Department of Health and Human Services
Office of Inspector General
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DATA SNAPSHOT

September 2025 | OEI-BL-24-00420

Medicare Part B Payment Trends for Skin Substitutes Raise Major Concerns About Fraud, Waste, and Abuse

HHS Office of Inspector General
HIGHLIGHTS

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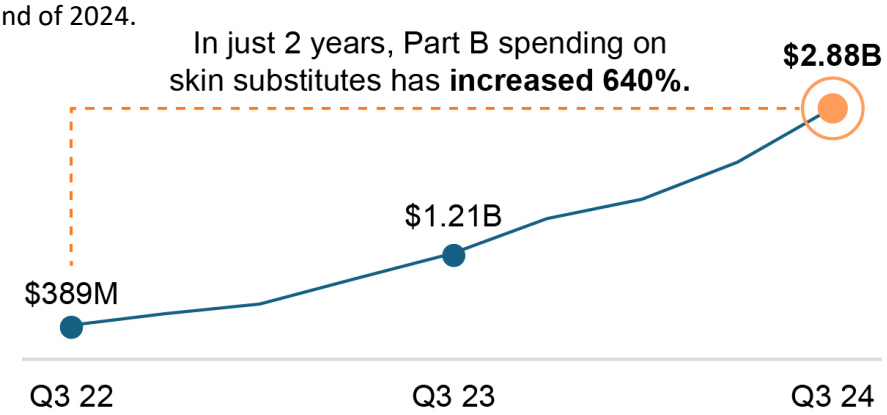
Medicare Part B and Skin Substitutes

Medicare Part B covers wound-care products known as skin substitutes[1] when reasonable and necessary for the treatment of an enrollee's condition.[2] For payment purposes, CMS treats skin substitutes like approved prescription biologics, although most are regulated by FDA through much less rigorous processes.[3] As such, providers of skin substitutes in non-institutional Part B settings are reimbursed at 106 percent of the average sales price (ASP) (note: hereinafter, "Part B" refers only to skin substitutes provided in non-institutional settings). In cases in which ASPs are not available (e.g., a new billing code), Medicare typically uses Wholesale Acquisition Costs (WACs) or payment invoices to determine a payment amount.

In March 2023, OIG issued a report that identified significant gaps in manufacturer compliance with new ASP reporting requirements for skin substitutes.[4] **Despite efforts by CMS to address the accuracy and completeness of ASP reporting, significant increases in expenditures since the OIG report was released raise concerns about what could be driving these trends.** To explore these concerns, we analyzed Medicare Part B and Medicare Advantage claims data from non-institutional settings in 2023 and 2024, and manufacturer-reported sales data for skin substitutes from those same years.

Key Takeaways

Part B expenditures for skin substitutes provided in non-institutional settings have skyrocketed over the last 2 years, surpassing $10 billion annually by the end of 2024.



Several aspects of Part B spending trends raise serious concerns:

- Large increases in the number of enrollees with skin substitute claims and the amount of product billed for each enrollee, particularly in home care.
- A massive gap in spending between Part B and Medicare Advantage.
- A steep rise in the cost of individual skin substitutes combined with providers' propensity to shift to more and more expensive products.
- Fraud schemes that allow bad actors to quickly get paid tens of millions of dollars when billing for just a small number of Part B enrollees.

Factors that may be driving these trends include (1) manufacturers' ability to quickly bring new skin substitutes to the market compared to typical products paid using ASP and (2) financial incentives that make certain products more attractive to providers. **Under the current payment system, Medicare often pays providers for skin substitutes at amounts much higher than the providers' purchase prices, and providers keep the "spread."** This creates incentives to bill for more and more units of skin substitutes and to choose products with the greatest spreads – the same types of billing trends highlighted in this report.

Call to Action

Action is urgently needed to rein in the massive increases in Medicare Part B spending for skin substitutes. OIG's findings illustrate the critical need for payment reforms that address fraud, waste, and abuse in Medicare skin substitute billing. As policymakers consider options, any solutions should ensure that Medicare enrollees continue to receive appropriate care while removing incentives for inappropriate and even fraudulent billing. CMS has recently taken steps toward addressing these concerns.

Primer: Average Sales Price

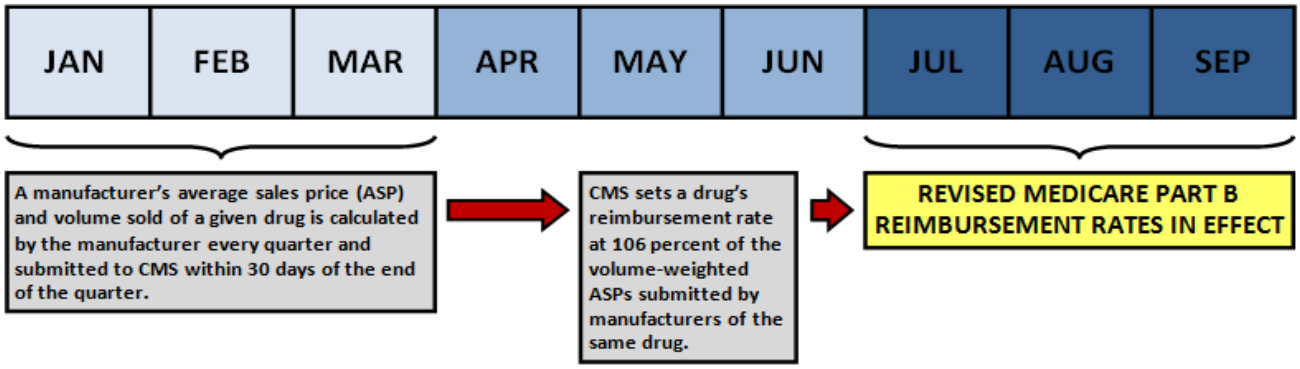
What is ASP?

