

U.S. Department of Health and Human Services
Office of Inspector General



Some Skin Substitute Manufacturers Did Not Comply with New ASP Reporting Requirements

Ann Maxwell
Deputy Inspector General
for Evaluation and Inspections
March 2023, OEI-BL-23-00010





Some Skin Substitute Manufacturers Did Not Comply with New ASP Reporting Requirements

Key Results

- CMS calculated ASP-based payment amounts for 38 of the 68 skin substitutes included in our review.
- CMS was unable to calculate ASP-based payment amounts for the remaining 30 skin substitutes because manufacturers did not report the required ASP data.
- These 30 skin substitutes represent a disproportionate share of Part B spending.
- Transitioning skin substitutes to ASP-based payments has the potential to substantially reduce Part B expenditures.
- CMS faces hurdles in setting ASP-based payments for skin substitutes.

Why OIG Did This Review

Ensuring the appropriate reporting of average sales prices (ASPs) is vital because the Centers for Medicare & Medicaid Services (CMS) uses them to directly calculate payments under Medicare Part B. Federal law requires manufacturers to provide CMS with the ASP for each of their Part B drugs and biologicals on a quarterly basis.^{1, 2} Prior to 2022, ASP reporting requirements did not generally apply to manufacturers of certain Part B drugs and biologicals, including skin substitutes, although some manufacturers voluntarily reported these data. Congress addressed the reporting gap through the Consolidation Appropriations Act, 2021 (CAA), which required manufacturers of skin substitutes (and the other Part B-covered products referenced above) to begin reporting ASPs to CMS for the first quarter of 2022.³

What OIG Found

Despite the new legislative requirements, CMS was unable to calculate ASP-based payment amounts in the first quarter of 2023 for 30 of 68 skin substitute billing codes because their manufacturers did not report the required ASP data. According to our analysis, Part B payment amounts would be reduced substantially if ASPs were consistently reported and used, potentially leading to tens of millions of dollars in savings each quarter. However, CMS faces several

unique hurdles in implementing ASP-based reimbursement for skin substitutes. For example, because skin substitutes are not actually prescription drugs, CMS cannot employ its usual methods and data sources to corroborate manufacturer-reported data on pricing and packaging. CMS is actively considering changes to the payment methodology for skin substitutes and, in January 2023, conducted a skin substitutes Town Hall to address stakeholder concerns and discuss potential payment approaches.⁴

What OIG Concludes

OIG appreciates that CMS is carefully considering its options regarding the potential impacts of different payment approaches for skin substitutes. Further, we also recognize that CMS's current processes for collecting and validating ASP data are less effective for these products. However, every quarter in which wholesale acquisition costs/invoices are used as the payment basis for some skin substitutes potentially leads to tens of millions of dollars in higher payments for Medicare and its enrollees. Therefore, we encourage CMS to quickly address the issues identified in this report. This might include establishing interim approaches while working on a more systemic solution.

RESULTS

Despite the new legislative requirements, manufacturers are not consistently reporting the ASPs needed to set payment amounts for skin substitutes

In the third quarter of 2022 (i.e., the initial quarter in which payment amounts would have been affected by CAA reporting requirements), Medicare Part B and its enrollees paid almost \$400 million for 68 unique skin substitute billing codes.⁵ CMS used ASPs to set payment for only 16 of the 68. Prior to the new legislative requirements, manufacturers already had been voluntarily reporting ASPs for each of these 16 products and CMS had subsequently calculated the appropriate payment amounts using those ASP data. In other words, no additional skin substitutes (i.e., those beyond the 16 products for which manufacturers had previously reported on a voluntary basis) were paid for on the basis of ASPs in the quarter in which the new requirements took effect. CMS informed OIG that it did not add additional skin substitutes to the payment file (even in the case of several codes for which manufacturers reported ASPs) as CMS was closely evaluating the impact of doing so and determining the appropriate next steps relative to the CAA requirements.

