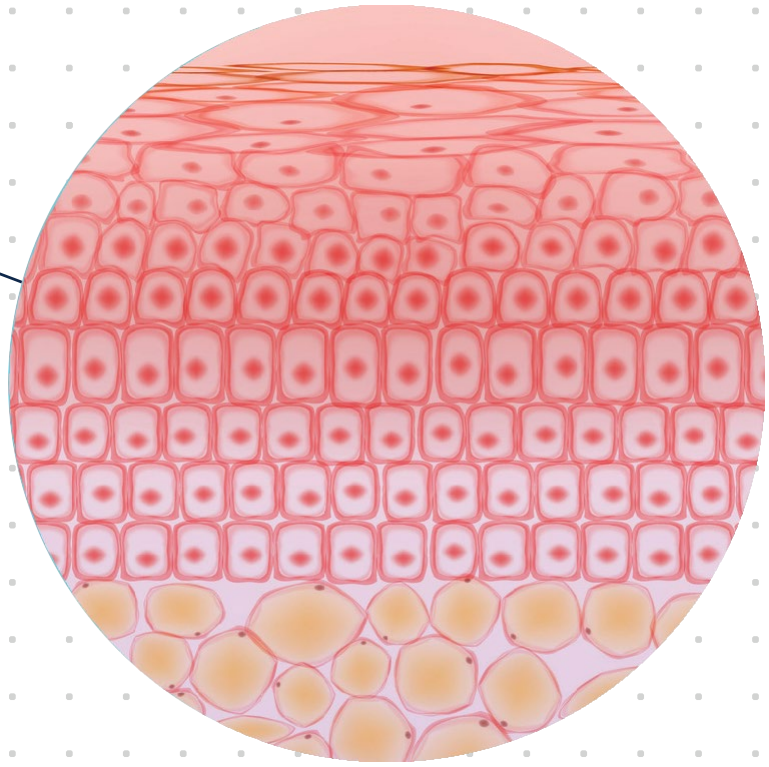

Study of Costs of Skin Substitutes for Development of Future Medicare Reimbursement Rates

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Executive Summary

In 2024, Medicare Administrative Contractors proposed Local Coverage Determinations ("LCD") that would have placed substantial limits on Medicare's coverage for skin substitute products, which provide an important treatment option for Medicare beneficiaries with Diabetic Foot Ulcers and Venous Leg Ulcers.[1] On April 11, 2025, the implementation of the LCDs was delayed until January 2026.[2] In lieu of the LCDs and coverage limits, the Centers for Medicare & Medicaid Services ("CMS") published a Final Rule setting a national payment rate for all skin substitute products at $127.14 per square centimeter across all places of service, effective January 1st, 2026.[3]

The Medicare Access to Skin Substitutes ("MASS") Coalition hired BRG consultants in 2025 to conduct an independent study of the industry to inform reimbursement decisions for allograft[4] skin substitute products. In this report, we describe the data and methodologies used to create three (3) cost models for skin substitute products that could be used as a basis for updates to reimbursement for the products. Our approach combined interviews (with providers, manufacturers, and distributors) and manufacturer-provided financial data related to skin substitute products;[5] and was informed by industry-specific and other research.

Our study relies on data collected in 2025 from skin substitute manufacturers, which was not used by CMS in the methodology outlined in the January 2026 Final Rule. Our process involved collecting data but not independent verification of the data. We view our study as supplemental to the work CMS has performed, as it uses a different data source to determine a potential reimbursement rate for skin substitute products. Reimbursement amounts should be established at levels that allow manufacturers, distributors, and providers to continue providing patients with these products, encourage intra-industry innovation, and establish appropriate but not excessive payments, thus ensuring continued access. These products treat diabetic foot ulcers, venous leg ulcers, and other conditions and are a treatment option for seniors including Medicare beneficiaries.[6] We did not evaluate the clinical effectiveness or efficacy of these products.

Using manufacturer-provided cost data, we determined that the costs for these products ranges from $282 to $478 per square centimeter ("sq cm"). We believe that reimbursement amounts in this range would allow entities within the distribution system to cover their costs and continue to effectively operate within the current industry framework.

Our cost models consider the highly skilled and technical work required in manufacturing and distributing skin substitute products to providers. A cost-based approach like this also aligns with other provider reimbursement approaches employed by CMS.