By statute, ASP is defined as a manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter (net of most discounts) divided by the total number of units of the drug sold by the manufacturer in that same quarter.[5]

$$\text{ASP} = \frac{\text{Manufacturer's sales of drug to all purchasers in US in calendar quarter}}{\text{Total number of units of drug sold by manufacturer in same quarter}}$$

How are ASPs used to set Part B payment?

Manufacturers are required to report the ASPs and total sales volume for each of their Part B drugs to CMS within 30 days of the end of every quarter.[6] CMS then uses this data to calculate a payment amount for the billing code representing the drug. Because different versions (i.e., dosage amounts, package sizes) of a drug may be included within the same billing code, CMS calculates an overall volume-weighted ASP for the code using the manufacturer-reported sales data. By statute, Part B payment is set at 106 percent of the volume-weighted ASP.[7] In cases in which CMS is unable to calculate a volume-weighted ASP for a code (e.g., a new code for which ASPs have yet to be reported), Medicare Part B contractors typically use WACs (i.e., list prices) or payment invoices to determine a payment amount.[8] Allowing for the time it takes for manufacturer price reporting and the subsequent CMS validation and calculations, there is a two-quarter lag in the ASP-payment process (e.g., first-quarter 2024 ASPs were used as the basis for third-quarter 2024 payment amounts).



Source: ASPE, *Medicare Part B Reimbursement of Prescription Drugs*.[9]

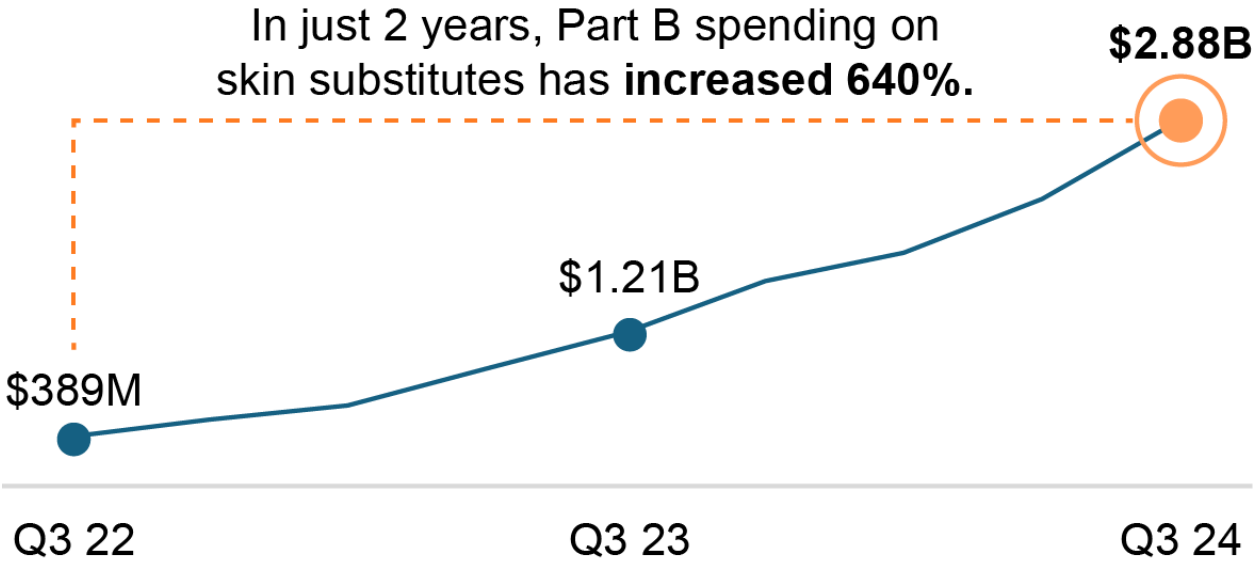
What are some potential incentives under the ASP payment methodology?

Part B providers can retain the "spread" between their acquisition cost for a drug and the Medicare payment amount. Previous OIG work has found that higher spreads may correlate with increased utilization for certain drugs.[10, 11] Numerous factors can influence the amount of spread for a particular product:

- WACs, which represent list prices, are generally higher than ASPs. Therefore, the spread a provider receives for a product with a WAC-based payment would generally be higher than one with an ASP-based payment.
- The two-quarter lag in ASP-based payments may lead to higher spreads (1) during the period after a new product has entered the market but ASPs are not yet available and (2) when prices for a product drop substantially and ASP-based payment amounts take up to 6 months to catch up.
- The statutory 6-percent add-on to ASP can create financial incentives that favor the prescribing of higher-priced drugs.[12]

Medicare Part B spending on skin substitutes has skyrocketed over the past 2 years

Part B spending on skin substitutes has increased from approximately $400 million to nearly $3 billion per quarter in just 2 years.



Source: OIG Analysis of Part B claims data.

These increases in Part B expenditures have occurred despite better ASP reporting, which decreases the reliance on list prices (i.e., WACs) and potentially inflated invoices to set payments. Since OIG's last review, the number of skin substitute products that were paid based on ASPs increased from 56 percent in the first quarter of 2023 to 82 percent in the fourth quarter of 2024.[13]

The rapid growth in expenditures is driven by both increased utilization and higher prices

Utilization of skin substitutes has increased steadily, with more enrollees having skin substitute claims and a higher number of units being billed per enrollee. At the same time, the costs of individual skin substitute products also dramatically increased.

