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DATA BRIEF

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Congressional Mandate: Part B Payment Amounts for One Drug Included Noncovered Self-Administered Versions in 2024

HHS Office of Inspector General
HIGHLIGHTS

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Why OIG Did This Review

Medicare Part B generally does not cover self-administered drugs. However, CMS interprets a relevant statute to require the inclusion of average sales prices (ASPs) for noncovered self-administered versions in certain circumstances when setting Part B payment amounts for the provider-administered versions of the drugs, which are covered under Part B. In some cases, including noncovered versions when setting payment drives up the amount that Part B pays for the covered versions.

OIG is required by statute to conduct periodic studies to identify, and inform CMS about, billing codes for which both covered provider-administered versions and noncovered self-administered versions of a drug are used to set Part B payment amounts if OIG determines that noncovered self-administered versions should be excluded from the Part B payment amount calculations.[1] In general, for the drugs that OIG identifies, CMS is required to remove noncovered self-administered versions from payment amount calculations in subsequent quarters if the exclusions would result in lower payment amounts; however, the statute provides CMS with some discretion in addressing the requirement. For this review, OIG examined 2023 and 2024 ASP-based Part B payment amounts in accordance with its congressional mandate.

What OIG Found

Payment amounts for Omvoh included noncovered self-administered versions; excluding these versions would have led to lower costs for Part B and its enrollees. Omvoh is available as a vial intended for provider administration, as well as a prefilled syringe and a prefilled pen, both marketed for self-administration. CMS began including noncovered self-administered versions of Omvoh in the latter half of 2024, increasing payment amounts for the drug. For example, excluding noncovered versions would have lowered Omvoh's fourth-quarter 2024 payment amount by 15 percent, a savings of $1,742 per vial.

CMS's removal of noncovered self-administered versions previously identified by OIG saved Part B and its enrollees $1.3 billion from 2023 through 2024. CMS removed noncovered self-administered versions of Orencia, Cimzia, Fasenra, Xolair, and Tezspire when calculating payment amounts, as required by law. For three of these drugs, the resulting changes led to smaller payment reductions (i.e., less than 7 percent). However, for Orencia and Cimzia, removing the noncovered self-administered versions led to significantly lower payment amounts. Medicare Part B and its enrollees saved a total of $1.3 billion from 2023 through 2024 for the five drugs.

Conclusion

As required by statute, OIG has identified Part B drug payments that include both covered provider-administered and noncovered self-administered versions. It is now incumbent upon CMS to use its statutory authority, exercising its discretion as permitted, to remove self-administered versions of Omvoh from future payment amount calculations if the exclusion would result in lower payment amounts.

FINDINGS

Part B payment amounts for Omvoh included noncovered self-administered versions in the third and fourth quarters of 2024

CMS included both covered provider-administered and noncovered self-administered versions when setting ASP-based payment amounts for Omvoh in the second half of 2024. The self-administered versions were approved by FDA under the same application number as the provider-administered version, meaning that CMS was following its interpretation of Federal law when setting payment amounts.[2] In 2024, Medicare Part B and its enrollees paid a total of $1.2 million for Omvoh.

Omvoh is a brand-name drug indicated for the treatment of moderate to severe active ulcerative colitis, and for the treatment of moderate to severe active Crohn's disease.[3, 4] Omvoh is available as (1) a single-dose vial intended for provider administration, (2) a single-dose prefilled syringe marketed for self-administration, and (3) a single-dose prefilled pen marketed for self-administration (see Exhibit 1).[5] During the initial phase of treatment, a provider administers a vial of Omvoh to the patient via intravenous infusion three times over an 8-week period. During the subsequent maintenance phase of treatment, the patient self-administers either the prefilled pen or the syringe version of Omvoh subcutaneously once every 4 weeks.

Exhibit 1: CMS included self-administered versions in payment amounts for Omvoh (J2267) in 2024

2024 Part B Expenditures	Indications	Administration Frequency	Product Formulation	Administration Method	Marketing Start Date	Quarters Included in Part B Payments
$1.2 million	Moderate to severe active ulcerative colitis; moderate to severe active Crohn's disease	Used during the induction phase: Every 4 weeks for the first 3 doses	Vial	Provider-administered	October 2023	3rd & 4th Quarter 2024
		Used during the maintenance phase: Every 4 weeks	Prefilled pen	Self-administered	October 2023	3rd & 4th Quarter 2024
		Used during the maintenance phase: Every 4 weeks	Prefilled syringe	Self-administered	April 2024	4th Quarter 2024

Source: OIG analysis of CMS ASP files, drug product data, and Part B expenditure data.
Note: Two dosage sizes are available for the prefilled pen and prefilled syringe. Only one dosage size is available for the vial.