1 Centers for Medicare & Medicaid Services, "Skin Substitute Grafts/Cellular and Tissue-Based Products for the Treatment of Diabetic Foot Ulcers and Venous Leg Ulcers," LCD ID L39764 (updated November 8, 2024). https://www.cms.gov/medicare-coverage-database/view/lcd.aspx?lcdid=39764

2 Centers for Medicare & Medicaid Services, "CMS Statement on Local Coverage Determination for Certain Skin Substitute Grafts," (April 11, 2025). https://www.cms.gov/newsroom/press-releases/cms-statement-local-coverage-determination-certain-skin-substitute-grafts

3 Centers for Medicare & Medicaid Services, "Medicare and Medicaid Programs; CY 2026 Payment Policies under the Physician Fee Schedule and Other Changes to Part B Payment and Coverage Policies; Medicare Shared Savings Program Requirements; and Medicare Prescription Drug Inflation Rebate Program," (November 5, 2025). https://www.cms.gov/newsroom/fact-sheets/calendar-year-cy-2026-medicare-physician-fee-schedule-final-rule-cms-1832-f

4 Human tissue-based grafts, such as skin or placenta.

5 Collected from members of the MASS Coalition.

6 Products include allografts, and non-allografts (xenograft & synthetics), with sq cm and non-sq cm units.

Background

Reimbursement for Skin Substitute Products

Wound treatment using skin substitute products is reimbursed via two HCPCS[7] codes: one for the application of the skin substitute product (HCPCS codes 15271 – 15278) and a second that identifies the specific skin substitute product used.

When patients are treated in an office or home setting, the wound application HCPCS codes—as well as a handful of historic product-specific A-series HCPCS codes for xenografts[8] and synthetic skin substitute products (HCPCS codes A2001 – A2035)—are reimbursed using the Medicare Physician Fee Schedule ("MPFS"). The MPFS lists the rate that CMS has set for each HCPCS code based on the physician work, practice expense, and malpractice expense attributable to the service. The rate is then adjusted based on the labor costs in the geographic location where a service is provided. CMS updates and publishes the MPFS quarterly.

The majority of skin substitute products were assigned Q-series codes (HCPCS codes Q4100 – Q4440) and were reimbursed by Medicare using the Part B Drug Average Sales Price ("ASP") drug-pricing files. Under ASP pricing, manufacturers submitted product information and relevant financial data to CMS for a specific Q-code, including the manufacturer's ASP and number of ASP units.[9] CMS used this data to calculate an ASP payment limit to reimburse providers who submit claims for skin substitute products. Over the last few years, the number of products on the ASP fee schedule and the rates per sq cm increased with reimbursement ranging from $100 to over $1,000 per sq cm.

The CMS Final Rule for 2026 set reimbursement for all skin substitute products at $127.14 per sq cm, removing product-specific rates. CMS has begun reimbursing these products through the MPFS. The CMS methodology to determine the reimbursement rate relied on the Q4 2024 ASP, weighted by the utilization of skin substitute products in the outpatient hospital setting in Q4 2024.

Interviews

To gain insight into the current skin substitute market, we interviewed individuals operating in the wound care marketplace. We conducted virtual interviews with representatives from six (6) manufacturers that are members of the MASS Coalition, four (4) provider groups that run large wound care practices, and two (2) distributors that provide services to skin substitute manufacturers. We completed these interviews to better understand how the industry operates as well as concerns about the present and future states of the industry from the perspective of various stakeholders.

Reimbursement Framework

All interviewed stakeholders agreed that predictable coverage and consistent pricing would best balance all stakeholder interests: manufacturers maintaining a viable business, providers seeking to preserve access to this treatment option, and CMS attempting to reduce its cost burden.

To create a reimbursement approach that is more transparent and consistent than the ASP approach, we agree with CMS that the ASP-based prices for skin substitute products be replaced by a rate contained within the MPFS. Similarly, we agree that all allograft products with units in sq cm, the focus of this study, be assigned a single reimbursement rate.

Our pricing study focuses on allograft products measured per sq cm (due to a lack of available data covering non-sq cm categories and the predominance of sq cm products, which made up the majority of the skin substitute market in 2024). However, capping the allograft per sq cm reimbursement could incentivize manufacturers to develop products that are not reimbursed per sq cm, if higher reimbursement can be obtained through a different pricing methodology. CMS may consider reimbursing these products on a per sq cm basis to potentially mitigate this incentive.