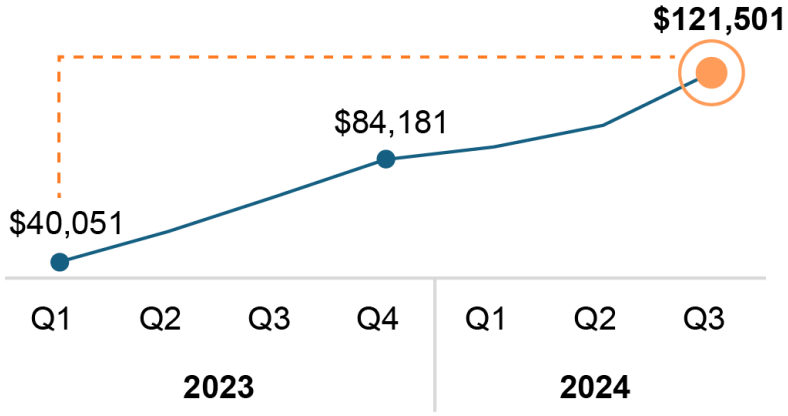
Between the first quarter of 2023 and the third quarter of 2024:

The number of unique Part B **enrollees** with a skin substitute claim **increased by 53 percent**.

The total number of **units** paid under Part B **increased by 83 percent**.

The average **Part B payment amount** for each unit of skin substitute **increased by 153 percent**.

In less than 2 years, the **amount paid per Part B enrollee has tripled.**

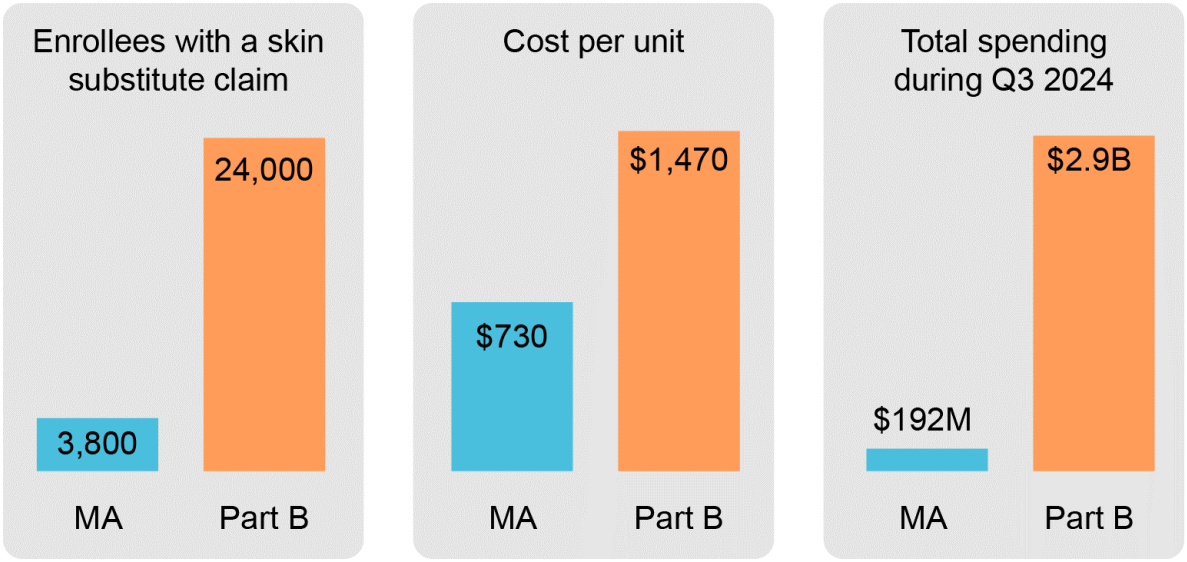


Source: OIG Analysis of Part B claims data.

Medicare Advantage spends far less than Part B on skin substitutes

In 2024, more than half of Medicare enrollees were covered under Medicare Advantage (MA) plans rather than Original Medicare (i.e., Parts A and B).[14] However, in the third quarter of that year, only **3,800 MA enrollees** were associated with a skin substitute claim, compared to **24,000 enrollees in Part B**. Further, providers who billed MA for skin substitutes that quarter typically used fewer units per patient (**69** versus **82**) and less expensive products (**$730** versus **$1,470**) than providers who billed Part B. As a result, total spending for skin substitutes under MA was just 7 percent of spending under Part B that quarter – **$192 million in MA** compared to **$2.9 billion in Part B**.

Utilization and expenditures for skin substitutes under Medicare Advantage are just a fraction of utilization and expenditures under Original Medicare.



