U.S. Department of Health and Human Services
Office of Inspector General
Data Snapshot
June 2021, OEI-03-21-00130

Medicare Part B Drug Payments: Impact of Price Substitutions Based on 2019 Average Sales Prices

What OIG Did

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. Generally, Part B-covered drugs are those that are injected or infused in physicians' offices or outpatient settings. The Social Security Act (the Act) mandates that our office compare ASPs with average manufacturer prices (AMPs). 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. Through regulation, the Centers for Medicare & Medicaid Services (CMS) stated that it would make this substitution 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.

This data snapshot quantifies the savings to Medicare and its beneficiaries that are a direct result of CMS's price-substitution policy based on ASPs from 2019. 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 2019 ASP data, we then multiplied the difference by the Medicare utilization for each of these drugs for the time period when the price substitutions occurred—the fourth quarter of 2019 through the third quarter of 2020.

Key Takeaway
Medicare and its beneficiaries saved $6.2 million over 1 year based on CMS's price-substitution policy that limits excessive payments for drugs in Medicare Part B.

Results

CMS's price-substitution policy saved Medicare and its beneficiaries $6.2 million over 1 year

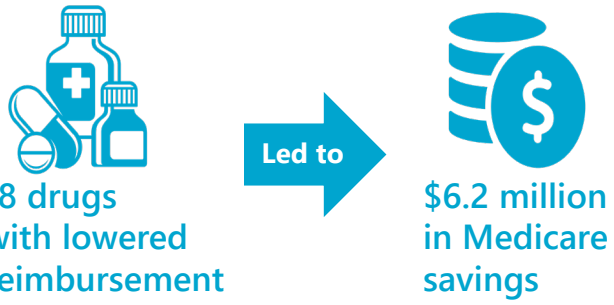
- CMS initiated price substitutions for **18 drugs** based on 2019 data.
- Price substitutions for these drugs saved Medicare and its beneficiaries **$6.2 million** over 1 year, as shown in Exhibit 1.
- Since CMS instituted its price-substitution policy in 2013, Medicare and its beneficiaries have saved $73.1 million, including the $6.2 million amount in 2019.

Expanding the price-substitution policy could have generated additional savings for Medicare and its beneficiaries

If CMS expanded its price-substitution criteria to include drugs that exceeded the 5-percent threshold in a single quarter, Medicare and its beneficiaries could have saved up to an additional **$11.2 million** over 1 year for another **24 drugs**.

These **24 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 that prices exceed the threshold in the two previous consecutive quarters or three of the previous four quarters.[1]

Exhibit 1: Results of the Medicare Part B Price-Substitution Policy



Even greater savings could be realized:

$11.2 million in additional savings if CMS expanded the price-substitution criteria.

Source: OIG analysis of ASP and AMP data from 2019.

Why This Matters

Medicare Part B annually spends billions to cover a limited number of outpatient prescription drugs. To safeguard Medicare and its beneficiaries from excessive payment amounts, Congress established a mechanism for monitoring market prices, and CMS implemented a price-substitution policy that results in lower costs for important, lifesaving drugs covered by Medicare Part B.

Since CMS implemented the policy in 2013, OIG has produced annual reports quantifying the savings to Medicare and its beneficiaries from CMS's price-substitution policy. These reports document millions in actual annual savings and continue to demonstrate that price substitution is an important and effective mechanism for ensuring reasonable payments for drugs in Medicare Part B.

What OIG Concludes

Since the inception of CMS's price-substitution policy, Medicare and its beneficiaries have saved $73.1 million. However, CMS could have achieved even greater savings for Medicare and its beneficiaries by expanding its criteria for AMP-based price substitutions. Specifically, Medicare and its beneficiaries could have saved up to an additional $42 million since 2013 if CMS had expanded its criteria for price substitutions.

OIG has previously recommended that CMS expand the price-substitution criteria. However, CMS did not concur with expanding the price-substitution policy and expressed concern that expanding price-substitution 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 substitutions for drugs that the Food and Drug Administration 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. To provide greater flexibility and achieve this continued balance, any future expansion of the payment-substitution policy could contain a provision that would prevent a price substitution when there are indications that the substitution amount would be below provider acquisition costs.

To more effectively limit excessive payment amounts based on ASPs and to generate greater savings for Medicare and its beneficiaries, we continue to believe that CMS should expand its price-substitution criteria to include some additional drugs. For example, a more expansive policy might include all drugs (with complete AMP data) that exceed the 5-percent threshold in a single quarter. However, CMS also could consider other approaches to expanding the price-substitution policy that are designed to capture more drugs that repeatedly exceed the threshold.