7 Healthcare Common Procedure Coding System.

8 Tissue grafts from other species, such as bovine or porcine grafts.

9 Centers for Medicare & Medicaid Services, "Average Sales Price (ASP) Data Collection System Webinar: Skin Substitute Manufacturer Session" (July 2024). https://www.cms.gov/files/document/average-sales-price-asp-data-collection-system-webinar.pdf

Cost Data Collection

Data Requested from Manufacturers

We requested data from ten (10) manufacturers to understand the costs involved in the production and distribution of skin substitute products. We requested financial/accounting data at both aggregated and product-specific levels across as many years as manufacturers had available. We requested, at a minimum, product names, descriptions, quantity of products sold, and both direct and indirect costs incurred by each manufacturer.[10]

We defined direct costs to include "costs of goods sold" ("COGS"), or costs directly related to the manufacturing of skin substitute products. Indirect costs can vary substantially, depending on how an organization conducts its business, but typically include realized general overhead costs regardless of specific manufacturing practices.

Eight (8) manufacturers provided data, which included a wide array of cost information organized and formatted in a variety of ways. We relied on the manufacturer-provided information as an accurate reflection of the costs and did not independently verify these costs as that was outside our scope. Non-disclosure agreements were signed with all manufacturers that provided data to ensure that a specific manufacturer's cost data was protected. For this reason, all reported cost data was de-identified and aggregated.

Data Provided by Manufacturers

To evaluate costs associated with the production, sale, and distribution of allograft skin substitute products, we collected and grouped manufacturer data into direct and indirect costs, based on the descriptions provided by the manufacturers. The data provided related to allograft products sold in sq cm units.[11]

Manufacturers reported cost data for the time period covering January 2022 through March 2025. We reviewed and aggregated the data across manufacturers and time periods. Manufacturers also provided the quantity (in sq cm) of allograft skin substitute products sold during the same time period.

Data varied across manufacturers in the following ways:

- **Time period:** Some manufacturers provided one year and/or partial years of data, while others provided multiple years of data.
- **Granularity:** Manufacturers provided data at various levels of detail (e.g., annual, transaction and/or product level).

Direct Costs and Indirect Costs

All manufacturers specifically reported direct costs or COGS, but reporting of indirect costs varied. Some manufacturers reported indirect costs in aggregate fashion as "overhead" or "selling, general, and administrative expenses" ("SGA"). Other manufacturers reported indirect costs by specific category. The most common indirect cost categories included:

- Facility expenses, including rent and utilities
- Labor costs, including employee salaries
- Legal, consulting, and accounting fees
- Sales and marketing expenses
- Research and development costs, including clinical trials
- Licensing fees
- Distributor commissions and bona fide service agreements[12]

Based on our research regarding the skin substitute industry and its supply chain, we determined that commissions and bona fide service fees should be considered separately from direct and indirect costs.

We included all direct and indirect costs reported by the manufacturers in all three (3) models presented below, with the exception of commissions and bona fide service fees, which are included in Models 2 and 3 only.

Square Centimeters Sold

Manufacturer data included the total sq cm of allografts sold per year, which was sometimes segmented by product.

10 Some manufacturers provided more specific data such as the components of their direct and indirect costs, while manufacturers that had other service lines provided data based on allocated percentages of total costs.

11 A small amount of reported financial data relates to xenograft products, but the volume was not large enough to parse out the costs from the rest of the data.

12 Bona fide service fees are paid by a manufacturer to a distributor or other third-party entity for services performed on a manufacturer's behalf. These services may include marketing, reporting and compliance, and product management. Bona fide service fees are defined in the industry. The use of the term "bona fide" does not imply our review or analysis of the costs manufacturers identified related to these services.

Data Analysis and Cost Models

Data Preparation

Data were organized to calculate the following for each manufacturer:

- Total Square Centimeters Sold
- Total Direct Costs
- Total Indirect Costs
- Total Indirect Costs without Bona Fide Service Fees and Commissions
- Bona Fide Service Fees and Commissions
- Direct Costs Per Square Centimeter[13]
- Indirect Costs Per Square Centimeter
- Indirect Costs without Bona Fide Service Fees and Commissions Per Square Centimeter
- Bona Fide Service Fees and Commissions Per Square Centimeter

We included direct and indirect costs for all manufacturers in our cost models.