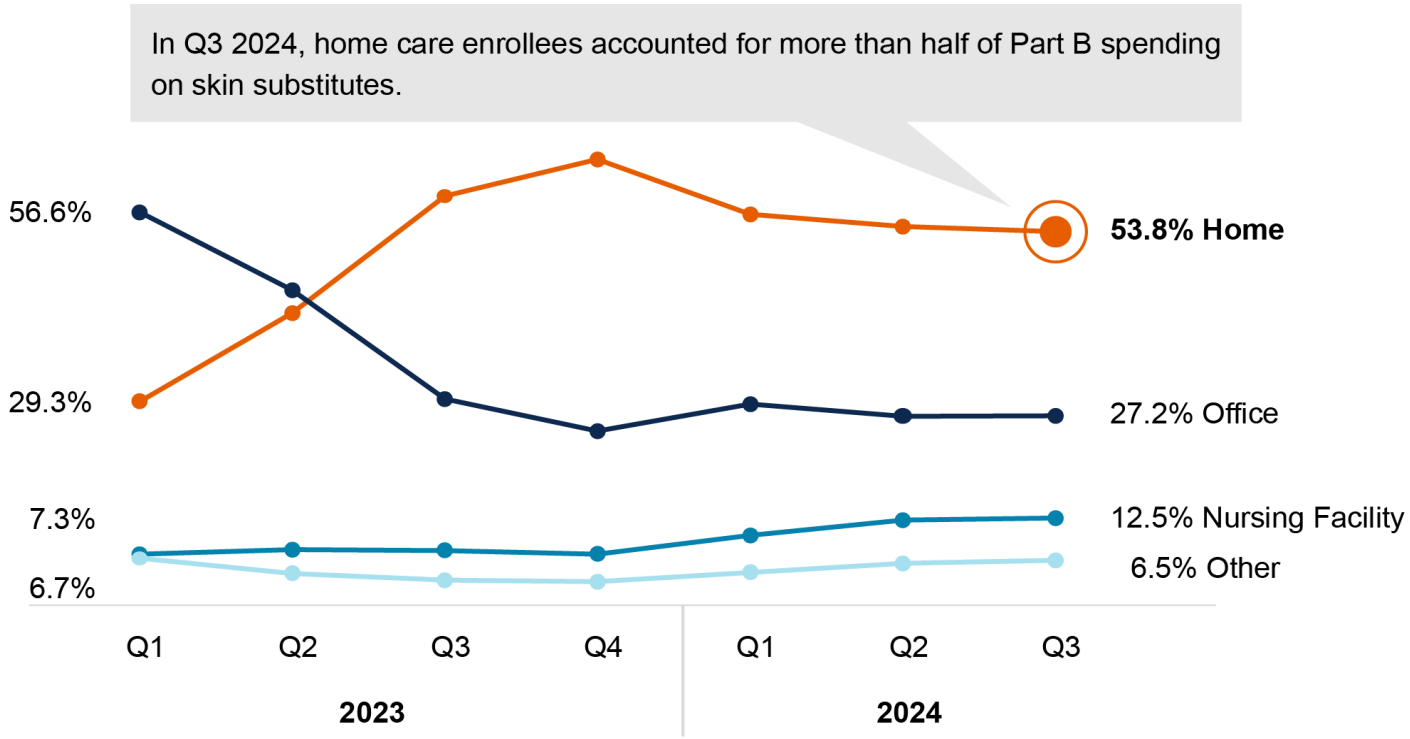
Source: OIG Analysis of Part B and Part C claims data.

No obvious differences in the enrollee demographics of Original Medicare and Medicare Advantage explain the massive variance in skin substitute utilization. Instead, the variance is likely driven by MA plans' ability to use numerous reimbursement and utilization management tools to set payment rates and coverage for products such as skin substitutes. Examples include:

- Negotiated contracts for provider reimbursement, which can range from a fee-for-service rate as with Part B (e.g., ASP plus a percentage add-on payment) to a capitated amount based on a larger set of services provided during treatment.[15, 16]
- Prior authorization (e.g., step therapy).

Home care represented a disproportionate share of Part B expenditures

The growth of skin substitute utilization and payments in the home care setting is particularly notable. By the third quarter of 2024, 28 percent of enrollees with a paid skin substitute claim under Part B were reportedly being treated in their home. These home care enrollees accounted for more than half of Part B spending for skin substitutes that quarter.



Source: OIG Analysis of Part B claims data.

Home care providers billed for substantially more units and markedly more expensive products than office-based providers

In the third quarter of 2024, the typical enrollee reportedly being treated at home received 2.6 times more units on average than enrollees in a physician's office (134 units versus 52 units). That same quarter, the average cost of skin substitutes reportedly used in home settings was $1,718 per unit, compared to $1,099 per unit in offices. As a result, Medicare paid substantially more for enrollees with home-care claims compared to enrollees with office-based claims.

The cost per enrollee in the third quarter of 2024 was four times as high for patients reportedly treated at home compared to in an office setting.

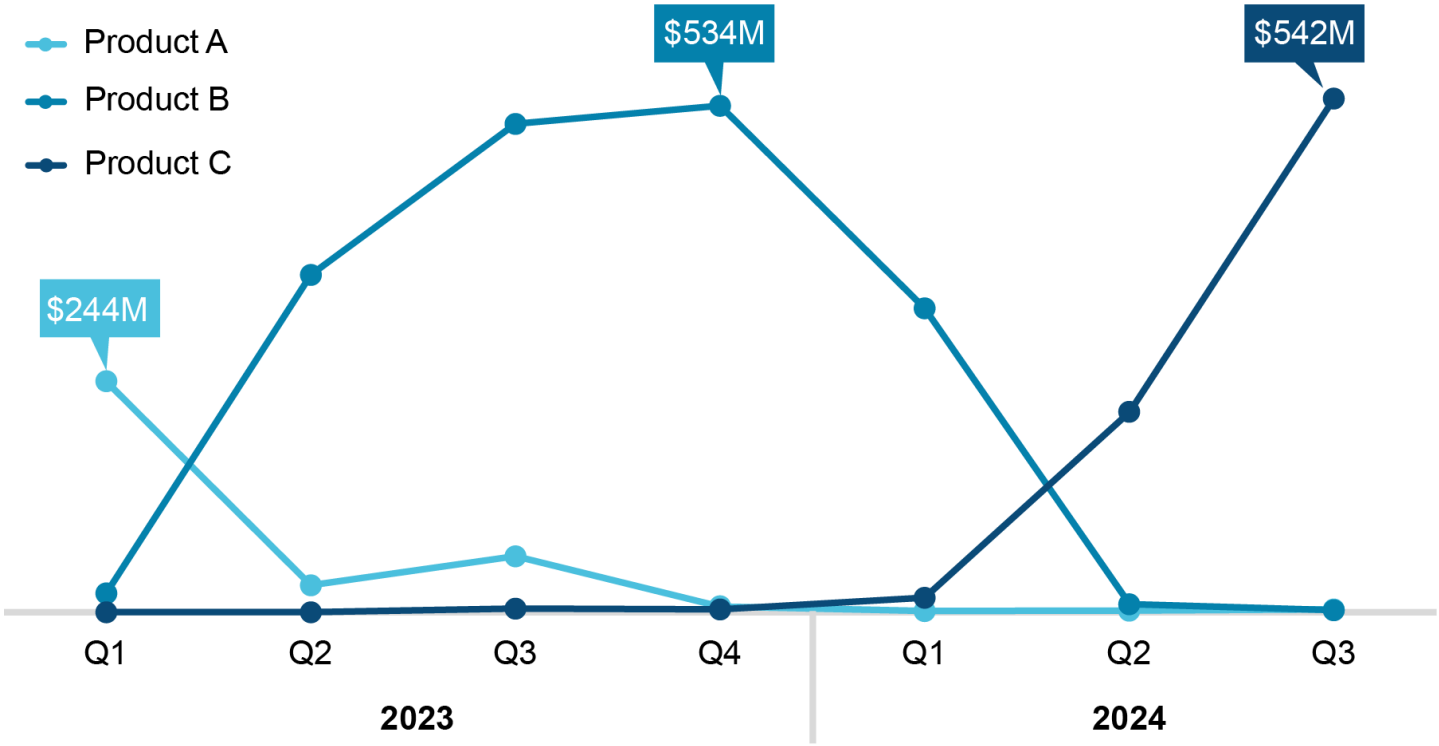
Source: OIG Analysis of Part B claims data.

