HHS Office of Inspector General
HIGHLIGHTS

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

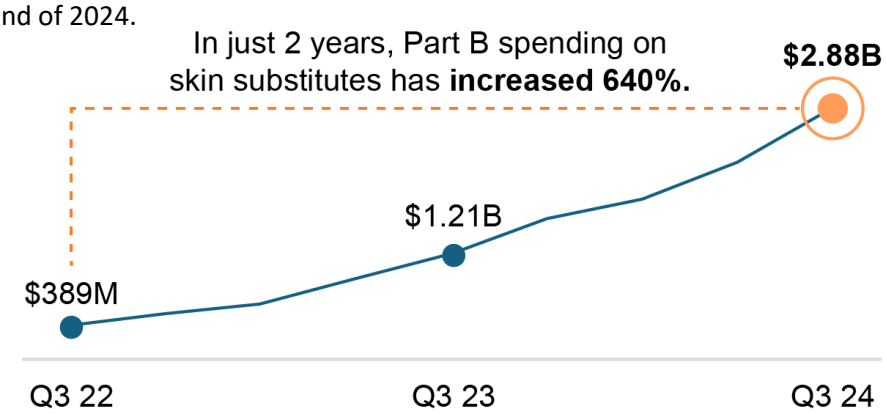
Medicare Part B and Skin Substitutes

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.