Cost Models

We created three (3) models to calculate the cost per sq cm for allograft skin substitute products. While similar in some ways to the pharmaceutical market and distribution system (and hence skin substitute placement on the ASP fee schedule), the allograft skin substitute market differs in that manufacturers and distributors sometimes share roles that may be mutually exclusive in the pharmaceutical space (or other similar industries such as medical devices and implantables). For example, manufacturers of allograft skin substitutes may be responsible for storage, packaging, shipment, and physical inventory management, while distributors may not take possession of products, instead providing services such as logistics, marketing, training, sales, administration, and other support.

Because little published research exists regarding the allocation of costs across the distribution system of the skin substitute industry, we created three (3) cost models. Models 1 and 3 rely in some capacity on a study published by the Schaeffer Institute for Public Policy & Government Service at the University of Southern California.[14] Model 2 uses only the costs associated with the skin substitute industry, as reported to us by the manufacturers of these products. We present the three (3) models below.

MODEL 1: SKIN SUBSTITUTE MANUFACTURING COSTS ADJUSTED BASED ON THE PHARMACEUTICAL INDUSTRY DISTRIBUTION SYSTEM

The Schaeffer Institute study found that "for every $100 spent at retail pharmacies, $17 compensates for direct production costs" e.g., the total retail price for a prescription drug is 5.88 times the direct cost. We called this the Direct Product Cost Factor ("DPCF"). The study includes the entire pharmaceutical market, which is inclusive of branded products and generic products. Researchers found that the remaining $83 compensates for the costs and profit margins for multiple entities involved in the pharmaceutical market, including distributors, pharmacies, pharmacy benefit managers, and insurers.[15]

In Model 1, we first calculated the average direct and indirect costs for skin substitute products across all manufacturers and then weighted them by manufacturer market share (i.e., the average number of sq cm sold per year for each manufacturer). Then, using the DPCF from the Schaeffer Institute study, we adjusted the weighted average direct cost per sq cm across manufacturers to estimate a comparable dollar direct cost in the skin substitute industry. Finally, we added the average indirect cost per sq cm across skin substitute manufacturers to the adjusted average direct cost. This is shown in the formula below.

$$\text{Adjusted Direct Costs} = \left(\frac{\text{Direct Costs}}{\text{Total sq cm}}\right) \Big/ \underbrace{\left(0.17\right)}_{\substack{\text{Comparable Industry}\\ \text{Direct Production Cost}\\ \text{Factor}}} + \underbrace{\left(\frac{\text{Indirect Costs}}{\text{Total sq cm}}\right)}_{\substack{\text{Less bona fide}\\ \text{service fees}}}$$

13 Where a manufacturer provided partial years, the number of months was divided by 12, such that data present from 2022 to June 2023 would be recorded as 1.5.

14 N. Sood et al., Flow of Money Through the Pharmaceutical Distribution System, USC Schaeffer Institute for Public Policy & Government Service (July 6, 2017). https://schaeffer.usc.edu/research/flow-of-money-through-the-pharmaceutical-distribution-system/

15 Sood et al. (2017).

Manufacturers in our study reported $282 million in direct costs attributable to 7.2 million sq cm of skin substitute products for products sold between January 2022 and March 2025. We used these data, weighted by manufacturer market share, to calculate an average direct cost per sq cm of $37.49. The direct costs exclude costs for distribution, promotion, and marketing to operate the business. We then divided this amount by the DPCF of 0.17 from the Schaeffer Institute study (the equivalent of multiplying the average direct cost by 5.88), which results in an adjusted average direct cost of **$220.52**.

The manufacturers in our survey reported $523 million in indirect costs (excluding bona fide service fees and commissions) attributable to 7.2 million sq cm of skin substitute products. We used these data to calculate a weighted average indirect cost per sq cm of **$61.24**.

We then added the adjusted average direct cost per sq cm of $220.52 to the weighted average indirect cost per sq cm of $61.24, resulting in reimbursement per sq cm of **$281.76**.

Adjusting the average direct costs in this way and then adding indirect costs likely overstates the total costs because the adjusted direct cost amount includes indirect costs and margins for manufacturers as well as the costs and margins of other intermediaries. However, our understanding, based on discussions with industry representatives, is that the skin substitute market is more similar to the branded (as opposed to the generic) pharmaceutical market[16] because branded drug manufacturers realize higher profit margins on their products compared to generic drug manufacturers. Therefore, Model 1 includes the reported indirect costs reported by the manufacturers and the adjusted direct costs.