Provider preferences for skin substitute products tend to shift rapidly

Unlike drugs paid under Part B, the highest-expenditure skin substitute products can change frequently as new competitors enter the market.

- In the first quarter of 2023, the 10 highest-expenditure skin substitutes accounted for 81 percent of Part B spending on those types of products. One year later, only 2 were still among the top 10 (the other 8 ranked between 19th and 73rd in expenditures).
- In contrast, 8 of the 10 highest-expenditure non-skin substitutes (i.e., prescription drugs and biologics) remained the same during that period (the other 2 dropped to 11th and 12th).
- The tendency for skin substitutes to swiftly jump to the top in terms of quarterly Medicare expenditures and then quickly fall off is illustrated by spending trends for three products:

Three top skin substitutes saw their Part B expenditures rise and fall by hundreds of millions of dollars over their first few quarters on the market.



Source: OIG Analysis of Part B claims data.

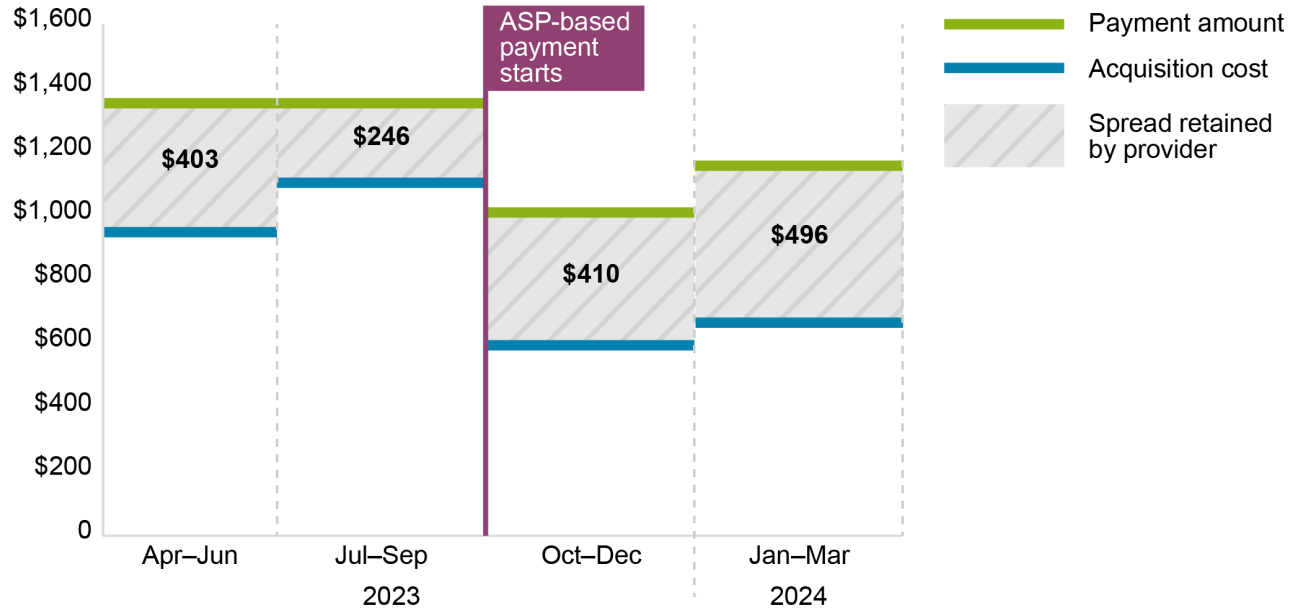
- At the start of 2023, the highest-expenditure skin substitute in Part B was Product A, a newer skin substitute that quickly dominated the Medicare market. In the first quarter of 2023, Part B expenditures for Product A reached $244 million, representing nearly 40 percent of all skin substitute payments. The next quarter, Part B expenditures fell to $28 million. By the start of 2024, Medicare spent just $1.2 million for Product A, a 200-fold decrease in a single year.
- The skin substitute which replaced Product A at the top (Product B, sold by the same manufacturer) followed a similar pattern. It was introduced in January 2023 and accounted for $20 million in Part B spending in its initial quarter of sales. In the second quarter of 2023, Medicare spending for Product B skyrocketed to $356 million. Expenditures peaked at $534 million two quarters later, before plummeting to $2 million soon after.
- As demand for Product B disappeared, yet another newer product saw huge increases in its Part B expenditures. Product C was introduced by its manufacturer in July 2023 and attained only minor usage during its initial 9 months on the market, with expenditures reaching just $15 million in the first quarter of 2024. One quarter later, Part B expenditures for Product C jumped to $211 million; they then more than doubled to $542 million in the third quarter.