Including the self-administered versions substantially increased payment amounts for Omvoh in the fourth quarter of 2024

CMS began calculating ASP-based payment amounts for Omvoh in the third quarter of 2024.[6] That quarter, CMS included both the provider-administered vial and the noncovered self-administered prefilled pen. Excluding the self-administered prefilled pen would have decreased the third-quarter payment amount for Omvoh from $10,423 to $10,145 per vial (a 3-percent decrease).[7]

The self-administered prefilled syringe was launched in the U.S. market in April 2024. CMS subsequently included that version in payment amount calculations, along with the prefilled pen and vial, for the fourth quarter of 2024. Excluding both self-administered versions of Omvoh (i.e., the prefilled syringe and pen) would have decreased Medicare payment amounts from $11,863 to $10,121 per vial (a 15-percent decrease) that quarter.

CMS's removal of noncovered self-administered versions previously identified by OIG saved Part B and its enrollees $1.3 billion from 2023 through 2024

In accordance with statute, CMS removed higher-cost, self-administered versions of five drugs—Orencia, Cimzia, Fasenra, Xolair, and Tezspire—that OIG previously identified.[8] For three of these drugs, the resulting changes led to smaller payment reductions (i.e., less than 7 percent). However, for Orencia and Cimzia, removing the noncovered self-administered versions led to significantly lower payment amounts. For example, the fourth-quarter 2024 payment amount for a typical 750 mg injection of Orencia was reduced from $4,706 to $3,258 (31 percent).[9] For Cimzia, the fourth-quarter 2024 payment amount for a typical 400 mg injection was reduced from $3,083 to $1,861 (40 percent).[10] As a result, Part B and its enrollees saved a total of $1.3 billion on these five drugs from 2023 through 2024 (see Exhibit 2). Orencia and Cimzia accounted for 97 percent of this total. Since July 2021, when the Congressionally mandated exclusion of noncovered self-administered versions of drugs identified by OIG first took effect, Part B and its enrollees have saved a total of $2 billion.

Exhibit 2: OIG's noncovered versions work saved Part B and its enrollees $1.3 billion from 2023 through 2024

Orencia and Cimzia accounted for **97%** of total savings

Drug Name	Billing Code	Total Savings 2023-2024
Orencia	J0129	$791.6 million
Cimzia	J0717	$503 million
Xolair	J2357	$22.7 million
Tezspire	J2356	$6.8 million
Fasenra	J0517	$5.2 million
Total Savings		$1.3 billion

Source: OIG analysis of CMS average sales price (ASP) files, and Part B expenditure data.

CONCLUSION

Congress requires OIG to conduct periodic studies to identify billing codes for which both noncovered self-administered versions and covered provider-administered versions of drugs are used to set Part B payment amounts, and to determine whether the self-administered versions should be excluded from Part B payment amount calculations.[11, 12] OIG found that CMS included noncovered self-administered versions of Omvoh when calculating 2024 ASP-based Part B payment amounts, and that excluding the noncovered versions would generate savings for Medicare and its enrollees. It is now incumbent upon CMS to use its statutory authority, exercising its discretion as permitted, to remove self-administered versions of Omvoh from payment amount calculations in subsequent quarters if the exclusion would result in lower payment amounts.

METHODOLOGY

Medicare sets payment amounts for Part B drugs using Healthcare Common Procedure Coding System (HCPCS) codes. Because more than one National Drug Code (NDC) may meet the definition of a HCPCS code, CMS must first "crosswalk" manufacturers' NDCs to their corresponding HCPCS codes. We used CMS's ASP files to identify all NDCs used to set Part B 2023 and 2024 ASP-based payment amounts.

Using drug compendia data; prescription drug packaging and labeling information from FDA; and manufacturer resources, we identified NDCs representing products that are usually self-administered. We based our definition of "usually self-administered" on CMS's guidance.[13]

We then identified the HCPCS codes to which each identified self-administered NDC is crosswalked. We removed HCPCS codes that were not also crosswalked to a provider-administered product, and we removed HCPCS codes for which self-administration is allowed under Part B coverage criteria (e.g., HCPCS codes representing blood clotting factors).