It is also important to note that under Model 1, **commissions and bona fide service fees are excluded** because the adjustment of average direct costs using the DPCF considers the costs attributable to other participants in the distribution system such as distributors and providers.

In summary, **Model 1 results in total costs equal to $281.76 per sq cm:**

($37.49 / 0.17) + $61.24 = $281.76[17]

$220.52 + $61.24 = $281.76

MODEL 2: SKIN SUBSTITUTE MANUFACTURING COSTS AND DISTRIBUTION SYSTEM COSTS

Model 2 measures the costs attributable to the skin substitute industry as reported to us, with no adjustments to costs based on the distribution system. A unique feature of the skin substitute industry is "bona fide service agreements," and the fees associated with these agreements, which some manufacturers reported to us. Bona fide service fees and commissions are paid by manufacturers to distributors for services such as marketing, training, sales, administration, and legal/ regulatory support.

Not all manufacturers reported commissions and/or bona fide service fees in their indirect costs, but because these fees represent a substantial expense across the skin substitute distribution system, we imputed these costs for manufacturers that did not report them by applying the weighted average bona fide service fee per sq cm based on manufacturers who reported these fees.

Manufacturers that provided data for this study reported $2.4 billion in bona fide service fees and commissions attributable to 6.1 million sq cm in skin substitute products, which resulted in a weighted average bona fide service fee of **$345.15** per sq cm.

As described previously, we collected both direct and indirect costs from manufacturers of skin substitute products. Model 2 includes these direct and indirect costs with no adjustments as well as the costs of bona fide service agreements. Since the bona fide service fees represent the costs of the skin substitute distribution system (rather than the pharmaceutical industry), the direct costs reported by manufacturers were not adjusted in this model. Instead, the average direct and indirect costs per sq cm were added to the average bona fide service fees per sq cm to obtain the total costs per sq cm.

16 Branded pharmaceuticals incur greater costs for clinical trials and marketing.

17 The equation includes rounded numbers. Calculations in Excel include additional decimal places.

Therefore, in Model 2, the (unadjusted) weighted average direct costs per sq cm ($37.49) are added to the weighted average indirect costs per sq cm ($61.24) and the weighted average bona fide service fee per sq cm ($345.15) for a total cost per sq cm of **$443.87**. This model accounts for all costs reported to us by skin substitute manufacturers and is shown in the formula below:

$$\left(\frac{\text{Direct Costs}}{\text{Total sq cm}}\right) + \left(\frac{\text{Indirect Costs}}{\text{Total sq cm}}\right) + \left(\frac{\text{Bona Fide Service Fees*}}{\text{Total sq cm}}\right)$$

Less bona fide service fees

* Bona fide service fees were included for all manufactures. The weighted average fee was calculated using the reported bona fide service fees and commissions applied for all manufacturers.

In summary, **Model 2 results in total costs equal to $443.87 per sq cm:**

$37.49 + $61.24 + $345.15 = $443.87

MODEL 3: HYBRID APPROACH (BLEND OF DISTRIBUTION COSTS FROM PHARMACEUTICAL AND SKIN SUBSTITUTE INDUSTRIES)

As described previously, the allograft skin substitute market is unique in that manufacturers and distributors may share roles that may be mutually exclusive in other comparable industries such as pharmaceuticals and medical devices.

Considering these unique roles and potential additional costs attributable to the services provided by intermediaries in the skin substitute industry while at the same time considering similarities between the pharmaceutical and skin substitute industries, Model 3 blends the costs calculated in Models 1 and 2 to create a hybrid cost model.

In Model 3, we first used the adjusted weighted average direct costs per sq cm ($220.52) from Model 1, which account for the costs and margins in the skin substitute distribution system in a proportion similar to the pharmaceutical industry. Next, we added the average indirect cost per sq cm of $61.24, as also done in Model 1.

To account for at least a portion of the unique services provided by distributors in the skin substitute industry, we then added a portion of the bona fide service fees to the calculation, again using the Schaeffer Institute study of the pharmaceutical distribution system.