Data: Results of the Medicare Part B Price-Substitution Policy

Exhibit 2: Price Substitutions Saved Medicare and Its Beneficiaries $6.2 million

		Quarter(s) in Which Price Substitution Occurred				
Drug	**Description**	**Fourth Quarter 2019**	**First Quarter 2020**	**Second Quarter 2020**	**Third Quarter 2020**	**Savings**
J0287	Amphotericin B lipid complex	✓				$1,039
J0610	Calcium gluconate injection	✓	✓			$31,547
J0670	Mepivacaine HCl injection	✓	✓			$1,363
J0720	Chloramphenicol sodium injection			✓	✓	$106
J1245	Dipyridamole injection	✓		✓		$247,440
J1570	Ganciclovir sodium injection		✓			$17,855
J1756	Iron sucrose injection		✓	✓	✓	$117,928
J2400	Chloroprocaine HCl injection				✓	$137
J2501	Paricalcitol	✓	✓	✓	✓	$134
J2720	Protamine sulfate injection	✓	✓	✓	✓	$618
J3411	Thiamine HCl	✓	✓			$145,755
J3486[a]	Ziprasidone mesylate	✓	✓	✓	✓	$0
J7520	Sirolimus oral	✓	✓	✓		$2,776,401
J9100	Cytarabine HCl injection	✓		✓	✓	$1,777
J9315	Romidepsin injection		✓			$645,382
Q0167	Dronabinol oral	✓	✓	✓		$2,510
Q5105	Retacrit injection, ESRD			✓		$265
Q5106	Retacrit injection, non-ESRD			✓		$2,189,591
					Total	**$6,179,848**

Source: OIG analysis of ASP and AMP data from 2019.
[a] Ziprasidone mesylate did not have any allowed Part B utilization during any of these quarters. Therefore, the savings for this drug were $0.

Methodology

Data Collection. We obtained national drug code (NDC)-level ASP data and AMP data for Part B drugs from CMS for 2019. In addition, we obtained the drugs that had price substitutions based on ASP data from 2019. We also obtained ASP-based reimbursement amounts and Part B drug utilization for the quarters in which price substitutions occurred—i.e., the fourth quarter of 2019 through the third quarter of 2020.

Data Analysis. For each quarter of 2019, 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 did not meet CMS's duration criteria for price substitution—i.e., they did not exceed the threshold in the two previous consecutive quarters or three of the previous four quarters.

To calculate the savings associated with price substitutions or potential price substitutions that could be made by expanding the policy, we first reduced AMP-based and ASP-based reimbursement amounts (103 percent of the volume-weighted AMP and 106 percent of the volume-weighted ASP, respectively) by the 2-percent reduction required by sequestration for the first three quarters of 2019. The payment reduction required by sequestration was suspended beginning May 1, 2020; therefore, we did not reduce the reimbursement amounts from the fourth quarter 2019.[2] We then subtracted the AMP-based reimbursement amount from the ASP-based reimbursement amount for the quarter in which the price substitution occurred.[3] We then multiplied this difference by each drug's Part B utilization for the quarter(s) that the price substitution occurred.

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. We also did not verify the accuracy of CMS's calculations of reimbursement amounts for Part B drugs. 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.

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

Conswelia McCourt served as team leader for this study. Office of Evaluation and Inspections staff who provided support include Althea Hosein, Christine Moritz, Angela Tvarozek, and Kelsey Ridenour. 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] These 24 drugs had complete AMP data and were not identified by the Food and Drug Administration as being in short supply. They also did not have AMP-based substitution amounts that were greater than the ASP-based reimbursement amounts for the quarters in which substitutions would have occurred. Two of these drugs had no Part B utilization during the reviewed period; therefore, the estimated savings for these drugs were $0.

[2] Coronavirus Aid, Relief, and Economic Security Act (CARES Act), P.L. No. 116-136 § 3709. The Consolidated Appropriations Act, 2021 (P.L. 116-260) amended the CARES Act to extend the suspension of the payment reduction through March 31, 2021. The payment reduction was suspended in the middle of the second quarter of 2020 (May 1, 2020). We were unable to determine the portion of each drug's utilization from this quarter that was from before or after May 1, 2020. Therefore, to be conservative in our calculation of savings, we reduced the reimbursement amounts for the third quarter of 2019 by 2 percent.

[3] In the fourth quarter of 2019, CMS would have established a reimbursement amount based on wholesale acquisition cost instead of ASP for drug code J1245 (Dipyridamole injection). CMS establishes a reimbursement amount that is not based on ASP for a drug code when the ASP and/or the units sold for all NDCs associated with that drug code are reported by the manufacturer as 0 or a negative value. Therefore, for the fourth quarter of 2019, we determined savings for J1245 by first calculating the difference between the AMP-based substitution amount and the reimbursement amount CMS would have calculated based on wholesale acquisition cost. We then multiplied this difference by the drug's Part B utilization for the fourth quarter of 2019.