The two-quarter lag in ASP payments and the 6-percent add-on could both drive incentives to switch among skin substitute products

The expenditure patterns for Product B described above illustrate how the timing of ASP reporting and the inherent two-quarter lag can create utilization incentives for providers:

- As Product B was a newer skin substitute, Medicare contractors used WACs/invoices to set payment during the second and third quarters of 2023. Given that WACs represent list prices and invoices do not include any post-purchase rebates, the resulting payment amounts significantly exceeded provider costs with average spreads of $403 per square cm and $246 per square cm in those quarters.
- Once ASP-based payments for Product B took effect in the fourth quarter of 2023, its manufacturer employed pricing tactics that took advantage of the two-quarter lag, thus helping Product B maintain a heavy market presence for additional quarters despite a substantially lower payment amount.
  - In the fourth quarter of 2023, the move from WACs/invoices to ASP caused the Medicare payment amount for Product B to decrease from roughly $1,350 per square cm to around $1,000 per square cm.
  - However, at the same time, its manufacturer cut the sales price by almost half, thus allowing providers to retain even greater spreads under ASP in the fourth quarter of 2023 and first quarter of 2024 ($410 and $496 per square cm, respectively) than they retained under WAC/invoice-based payment.

Decreasing prices for Product B combined with the two-quarter lag helped providers retain large spreads.



Source: OIG Analysis of Part B claims data and ASP-based payment data.

The 6-percent add-on for ASP is intended to help providers cover their overhead costs; however, the Medicare Payment Advisory Commission has stated that it also "can create financial incentives that favor prescribing higher-priced drugs in some circumstances."[17] This is borne out by the data, which shows that skin substitutes with higher ASP-based payment amounts were billed in much greater numbers than those with lower payment amounts. In the third quarter of 2024:

The average ASP-based payment amount among all skin substitutes was $587, **reflecting a 6-percent add-on of $33.**

If one takes the actual products billed by Medicare providers into account, the volume-weighted average (i.e., the products billed had higher ASP-based payment amounts than average) was $1,313, **reflecting a 6-percent add-on of $74.**

That quarter, a typical enrollee received 82 units of skin substitutes, meaning that the **$74 add-on alone was worth over $6,000 per patient.**

Skin substitutes seem particularly vulnerable to questionable billing and fraud

OIG investigations have uncovered numerous fraud schemes involving skin substitutes.

OIG has worked closely with the Department of Justice to uncover numerous fraud schemes related to inappropriate billing for skin substitutes, including one that resulted in over $1 billion in restitution.[18] OIG also investigates leads developed internally.

Office of Public Affairs
U.S. Department of Justice

Arizona Couple Pleads Guilty to $1.2B Health Care Fraud (January 31, 2025)

An Arizona couple, Alexandra Gehrke and Jeffrey King, pled guilty for causing over $1.2 billion of false and fraudulent claims to be submitted to Medicare and other health insurance programs for medically unnecessary skin substitute products. The defendants targeted elderly patients, including hospice patients. Among other things, Gehrke instructed and financially incentivized sales representatives to order grafts larger than the size of the wounds to maximize health insurance reimbursement. The defendants submitted more than $1.2 billion in false or fraudulent claims, including over $960 million to federal health care programs. Federal and private insurers paid over $610 million. Medicare paid more than $600 million as a result of the fraud scheme, paying on average more than $1 million per patient. Gehrke and King ultimately pled guilty and agreed to pay $1.2 billion in combined restitution while facing up to 20 years each in prison.[19]

In addition, OIG investigations have identified **several concerning characteristics associated with skin substitute billing**, including:

- New providers (i.e., those who recently received a national provider identifier) for whom **almost 100 percent of their claims are for skin substitutes with no other associated wound care management**.
- Providers who are **submitting multiple skin substitute claims for a single date of service to circumvent Medicare claims processing systems** that reject any claim above $99,999.99.
- The use of skin substitutes **for non-approved conditions** (e.g., minor scrapes or blisters) or with **an excessive quantity for the given condition** (e.g., total body surface treatments).
- The consistent use of skin substitutes **during enrollees' first visit without attempting prior conservative treatments**.
- **Provider specialties that seem out of scope for the treatment** (e.g., a neurologist or psychiatrist billing for skin substitutes).

One high-expenditure skin substitute displays the type of concerning billing patterns that could indicate potential fraud.

- Over its first five quarters of ASP submissions **(i.e., second-quarter 2023 through second-quarter 2024 ASPs)**, the manufacturer of Product D reported total sales of just a few thousand units. During this same period, providers billed for over 200,000 units. Potential explanations for this huge gap include the following:
    - Providers purchased hundreds of thousands of units of Product D at much lower prices before the manufacturer began reporting ASPs, holding onto them for over a year before using them on patients.
    - The manufacturer incorrectly under-reported the number of units sold in its ASP submissions to CMS.
    - Providers billed Medicare for a product they never actually purchased.
- **The ASP-based payment amount** for Product D ranged from roughly $1,300 to $1,600 per square cm, making it a lucrative target for fraudulent billing.

Conclusion

Medicare Part B paid more than $10 billion for skin substitutes in 2024, meaning these products accounted for over 15 percent of the $66 billion the program spent on all Part B drugs that year. Several other aspects of Part B spending trends raise serious concerns, including (1) large increases in the number of enrollees with skin substitute claims and the amount of product administered to each enrollee; (2) a massive gap in spending between Part B and Medicare Advantage; (3) a steep rise in the cost of individual skin substitutes; and (4) potential fraudulent schemes that allow bad actors to quickly get paid millions of dollars with just a small number of Part B enrollees.