The Schaeffer Institute study found that "…for every $100 spent at retail pharmacies, $41 is allocated to intermediaries in the distribution system."[18] We assumed that the bona fide service fees represent the costs attributable to "intermediaries in the distribution system," therefore we calculated the percentage of bona fide service fees per sq cm that would equate to 41 percent of the total costs, which is $196.73.[19] This amount was added to the adjusted average direct costs per sq cm and the average indirect costs per sq cm. This is shown in the formula below.

$$\left(\text{Adjusted Direct Costs}\right) + \left(\frac{\text{Indirect Costs}}{\text{Total sq cm}}\right) + \left(\text{Distribution Intermediary Weighted Average Cost per sq cm}\right)$$

See Methodology 1 | Less bona fide service fees | Based on 41% of bona fide service fees See Methodology 2

In summary, **Model 3 results in total costs equal to $478.49 per sq cm:**

($37.49 / 0.17) + $61.24 + ($345.15 x 0.57) = $478.49[20]

$220.52 + $61.24 + $196.73 = $478.49

18 Sood et al. (2017).

19 This accounts for 57 percent of the bona fide service fees.

20 The equation includes rounded numbers. Calculations in Excel include additional decimal places.

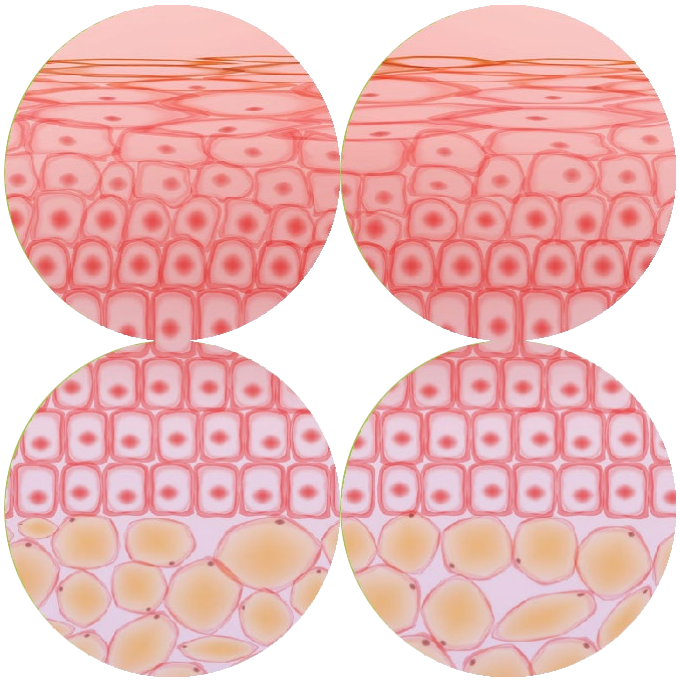
Discussion and Limitations

In creating the three (3) cost models described above, we sought to consider costs attributable to the participants in the skin substitute market and the unique characteristics of the distribution system. At the same time, recognizing the limited research related to the skin substitute industry, we sought alternatives to allocate costs for the distribution system in a reasonable manner based on academic research in the related pharmaceutical industry. As such, we created a model that considers the costs reported to us by skin substitute manufacturers (Model 2) and additional models that apportion these same costs in a manner that more closely approximates the pharmaceutical distribution system, which has been studied more extensively. Our objective was to create cost models that account for the complexities in the skin substitute production and distribution chain but also are grounded in academic research. Our models result in amounts ranging from $282 to $478 per sq cm.

In summary, the costs from Models 1, 2, and 3 are shown in the table below:

Model	Direct Costs	Indirect Costs	Distribution Costs	Total Costs
1	$220.52	$61.24		$281.76
2	$37.49	$61.24	$345.15	$443.87
3	$220.52	$61.24	$196.73	$478.49

As described previously, our calculations are based on data that skin substitute manufacturers reported to us. Our team did not verify the data that was provided to us as this was outside our scope. We have also previously described specific data limitations and limitations regarding research on the cost allocation of various participants in the skin substitute distribution chain. Finally, our models are limited to allograft skin substitute products that are produced in sq cm units. Limited manufacturer data was provided to us for allograft products reported in non-sq cm units, as well as non-allograft products (xenografts and synthetics). Therefore, we were not able to create cost models to support Medicare reimbursement rates for these products.



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This study was prepared at the direction of the Medicare Access to Skin Substitutes (MASS) Coalition.