



Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2020 Average Sales Prices

Why This Matters

Medicare Part B annually spends billions to cover a limited number of outpatient prescription drugs. Generally, Part B-covered drugs are those that are injected or infused in physicians' offices or outpatient settings.

When Congress established average sales prices (ASPs) as the basis for reimbursement for Medicare Part B drugs, it also provided a mechanism for monitoring market prices and limiting potentially excessive payment amounts for these drugs. The Social Security Act (the Act) mandates that the Office of Inspector General (OIG) compare ASPs with average manufacturer prices (AMPs).¹ If OIG finds that the ASP for a drug exceeds the AMP by 5 percent, the Act directs the Secretary of Health and Human Services to substitute the ASP-based payment amount with a lower calculated rate.² Through regulation, the Centers for Medicare & Medicaid Services (CMS) stated that it would make this reduction only if the ASP for a drug exceeds the AMP by 5 percent in the two previous consecutive quarters or three of the previous four quarters.³

This data snapshot is one in a series of annual reports—produced since CMS implemented the price-substitution policy in 2013—that quantifies the savings to Medicare and its beneficiaries that result from CMS's price-substitution policy.

Key Takeaways

- Since 2013, Medicare and its beneficiaries have saved \$73.1 million as a result of CMS's price-substitution policy for Part B-covered drugs.
- Medicare and its beneficiaries lost out on \$2.8 million in savings for 7 drugs because CMS did not correctly implement price reductions.
- The program and its beneficiaries could have realized an additional \$5.4 million in savings if CMS had expanded the price-substitution criteria.

What OIG Did

This data snapshot quantifies the actual and lost savings to Medicare and its beneficiaries that resulted from the price-substitution policy based on ASPs from 2020. To determine these savings, we calculated the difference between ASP-based payment and AMP-based payment for each drug with a price substitution. To calculate the savings based on 2020 ASP data, we multiplied this difference by the Medicare utilization for each drug during the time period in which the price reduction occurred—the fourth quarter of 2020 through the third quarter of 2021. We also determined the potential savings that could result from an expansion of the price-substitution criteria.

Because CMS did not implement all eligible drug price reductions, savings that should have totaled \$2.8 million over 1 year amounted to only \$8,158.

Exhibit 1. Lost savings and actual savings calculated by OIG for Part B drugs based on 2020 ASPs



Source: OIG analysis of ASP and AMP data from 2020.

There were 11 drugs eligible for price reductions based on 2020 ASPs. However, CMS did not correctly implement price reductions for seven of these eligible drugs. Consequently, the price reductions made by CMS based on 2020 ASP data amounted to only \$8,158 in actual savings—a loss of \$2.8 million in savings to Medicare and its beneficiaries.⁴ This is the lowest savings amount achieved since the inception of the price substitution policy in 2013. The actual and lost savings for each of the 11 drugs eligible for price reductions are provided in the Appendix.

OIG alerted CMS to the incorrect payment amounts for the seven drugs when we discovered them in February 2022. When reviewing payment amounts for the second quarter of 2021, OIG determined that CMS had set the Medicare payment amounts for two drugs at ASP plus 6 percent rather than at AMP plus 3 percent—the amount at which payments should have been set if CMS had implemented the appropriate price reduction. OIG also

determined that CMS implemented incorrect—and smaller—price reductions for five additional drugs. For these five drugs, CMS erroneously set the payment amounts at 100 percent of the ASP rather than at the correct amount—AMP plus 3 percent.

CMS confirmed that it input incorrect second-quarter 2021 payment amounts for these drugs in its pricing files. In March 2022, CMS corrected the second-quarter 2021 payment amounts for the seven drugs. Although CMS corrected these payment amounts for these drugs in its pricing files, it stated that it will not take action to retroactively reduce the payment amounts for these drugs on second-quarter 2021 claims paid prior to the pricing correction implemented in March 2022.

Medicare and its beneficiaries could realize millions in additional savings if CMS expanded its price-substitution criteria.

If CMS had expanded its price-substitution criteria to include drugs that exceeded the 5-percent threshold in just a single quarter, Medicare and its beneficiaries could have saved an additional \$5.4 million over 1 year for another 14 drugs.⁵ These 14 drugs exceeded the 5-percent threshold in at least one quarter, but they were not eligible for price substitution because they did not meet CMS's requirement for prices to exceed the threshold in the 2 previous consecutive quarters or 3 of the previous 4 quarters.

Since 2013, Medicare and its beneficiaries have saved millions as a result of reductions in Part B drug prices.

From 2013 through 2020, Medicare and its beneficiaries saved \$73.1 million as a result of CMS's price-substitution policy for Part B-covered drugs.