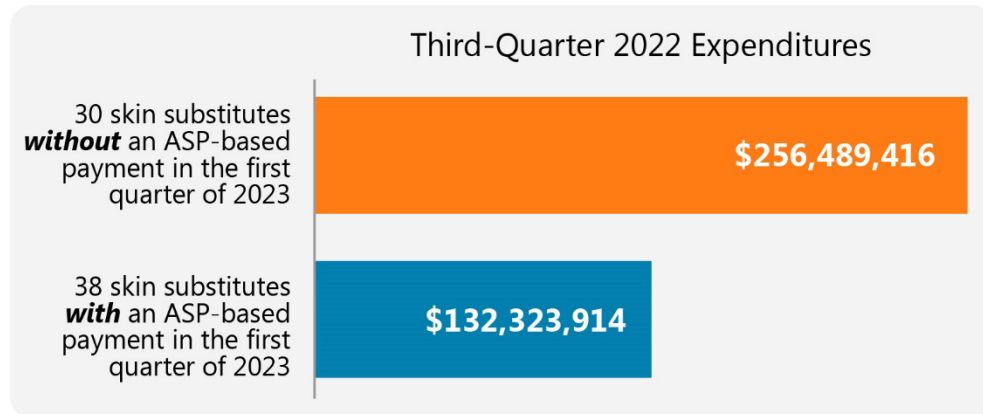
As of the first quarter of 2023, approximately half of skin substitutes (38 of 68 billing codes) are being paid for on the basis of manufacturer-reported ASPs

The number of skin substitutes for which CMS published an ASP-based payment amount increased dramatically in the first quarter of 2023. In total, 24 manufacturers (6 more than in the initial quarter) reported the required pricing data for 38 of the 68 codes included in our review, and CMS subsequently published an ASP-based payment amount for each of them.

Manufacturers did not report ASPs for the remaining 30 skin substitute billing codes

CMS was unable to calculate ASP-based payment amounts in the first quarter of 2023 for the remaining 30 skin substitute billing codes because their manufacturers (26 in total) did not report the required ASP data. These 30 codes represent a disproportionate share of Part B spending. For example, Medicare and its enrollees spent \$256 million for these 30 skin substitutes in the third quarter of 2022, accounting for nearly two-thirds of all payments for skin substitutes (see Figure 1).

Figure 1. Skin substitutes for which manufacturers did not report ASPs represented a disproportionate share of payments.



Source: OIG analysis of Third-Quarter 2022 Part B Expenditures and First-Quarter 2023 ASP Payment Amount Files.

Transitioning all skin substitutes to ASP-based payments has the potential to substantially reduce Medicare expenditures