For the remaining HCPCS code, representing Omvoh, we recalculated Part B payment amounts using CMS's volume-weighted ASP formula with the self-administered NDCs removed.[14] We calculated the difference between the actual and alternate payment amounts in each quarter.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued in 2020 by the Council of the Inspectors General on Integrity and Efficiency.

ENDNOTES

[1] Section 1847A(g)(1) and (g)(2) of the Social Security Act (the Act) as amended by Div. CC, Title IV, section 405 of the Consolidated Appropriations Act, 2021, Pub. L. No. 116-260.

[2] Medicare Administrative Contractors determined that the subcutaneous versions of Omvoh do not meet Part B coverage criteria and placed these versions on their self-administered drug exclusion lists starting January 13, 2024.

[3] Omvoh package insert: https://uspl.lilly.com/omvoh/omvoh.html#pi, accessed on January 15, 2026.

[4] The FDA approved Omvoh for the treatment of moderate to severe active Crohn's disease on January 15, 2025.

[5] Two dosage sizes are available for the prefilled pen and prefilled syringe. Only one dosage size is available for the vial.

[6] Omvoh launched October 2023. Therefore, ASP data became available starting in the first quarter of 2024 and was included in third-quarter 2024 payment amount calculations for the drug.

[7] The intravenous version of Omvoh is packaged as a 300 mg single-dose vial. The recommended dose for the treatment of ulcerative colitis is one vial as a single intravenous infusion; the recommended dose for the treatment of Crohn's disease is three vials as a single intravenous infusion.

[8] OIG, *Congressional Mandate: Part B Payment Amounts for Two Drugs Included Noncovered Self-Administered Versions in 2022* (OEI-BL-22-00380), November 2023; OIG, *Early Alert: Part B Payment Amount for Tezspire Included a Noncovered Self-Administered Version in 2023* (OEI-BL-24-00030), November 2023; OIG, *Update: Xolair Prefilled Syringes Likely Meet Part B Coverage Criteria* (OEI-BL-24-00440), December 2024. OIG also identified noncovered self-administered versions of Stelara biosimilars; however, the lower payment amounts did not take effect during this study's review period. See OIG, *Excluding Noncovered Versions Would Have Substantially Lowered Fourth-Quarter 2025 Part B Payment Amounts for Stelara Biosimilars* (OEI-BL-25-00240), December 2025.

[9] A typical dose of Orencia is determined on the basis of the condition for which Orencia is being administered and, in some cases, the patient's body weight. Prior OIG work found that most Part B claims for Orencia were for 750 mg. To maintain consistency with prior OIG work, we calculated the actual payment amount and potential payment amount based on a dose of 750 mg.

[10] A typical dose of Cimzia is determined on the basis of the condition and the patient. Prior OIG work found that most Part B claims for Cimzia were for 400 mg. To maintain consistency with prior OIG work, we calculated the actual payment amount and potential payment amount based on a dose of 400 mg.

[11] Section 1847A(g)(1) of the Act.

[12] If and when OIG identifies a noncovered self-administered national drug code (NDC) that OIG determines should be excluded from payment amount calculations, OIG shall inform the Secretary and the Secretary shall, to the extent the Secretary deems appropriate, apply a "lesser of" payment amount for the HCPCS code, as follows: (A) the amount of payment that would result if the self-administered drugs were excluded from the determination of the payment amount, or (B) the amount of payment determined without that exclusion. CMS is required to exclude the NDC from payment amount calculations if the exclusion would result in a lower payment amount. CMS regulations require that the agency exclude such an NDC from payment amount calculations beginning on the first day of the second quarter following the publication of the corresponding OIG report. Regulations provide an exception to not lower payment amounts if the drug is in short supply, as identified by FDA, for that quarter. See Section 1847A(g)(2) of the Act and 42 CFR § 414.904(d)(4)(i)–(ii) & (iv).

[13] For example, see *Medicare Benefit Policy Manual*, ch. 15 § 50.2.

[14] To calculate HCPCS code payment amounts, CMS averages pricing data by sales volume for all NDCs crosswalked to a HCPCS code. Medicare pays for most Part B drugs at 106 percent of the volume-weighted average sales prices. Section 1847A(b)(1) of the Act.

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