This massive increase in spending, utilization, and potential fraud is being driven by several factors related to the ASP payment methodology and its intersection with characteristics of the skin substitute market:

- The relatively simpler pathway for bringing new skin substitutes to the market compared to the typical products (i.e., prescription drugs and biologics) paid under the ASP-based methodology.
- The use of WAC/invoices to set payment during the initial quarters after a new skin substitute reaches the market, often creating hundreds of dollars per unit in spread.
- The two-quarter lag allowing providers to maintain spread when manufacturers reduce prices once ASPs are available to set payment.
- The 6-percent add-on to ASP creating incentives to use higher-cost products.

Call to Action

Action is urgently needed to rein in the massive increases in Medicare Part B spending for skin substitutes in non-institutional settings.

The findings presented in this data snapshot illustrate the critical need for payment reforms that address fraud, waste, and abuse in Medicare skin substitute billing. As policymakers consider options, any solutions should ensure that Medicare enrollees who need treatment continue to receive appropriate care while removing incentives for inappropriate and even fraudulent billing. Questions for policymakers to consider include the following:

- **Should skin substitutes be treated as "drugs and biologics" for Medicare payment purposes?**
- **Even if skin substitutes continue to be treated as "drugs and biologics," are there methods other than ASP that could be used to set payment?**
- **What lessons could Part B take from Medicare Advantage regarding coverage and payment, given that expenditures and utilization under the latter are just a fraction of Part B?**

CMS has recently taken two steps toward addressing these concerns.

In July 2025, the agency published the CY 2026 physician fee schedule proposed rule that would change the Part B payment methodology for skin substitutes.[20] The proposed rule highlights many of the same issues described in this OIG report, including the explosive growth in skin substitute expenditures and the incentives created by the current payment system. CMS estimates that under this proposal, Medicare Part B spending for skin substitutes would be reduced by $9.4 billion in CY 2026.

The second step is that in July 2025, CMS announced its plans to implement a new 6-year model that uses utilization management and artificial intelligence technologies to implement and streamline prior authorization for potentially fraudulent, wasteful, or harmful high-cost services in Medicare Part B. Under this model, which will operate in six States beginning in 2026, providing certain skin substitutes will be subject to review prior to payment.[21]

Methodology

Analysis: We used public payment amount data, confidential manufacturer-reported ASP data, and Medicare claims data to identify:

(1) how many skin substitutes had ASP-based payment amounts in the third quarter of CY 2024;

(2) trends in skin substitute Part B expenditures, utilization, places of service, and spread across CY 2023 and 2024; and

(3) how those trends compare to similar metrics in Medicare Advantage.

- **Identification of Medicare claims:** We identified all paid Medicare drug claims in Part B for 2023-2024. We then specifically identified all paid Medicare skin substitute claims in Part B and Part C (i.e., Medicare Advantage) for 2023-2024 in non-institutional settings. These products are classified using Healthcare Common Procedure Coding System (HCPCS) codes from Q4101 to Q4367.
- **Review of ASP reporting:** We developed a list of all skin substitute HCPCS codes with a paid claim under Medicare Part B in the third quarter of 2024. We compared this list to CMS's public fourth-quarter 2024 ASP Drug Pricing File to determine how many codes had an ASP-based payment amount.
- **Trends in Medicare claims by quarter:** We calculated quarterly totals, counts, and ratios of key variables in the Part B and Medicare Advantage claims data from the first quarter of 2023 through the third quarter of 2024 (data for the last quarter of 2024 was incomplete at the time of our analysis). We then identified trends in Medicare payment and utilization (e.g., total expenditures, number of enrollees receiving skin substitutes, average payment amount per unit) over the seven quarters under review.
- **Analysis by place of service:** We subset the above Part B claims data by place of service (e.g., office, nursing facility, home care) to further identify trends in Medicare payment and utilization for skin substitutes.
- **Analysis by HCPCS:** For selected high-expenditure skin substitute HCPCS codes, we individually tracked Part B expenditures and payment amounts over time.
- **Spread and payment amount calculation:** For selected high-expenditure skin substitute HCPCS codes, we determined the spread a provider would receive when billing a drug through Medicare Part B. A drug's spread per quarter was calculated as the average payment amount minus the ASP. A drug's ASP was calculated by dividing the Medicare payment amount listed two quarters later by 106 percent.
- **Data sources:** We used Part B and Part C claims data from the National Claims History files for 2023 and 2024. For 2020-2022, we used Part B National Summary Data Files (previously known as BESS). We also used the publicly available ASP Drug Pricing Files and CMS's non-public Manufacturer ASP Background Files.

Limitations: We did not independently verify the accuracy of Medicare claims data or ASP payment information obtained from CMS.

Standards: We conducted this study in accordance with the Quality Standards for Inspection and Evaluation issued by the Council of the Inspectors General on Integrity and Efficiency.

Contact

To obtain additional information concerning this report, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov. OIG reports and other information can be found on the OIG website at oig.hhs.gov.

Office of Inspector General

U.S. Department of Health and Human Services

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Sources

[1] FDA does not refer to any products as "skin substitutes." Rather, products treated as "skin substitutes" by CMS (at the time of analysis, HCPCS codes Q4101-Q4367) are regulated by FDA under one of four categories depending on their origin and composition: 361 HCT/P, 510(k), PMA, or BLA. Generally speaking, a skin substitute is a material used to cover and promote healing of skin wounds by acting as a temporary or permanent replacement for damaged skin.