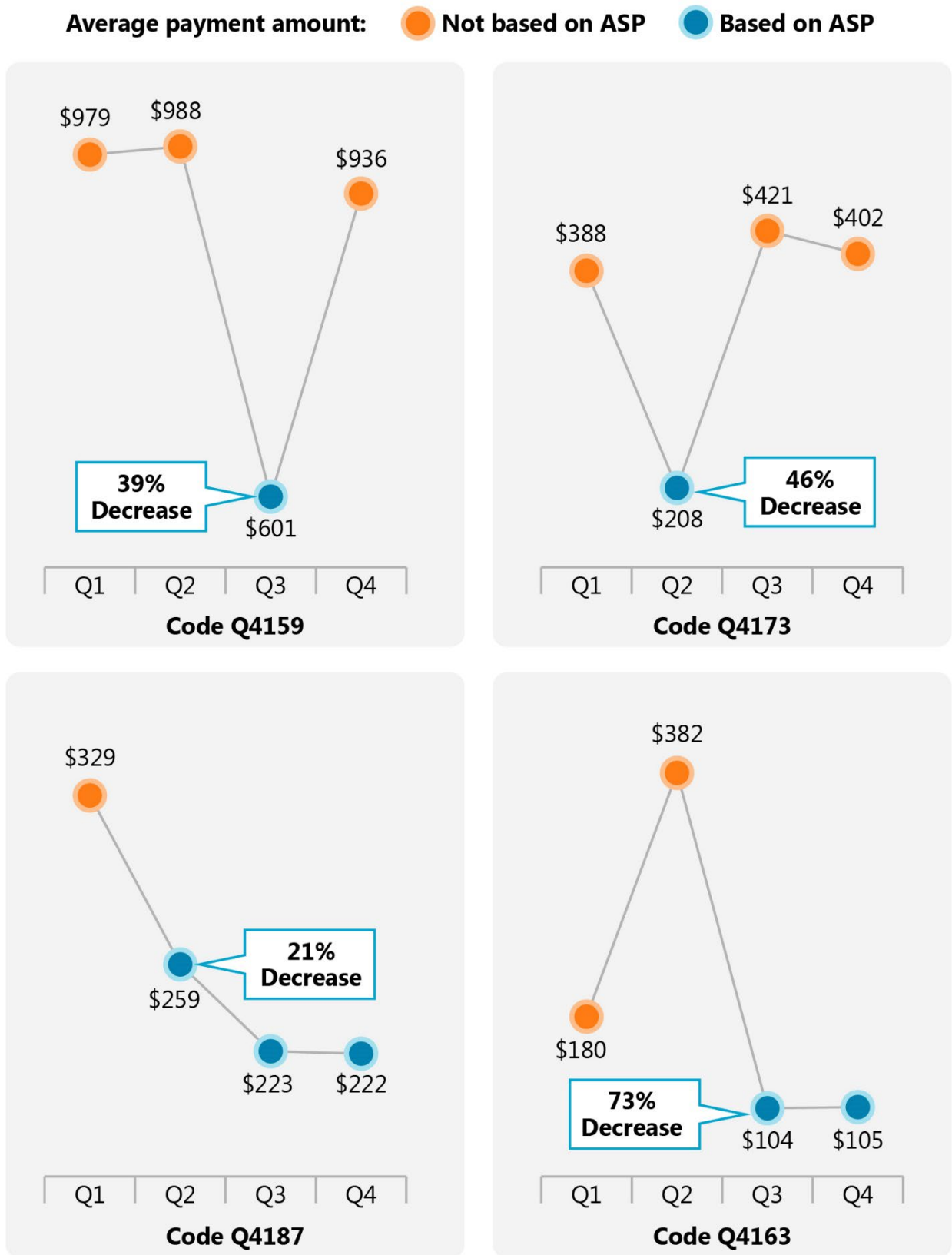
If CMS does not publish an ASP-based payment amount for a skin substitute billing code in a given quarter, the agency instructs its contractors to determine payment using either Wholesale Acquisition Costs (WACs) or actual invoices.⁶ Because WACs represent manufacturers' list prices and do not include any discounts, they are generally higher than ASPs. Similarly, to the extent invoices do not reflect post-purchase rebates that may be offered for skin substitutes, the resulting Medicare payments are likely to exceed ASPs as well if providers do not account for these discounts when submitting their claims.

In 2021, prior to the new requirements, Medicare payment amounts for four skin substitutes decreased dramatically when ASPs were voluntarily reported and used to set payment

To gain a sense of how WAC- or invoice-based payment amounts compared to ASP-based payments, OIG identified four skin substitutes for which Part B payments were determined using WAC/invoice prices in the first quarter of 2021 and then set using ASPs in a subsequent quarter later that year. (These are skin substitutes for which manufacturers had voluntarily reported ASPs and CMS had used those ASPs to set payments in 2021, before the new requirements took effect in 2022.) Once ASPs were used to set payment for these four drugs, average Medicare payment amounts fell between 21 percent and 73 percent (see Figure 2).

For two of these skin substitutes, CMS reverted to WAC/invoice pricing in the quarter immediately after the payment reduction—in one case because the manufacturer stopped reporting ASPs. The average Medicare payment amount dramatically increased to prior levels for both products once ASPs were no longer used.

Figure 2. Payment amounts were substantially lower when set on the basis of ASPs.



Source: OIG analysis of ASP Payment Amount Files from 2021.

ASP-based payment amounts for skin substitutes were one-third below their WACs

For the 38 skin substitutes with payments set using ASPs in the third quarter of 2022, their ASP-based payment amounts (i.e., ASP plus 6 percent) were 33 percent below published WACs (i.e., one of the potential benchmarks contractors may use to set payment in the absence of ASPs) at the median. If we use this median difference to estimate potential savings, we find that Medicare Part B and its enrollees could save \$84 million per quarter if all such products are paid for on the basis of ASPs. Twenty percent of that total (almost \$17 million) would stem from reductions in the amounts owed through enrollee coinsurance. Actual savings may be higher or lower than this estimate, given the specific differences between ASP and WAC or actual invoices for each product.