What OIG Concludes

Since the inception of CMS's price-substitution policy, Medicare and its beneficiaries have saved \$73.1 million, which highlights the significance of this effort to reduce costs while maintaining access to lifesaving drugs. Our findings indicate that CMS could have achieved even greater savings for Medicare and its beneficiaries by accurately implementing price reductions and expanding the price-substitution policy.

Price reductions play an important role in lowering drug costs. Therefore, CMS's error in not accurately implementing all price reductions demonstrates a gap in oversight that prevented the program and its beneficiaries from realizing millions in savings. OIG is conducting further work to examine CMS's oversight of ASP data and will continue to work with CMS to ensure that CMS maximizes the savings available to Medicare and its beneficiaries.⁶

In addition to the lost savings, we identified \$5.4 million in savings that could have been realized if CMS had expanded the price-substitution criteria. OIG has previously recommended that CMS expand the price-substitution criteria.⁷ However, CMS did not concur with expanding the price-substitution policy and expressed concern that expanding the criteria may impede physician and beneficiary access to drugs. OIG agrees that access to prescription drugs should always be considered when contemplating pricing policies, and OIG supports current safeguards to prevent reductions for drugs that the Food and Drug Administration (FDA) has identified as being in short supply. However, OIG continues to believe that CMS can achieve a better balance between safeguarding access to drugs and ensuring that Medicare and its beneficiaries do not overpay for drugs. We continue to believe that to more effectively limit excessive payment amounts based on ASPs and to generate greater savings for Medicare and its beneficiaries, CMS should expand its price-substitution criteria to include drugs that exceeded the 5-percent threshold in just a single quarter.

Appendix

Exhibit 2. CMS's price reductions based on 2020 ASP data resulted in limited savings.

HCPCS Code	Drug	Actual Savings	Lost Savings
J7626	Budesonide, noncompounded unit	\$0	\$2,794,213
J0610	Calcium gluconate injection	\$5,367	\$2,420
J2720	Protamine sulfate injection	\$409	\$134
J2501	Paricalcitol	\$113	\$33
Q0166	Granisetron	\$13	\$33
J8530	Cyclophosphamide	\$0	\$4
J0720	Chloramphenicol sodium injection	\$152	\$3
J2400	Chloroprocaine HCl injection	\$339	\$0
J9100	Cytarabine injection	\$631	\$0
J9360	Vinblastine sulfate injection	\$471	\$0
Q0167	Dronabinol	\$663	\$0
	Total	\$8,158	\$2,796,840

Source: OIG analysis of ASP and AMP data from 2020.

Methodology

Data Collection

We obtained national drug code (NDC)-level ASP data and AMP data for Part B drugs from CMS for 2020. In addition, we obtained the list of drugs that were eligible for price reductions based on ASP data from 2020 and the corresponding Medicare payment amounts. In January 2022, we obtained Part B drug utilization data from CMS's Part B Analytic Reports, which includes Medicare Part B physician and supplier data. We collected ASP-based reimbursement amounts and Part B drug utilization data for the quarters in which price reductions occurred—i.e., the fourth quarter of 2020 through the third quarter of 2021. We requested from CMS information to (1) confirm that it did not implement price reductions for all eligible drugs and (2) determine whether it would retroactively reduce payment amounts on claims for drugs that did not have accurate price reductions.

Data Analysis

For each quarter of 2020, we calculated the volume-weighted AMP for drugs consistent with CMS's methodology for calculating volume-weighted ASPs. We then compared the volume-weighted ASPs and AMPs and identified all drugs with ASPs that exceeded AMP by at least 5 percent. We also identified drugs that exceeded the 5-percent threshold but (1) did not undergo a correct price reduction and (2) did not meet CMS's duration criteria for price reduction—i.e., they did not exceed the threshold in the two previous consecutive quarters or three of the previous four quarters.

Actual Savings. To calculate the actual savings associated with drugs that underwent price reductions, we first identified the drugs for which CMS implemented price reductions.⁸ We did this by comparing the AMP-based reimbursement amount—calculated by OIG—to the drugs' payment amounts for the applicable quarter. If the amounts matched, we determined that the drug underwent a correct price reduction. For these drugs, we then subtracted the AMP-based reimbursement amount from the ASP-based reimbursement amount that otherwise would have been in effect for the quarter in which the price reduction occurred. We multiplied this difference by each drug's Part B utilization for the quarter(s) in which the price reduction occurred.

Lost Savings. To determine the lost savings associated with drugs that were eligible for price reductions but for which CMS did not implement the correct price reduction, we compared the AMP-based reimbursement—calculated by OIG—to the drugs' payment amounts for the applicable quarter. If the amounts did not match, we determined that the drug did not undergo the correct price reduction.

