Department of Health and Human Services
Office of Inspector General
Office of Evaluation and Inspections

DATA BRIEF

June 2026 | OEI-BL-26-00200

Congressional Mandate: Part B Billing Codes for Six Drugs Included Noncovered Self-Administered Versions During January 2025–March 2026

June 2026 | OEI-BL-26-00200

Congressional Mandate: Part B Billing Codes for Six Drugs Included Noncovered Self-Administered Versions During January 2025–March 2026

Why OIG Did This Review

OIG is required by statute to identify and inform CMS about billing codes for which both covered physician-administered versions and noncovered self-administered versions of a drug are used to set Part B payment amounts.[1] For this review, OIG examined Part B payment files over a five-quarter period to identify (1) any billing codes that included covered and noncovered versions and (2) whether CMS included the average sales prices (ASPs) for noncovered versions when calculating payment amounts for January 2025–March 2026.

What OIG Found

- Part B billing codes for six drugs included noncovered self-administered versions. For two of these drugs, ASPs were not actually used to set Part B payment during our review period, but the inclusion of ASPs for the noncovered versions of the drugs could affect payment amounts in future quarters.

- Payment amounts for four of the six drugs included noncovered self-administered versions. In most cases, including these versions increased costs for Part B and its enrollees. For example, in the fourth quarter of 2025, Medicare and its enrollees paid approximately $15,200 for an induction dose of infused Tremfya, compared to around $14,200 had noncovered versions been removed.

Drug Name	Billing Code	Effect on Payment Amount (Range by Quarter)	Total 2025 Part B Expenditures
Acthar Gel	J0801	6-10% increase	<$10 thousand
Tremfya	J1628	2-7% increase	$32 million
Vyvgart Hytrulo	J9334	1-2% increase	$539 million
Tyenne	Q5135	5% increase to 7% reduction*	$24 million

* For Tyenne, whether including noncovered versions led to higher payment amounts was dependent on the quarter.

Conclusion

OIG found that CMS included noncovered self-administered versions of four drugs when calculating ASP-based payment amounts; for two additional drugs, noncovered versions were included in the billing codes but payment amounts were not set using ASPs during our review period. It is now incumbent upon CMS to use its statutory responsibilities, exercising its discretion as permitted, to remove self-administered versions of any of the six drugs identified in this report from future payment amount calculations if the exclusions would result in lower payment amounts.[2]

FINDINGS

Part B billing codes for six drugs included noncovered versions from January 2025 through March 2026

OIG identified six drugs for which the associated Part B billing codes included both covered physician-administered and noncovered self-administered versions in at least one quarter during the review period (January 2025–March 2026). See Exhibit 1 below for a description of each drug. Please note that in some circumstances, a noncovered version may be included in the Part B billing code but an ASP for that version is not used to set payment (e.g., a new version for which ASPs have yet to be reported).

Exhibit 1: Billing codes for six drugs included noncovered versions in at least one quarter

Drug Name	Billing Code	Product Formulation	Route of Administration	Primary Administration Method	Payment Amounts Included ASPs for Noncovered Versions
Acthar Gel	J0801	Vial	Intramuscular; subcutaneous	Physician; self	✓
		Prefilled SelfJect injector	Subcutaneous	Self	
Tremfya	J1628	Vial	Intravenous	Physician	✓
		Prefilled syringe; pen; One-Press injector	Subcutaneous	Self	
Vyvgart Hytrulo	J9334	Vial	Subcutaneous	Physician	✓
		Prefilled syringe	Subcutaneous	Self	
Tyenne	Q5135	Vial	Intravenous	Physician	✓
		Prefilled syringe; autoinjector	Subcutaneous	Self	
Spevigo	J1747	Vial	Intravenous	Physician	*CMS set payment using WACs*
		Prefilled syringe	Subcutaneous	Self	
Avtozma	Q5156	Vial	Intravenous	Physician	*ASP data not available*
		Prefilled syringe; autoinjector	Subcutaneous	Self	

Source: OIG analysis of CMS ASP files, drug product data, and Part B expenditure data.

Note: CMS set payment amounts for Spevigo using wholesale acquisition costs (WACs) because the WACs were lower than the ASPs for the drug. In addition, intravenous Avtozma and subcutaneous Avtozma were launched for sale in October 2025 and March 2026, respectively, meaning that ASP data were not yet available during our period of review.

For four of the six drugs, Part B payment amounts were calculated using ASPs for noncovered versions

CMS included ASPs for noncovered versions when calculating Part B payment amounts for four of the six drugs described above.[3] Payment amounts for Acthar Gel, Tremfya, and Vyvgart Hytrulo ranged from 1 percent to 11 percent higher in quarters for which ASPs for noncovered versions were included. For example, in the fourth quarter of 2025, Medicare and its enrollees paid approximately $15,200 for an induction dose of infused Tremfya, compared to around $14,200 had noncovered versions been removed from payment calculations.

In the case of Tyenne, whether including noncovered versions led to higher payment amounts was dependent on the quarter, with effects ranging from a 5-percent increase to a 7-percent decrease. See Exhibit 2.