The inconsistent reporting and use of ASPs for skin substitutes has implications in addition to higher payments

Current reimbursement practices could create incentives for providers to prefer skin substitutes that are paid for on the basis of WACs/invoices rather than those paid for using ASPs, exacerbating the missed savings for Medicare and its enrollees. Because ASPs are calculated using actual sales data (including discounts), they presumably reflect provider acquisition costs. However, as described earlier, WACs/invoices for skin substitutes often significantly exceed their ASPs. As a result, providers can typically capture a much larger spread (i.e., the difference between what they pay for a product and the amount they are reimbursed by Medicare) when payment is set using WACs/invoices. This effectively penalizes manufacturers who comply with the law by potentially making their products less attractive to providers. The overall dynamic could therefore unintentionally discourage all manufacturers of skin substitutes from complying with ASP reporting requirements, further increasing the risks of higher payments by the program and enrollees.

CMS faces numerous hurdles in implementing ASP-based payments for skin substitutes

Skin substitutes present unique challenges for CMS to overcome when implementing the new reporting requirements, as these products differ significantly from most items covered under the Part B prescription drug benefit. For example, in its written response to OIG questions, CMS noted that:

- there is not a single database that lists all manufacturers of skin substitutes;
- many of these products are regulated as Human Cellular and Tissue-Based products for which the manufacturer is registered but the products do not receive individual FDA approval; and

- there is not a single database or drug compendium that CMS can use to verify the descriptive data associated with skin substitutes (e.g., package size).

In other words, the current methods CMS uses to collect and validate ASP data for other Part B drugs do not necessarily apply to skin substitutes. Therefore, CMS cannot readily determine which manufacturers should be submitting ASPs, nor can it consistently corroborate manufacturer-reported data on pricing and packaging by checking against FDA or private industry sources.

CMS is actively considering other changes to the payment methodology for skin substitutes under Medicare Part B

In the *Calendar Year 2023 Physician Fee Schedule Proposed Rule*, CMS proposed to package all skin substitute products as part of the related administration procedure beginning January 1, 2024 (i.e., they would no longer be separately paid for on a claim but instead would be included as part of the physician service payment).⁷ According to the Final Rule, CMS is not moving forward with the proposed changes at this time. Rather, the agency is continuing to evaluate the comments received through the rulemaking process to determine appropriate next steps for skin substitute products relative to the CAA requirements.⁸ To that end, CMS conducted a Town Hall in January 2023 to address commenters' concerns and discuss potential payment approaches.

CONCLUSION

OIG appreciates that CMS is carefully considering its options and engaging with stakeholders regarding the potential impacts of different payment approaches for skin substitutes. Further, we also recognize that the number of skin substitutes that are being paid for on the basis of ASPs has increased dramatically over the initial 6-month implementation period, despite the fact that current processes for collecting and validating ASP data are much less effective for these nondrug products.

However, the current system, which uses ASPs as the payment basis for many skin substitutes and WACs/invoices for numerous others, could potentially incentivize providers to prefer products without ASP-based payments to capture the larger spread between reimbursement and their cost. In turn, this dynamic (1) leads to higher payments for Medicare and its enrollees and (2) effectively penalizes manufacturers who comply with the law by making their products less attractive from a payment standpoint.

Every quarter in which the current practices remain in place will likely cost Medicare and its enrollees tens of millions of dollars. Therefore, we encourage CMS to address the issues identified in this report as quickly as possible. This might include establishing interim approaches to enforce manufacturer compliance with reporting requirements while working on a more systemic solution for how best to reimburse for skin substitutes. In the end, it is vital that manufacturers comply with Federal law and that the Medicare program pay appropriately for these high-cost products.

METHODOLOGY

Analysis of CMS Payment Data

Identifying Skin Substitutes For Which Part B Made Payments

For all billing codes associated with skin substitutes, we obtained Part B expenditure data for each quarter of 2021 and the third quarter of 2022 from CMS's Part B Analytics Reporting (PBAR) System. Using these claims summary data, we developed a list of all skin substitute billing codes for which Medicare Part B made payments in the third quarter of 2022 (the most recent data available).