[2] Section 1862(a)(1)(A) of the Social Security Act.

[3] 90 Fed. Reg. 32352–32522 (July 16, 2025).

[4] OIG, *Some Skin Substitute Manufacturers Did Not Comply with New ASP Reporting Requirements*, OEI-BL-23-00010, March 2023.

[5] Section 1847A(c)(1) and (c)(3) of the Social Security Act.

[6] Section 1927(b)(3)(A) of the Social Security Act.

[7] Section 1847A(b)(1) of the Social Security Act.

[8] Section 1847A(c)(4) of the Social Security Act and the Medicare Claims Processing Manual, CMS Pub. 100-04, Ch. 17, Section 20.1.3.

[9] Sherry Glied and Kevin Haninger, *Medicare Part B Reimbursement of Prescription Drugs*, ASPE, May 31, 2014. Accessed online at https://aspe.hhs.gov/reports/medicare-part-b-reimbursement-prescription-drugs-0 on May 21, 2025.

[10] OIG, *Least Costly Alternative Policies: Impact on Prostate Cancer Drugs Covered Under Medicare Part B*, OEI-12-12-00210, November 2012.

[11] OIG, *Beneficiary Utilization of Albuterol and Levalbuterol Under Medicare Part B*, OEI-03-07-00440, August 2009.

[12] Medicare Payment Advisory Commission, *June 2023 Report to the Congress: Medicare and the Health Care Delivery System, Chapter 1: Addressing high prices of drugs covered under Medicare Part B*, June 15, 2023. Accessed online at https://www.medpac.gov/document/june-2023-report-to-the-congress-medicare-and-the-health-care-delivery-system/ on May 7, 2025.

[13] OIG, *Some Skin Substitute Manufacturers Did Not Comply with New ASP Reporting Requirements*, OEI-BL-23-00010, March 2023.

[14] Meredith Freed et al., *Medicare Advantage in 2024: Enrollment Update and Key Trends*, Kaiser Family Foundation, August 8, 2024. Accessed online at https://www.kff.org/medicare/issue-brief/medicare-advantage-in-2024-enrollment-update-and-key-trends/ on May 7, 2025.

[15] Emily Gersema, *Medicare, Medicare Advantage Physician Reimbursement Rates Nearly Equal*, USC, July 10, 2017. Accessed online at https://schaeffer.usc.edu/research/medicare-medicare-advantage-physician-reimbursement-rates-nearly-equal/ on May 27, 2025.

[16] Kelly Anderson et al., *Prescribing of low- versus high-cost Part B drugs in Medicare Advantage and traditional Medicare*, HSR, December 14, 2021. Accessed online at https://pmc.ncbi.nlm.nih.gov/articles/PMC9108062/ on May 27, 2025.

[17] Medicare Payment Advisory Commission, *June 2023 Report to the Congress: Medicare and the Health Care Delivery System, Chapter 1: Addressing high prices of drugs covered under Medicare Part B*, June 15, 2023. Accessed online at https://www.medpac.gov/document/june-2023-report-to-the-congress-medicare-and-the-health-care-delivery-system/ on May 7, 2025.

[18] U.S. Department of Justice, Office of Public Affairs, *Arizona Couple Pleads Guilty to $1.2B Health Care Fraud*, January 31, 2025. Accessed online at https://www.justice.gov/opa/pr/arizona-couple-pleads-guilty-12b-health-care-fraud on May 20, 2025.

[19] U.S. Department of Justice, Office of Public Affairs, *Arizona Couple Pleads Guilty to $1.2B Health Care Fraud*, January 31, 2025. Accessed online at https://www.justice.gov/opa/pr/arizona-couple-pleads-guilty-12b-health-care-fraud on May 20, 2025.

[20] 90 Fed. Reg. 32352, 32512 (July 16, 2025). The physician fee schedule proposed policies for payment for skin substitutes are similarly being proposed in the CY 2026 Hospital Outpatient Prospective Payment and Ambulatory Surgical Center Payment Systems (OPPS) proposed rule with the intention to implement this policy in both the non-facility and hospital outpatient settings. Among other provisions, the rule would, if implemented as proposed, (1) stop treating skin substitutes as "drugs and biologics" and instead recharacterize most skin substitutes as "incident-to" supplies; (2) for payment purposes, assign skin substitutes to one of three groups based on their FDA regulatory category; and (3) set payment rates for each group using volume-weighted pricing data for all products included in the group. As a short-term measure, if the proposal were finalized as proposed, CMS would calculate weights using utilization data from only the hospital outpatient setting and establish for CY 2026 a single payment rate of approximately $125.38 per square cm that would apply to all three categories of skin substitute products.

[21] 90 Fed. Reg. 28749 (July 1, 2025). The Wasteful and Inappropriate Services Reduction (WISeR) Model focuses on reducing fraud, waste, and abuse for specific selected Medicare services, including certain skin substitutes. Under this model, CMS engages companies (model participants) with expertise in using enhanced technologies such as artificial intelligence to implement and streamline the prior authorization process for selected services in specific States to ensure that services being furnished are in line with existing coverage criteria. Beginning January 1, 2026, a model participant will review all skin substitute services that are subject to the WISeR model either through a voluntary request for prior authorization from the provider or supplier before the service occurs or as a pre-payment medical review after the service is performed.

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OIG Hotline Operations accepts tips and complaints from all sources about potential fraud, waste, abuse, and mismanagement in HHS programs. Hotline tips are incredibly valuable, and we appreciate your efforts to help us stamp out fraud, waste, and abuse.

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Every complaint helps OIG carry out its mission of overseeing HHS programs and protecting the individuals they serve. By reporting your concerns to the OIG Hotline, you help us safeguard taxpayer dollars and ensure the success of our oversight efforts.

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