We determined that the Medicare payment amounts for HCPCS codes J7626 and J8530 in CMS's drug pricing files were set at ASP plus 6 percent and not AMP plus 3 percent—the amount the payments should have been set at if CMS had implemented the appropriate price reduction. For these drugs, we subtracted the AMP-based reimbursement amount from the ASP-based reimbursement amount that was in effect for the quarter in which the price reduction should have occurred. To calculate the total savings lost, we multiplied this difference by each drug's Part B utilization for the quarter in which the price reduction should have occurred.

We also determined that CMS implemented incorrect—and smaller—price reductions for HCPCS codes J0610, J0720, J2501, J2720, and Q0166, i.e., the payment amounts were based on 100 percent of the ASP and not the AMP plus 3 percent. Because the payment amounts for these five drugs did not reflect all eligible reductions, these drugs had both actual and lost savings in the quarter for which the pricing error occurred. We calculated the actual and lost savings using the same methods described above.

Expanded Savings. To determine the savings associated with potential price reductions that could be made by expanding the number of drugs eligible for price substitution, we identified the drugs with an ASP that exceeded AMP by at least 5 percent in only a single quarter. For these drugs, we also determined whether they met CMS's additional requirements for price substitution. For drugs to be eligible for price substitution, CMS also requires that drugs (1) have complete AMP data, (2) not be identified as being in short supply by FDA, and

Methodology (continued)

(3) not have an AMP-based substitution amount that is greater than the ASP-based reimbursement amount for the quarter in which substitutions would occur. To calculate the potential savings for the drugs that exceeded the 5-percent threshold, we subtracted each drug's AMP-based reimbursement amount from the ASP-based reimbursement amount that was in effect for the quarter in which the price reduction could have occurred. We multiplied this difference by each drug's Part B utilization for the quarter(s) in which the price reduction could have occurred.

Total Savings. To calculate the overall savings associated with actual price reductions since CMS implemented price reductions, we added the total annual savings that OIG calculated for each year from 2013 through 2020.

Limitations. We did not verify the accuracy of manufacturer-reported ASP and AMP data, nor did we verify the underlying methodology that manufacturers used to calculate ASPs and AMPs. Manufacturers are required to submit their quarterly ASP and AMP data to CMS within 30 days of the close of the quarter. We did not determine whether manufacturers later provided any updated data to CMS. To calculate savings, we used Part B utilization data obtained in January 2022. CMS implemented the correction to the second-quarter 2021 payment amounts in March 2022. Therefore, any claims for the drugs associated with incorrect payment amounts billed after CMS implemented the corrected payment amounts would not be included in our calculation of savings.

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.

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This report was prepared under the direction of Linda Ragone, Regional Inspector General for Evaluation and Inspections in the Philadelphia regional office, and Edward Burley, Deputy Regional Inspector General.

To obtain additional information concerning this report or to obtain copies, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov.

Endnotes

¹ Section 1847A(d)(2) of the Act.

² Section 1847A(d)(3) of the Act.

³ 42 CFR § 414.904(d)(3).

⁴ CMS reported that it calculated lost savings that were 2 percent less—or approximately \$53,500 less—than OIG’s calculation of lost savings.

⁵ One of the drugs that met the criteria for inclusion in the expansion of price substitutions analysis did not have a payment amount based on ASP during the quarter in which the substitution would have taken place. For this drug, we used the same method to calculate potential savings as we used for drugs with ASP-based payment amounts. We subtracted the AMP-based reimbursement amount from the actual payment amount and multiplied that difference by the drug’s Part B utilization.

⁶ OIG, *OIG Work Plan*. Accessed at <https://www.oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000627.asp> on July 18, 2022.

⁷ OIG, *Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2017 Average Sales Prices*, OEI-03-19-00260, August 2019.

⁸ Part B claims dated on or after April 1, 2013, incur a reduction in payment in accordance with the Budget Control Act of 2011 and the American Taxpayer Relief Act of 2012 (see *CMS Medicare FFS Provider e-News*, Mandatory Payment Reductions in the Medicare Fee-for-Service (FFS) Program –“Sequestration,” March 8, 2013). Under this mandatory payment reduction, Medicare’s portion of the payment rate for most Part B drugs is reduced by 2 percent. This reduction does not apply to the coinsurance portion of the Medicare allowed amount for Part B drugs. However, the sequestration payment reduction was suspended from May 1, 2020, through December 31, 2021. (See the Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. No. 116-136 § 3709); the Consolidated Appropriations Act, 2021 (P.L. 116-260); and the Act to Prevent Across-the-Board Direct Spending Cuts, and for Other Purposes (P.L. No. 117-7)).