Determining Whether Manufacturers Reported ASPs

For the selected billing codes, we used CMS's nonpublic background file to determine whether manufacturers reported ASPs in the third quarter of 2022.

Determining Whether CMS Calculated ASP-Based Payment Amounts

We examined CMS's ASP Pricing File from the first quarter of 2023 (i.e., the quarter for which third-quarter 2022 ASPs would be used to set payment) to determine whether the agency calculated and published ASP-based pricing for the selected billing codes.

Estimating the Effect on Payment Amounts and Medicare Spending

To estimate the change in payment amounts and total spending that could have been achieved had reimbursement for all skin substitutes been set on the basis of ASP:

- 1) We identified 38 billing codes for which CMS set ASP-based payment amounts in the first quarter of 2023. For these drugs, we determined the median difference between their payment amount and the WAC from that same quarter. To estimate potential savings, we multiplied the median difference by the amount spent on drugs without ASP-based payments in the third quarter of 2022.
- 2) We identified four billing codes that were subject to WAC/invoice-based pricing in the first quarter of 2021 but ASP-based pricing in subsequent quarters. For these codes, we examined how Medicare payment changed once ASPs were used as the basis for Part B payment.

Written Questions Submitted to CMS Staff

We sent CMS staff a list of questions regarding the implementation of the new reporting requirements applicable to skin substitutes covered under Part B.

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.

ACKNOWLEDGMENTS AND CONTACT

Acknowledgments

Dave Tawes served as the team leader for this study. Others in the Office of Evaluation and Inspections Baltimore Regional Office who conducted the study include Bahar Adili and Brian Tomblin. Office of Evaluation and Inspections headquarters staff who provided support include Melissa Baker, Robert Gibbons, Christine Moritz, and Sarah Swisher.

We would also like to acknowledge the contributions of other Office of Inspector General staff, including Jessica Swanstrom.

This report was prepared under the direction of Dave Tawes, Regional Inspector General for Evaluation and Inspections in the Baltimore Regional Office; Heather Barton, Deputy Regional Inspector General; and Louise Schoggen, Assistant Regional Inspector General.

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
330 Independence Avenue, SW
Washington, DC 20201

ENDNOTES

¹ Section 1847A of the Social Security Act (the Act).

² Pursuant to sections 1927(b)(3)(C)(i) and 1847A(d)(4)(B) of the Act, manufacturers may face civil monetary penalties for failure to report ASP data within the required timeframe.

³ Prior to 2022, ASP reporting requirements applied only to manufacturers subject to Medicaid drug rebate agreements. Division CC, Title IV, Section 401, of the CAA, P.L. No. 116-260 (Dec. 27, 2020), amended section 1847A of the Act to add new section 1847A(f)(2), which requires manufacturers without a Medicaid drug rebate agreement to report ASP information to CMS for calendar quarters beginning on January 1, 2022, for drugs or biologicals payable under Medicare Part B and described in section 1842(o)(1)(C), (E), or (G) or 1881(b)(14)(B) of the Act, including items, services, supplies, and products that are payable under Part B as a drug or biological.

⁴ A full recording and transcript of the CMS Skin Substitutes Town Hall is available at <https://www.cms.gov/medicare/physician-fee-schedule/skin-substitutes>.

⁵ We limited our review to biological skin substitute Healthcare Common Procedure Coding System (HCPCS) codes Q4101–Q4258. We further limited our review to the 68 skin substitute billing codes with Part B expenditures in the third quarter of 2022. CMS also calculated ASP-based payment amounts in the first quarter of 2023 for additional billing codes not included in our review, as these codes did not have Medicare expenditures in the baseline quarter.

⁶ *Medicare Claims Processing Manual*, CMS Pub. 100-04, ch. 17, § 20.1.3.

⁷ *Calendar Year 2023 Physician Fee Schedule Proposed Rule*, 87 Fed. Reg. 45860, 46029 (July 29, 2022).

⁸ *Calendar Year 2023 Physician Fee Schedule Final Rule*, 87 Fed. Reg. 69404, 69655 (Nov. 18, 2022).