Exhibit 2: Including self-administered versions consistently resulted in higher payment amounts for three of the four drugs

Drug Name	Billing Code	Effect on Payment Amount (Range by Quarter)	Total 2025 Part B Expenditures
Acthar Gel	J0801	7-11% increase	<$10 thousand
Tremfya	J1628	2-7% increase	$32 million
Vyvgart Hytrulo	J9334	1-2% increase	$539 million
Tyenne	Q5135	5% increase to 7% reduction	$24 million

Source: OIG analysis of CMS ASP files, drug product data, and Part B expenditure data.

Note: For all drugs except Vyvgart Hytrulo, noncovered versions were included in payment amount calculations for the entire period under review. For Vyvgart Hytrulo, noncovered versions were included in payment amount calculations from October 1, 2025, through March 31, 2026.

CONCLUSION

Congress requires OIG to conduct periodic studies to identify billing codes for which both noncovered self-administered versions and covered physician-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. OIG found that CMS included noncovered self-administered versions of four drugs when calculating ASP-based payment amounts; for two additional drugs, noncovered versions were included in the billing codes but payment amounts were not set using ASPs during our review period (January 2025 through March 2026). It is now incumbent upon CMS to use its statutory responsibilities, exercising its discretion as permitted, to remove self-administered versions of any of the six drugs identified in this report from payment amount calculations in subsequent quarters if the exclusion would result in lower payment amounts.

METHODOLOGY

We first limited our analysis to all new national drug codes (NDCs) added to CMS ASP files since our previous noncovered versions review (i.e., all NDCs added to CMS ASP files since the second quarter of 2024).[4]

We then removed any new NDCs associated with billing codes that would not typically meet the criteria for having a noncovered version (e.g., billing codes representing covered self-administered drugs such as oral anti-cancer drugs, blood clotting factors, and inhalation drugs used with durable medical equipment). We also removed any NDCs associated with certain billing codes included on Medicare contractors' self-administered drugs exclusion lists (i.e., drugs that are without exception not covered under Medicare Part B).

Using drug compendia data; Food and Drug Administration packaging and labeling information; and manufacturer resources, we identified any remaining NDCs representing products that are typically self-administered. We based our definition of "self-administered" on CMS's guidance.[5] We then further limited our list to drugs with billing codes that potentially included both self-administered and physician-administered versions.

From the remaining billing codes, we recalculated Part B payment amounts using CMS's volume-weighted ASP formula with the self-administered NDCs removed. 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] 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" of the U.S. Department of Health and Human Services (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 drug 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 the Food and Drug Administration, for that quarter. See Section 1847A(g)(2) of the Act and 42 CFR § 414.904(d)(4)(i)–(ii) & (iv).

[3] For one of the remaining drugs (Spevigo), CMS set payment amounts using wholesale acquisition costs (WACs) because the WACs were lower than the manufacturer-reported ASPs. The other drug (Avtozma) was not launched for sale until October 2025, meaning that ASP data were not yet available during our period of review.

[4] Because of the two-quarter lag in ASP payments, second-quarter 2024 ASPs were used to calculate fourth-quarter 2024 Part B payment amounts.

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

Report Fraud, Waste, and Abuse

OIG Hotline Operations accepts tips and complaints from all sources about potential fraud, waste, abuse, and mismanagement in HHS programs. Hotline tips are incredibly valuable, and we appreciate your efforts to help us stamp out fraud, waste, and abuse.

TIPS.HHS.GOV

Phone: 1-800-447-8477

TTY: 1-800-377-4950

Who Can Report?

Anyone who suspects fraud, waste, and abuse should report their concerns to the OIG Hotline. OIG addresses complaints about misconduct and mismanagement in HHS programs, fraudulent claims submitted to Federal health care programs such as Medicare, abuse or neglect in nursing homes, and many more. Learn more about complaints OIG investigates.

How Does It Help?

Every complaint helps OIG carry out its mission of overseeing HHS programs and protecting the individuals they serve. By reporting your concerns to the OIG Hotline, you help us safeguard taxpayer dollars and ensure the success of our oversight efforts.

Who Is Protected?

Anyone may request confidentiality. The Privacy Act, the Inspector General Act of 1978, and other applicable laws protect complainants. The Inspector General Act states that the Inspector General shall not disclose the identity of an HHS employee who reports an allegation or provides information without the employee's consent, unless the Inspector General determines that disclosure is unavoidable during the investigation. By law, Federal employees may not take or threaten to take a personnel action because of whistleblowing or the exercise of a lawful appeal, complaint, or grievance right. Non-HHS employees who report allegations may also specifically request confidentiality.

Stay In Touch

Follow HHS-OIG for up to date news and publications.

 OIGatHHS

 HHS Office of Inspector General

Subscribe To Our Newsletter

OIG.HHS.GOV

Contact Us

For specific contact information, please visit us online.

U.S. Department of Health and Human Services
Office of Inspector General
Public Affairs
330 Independence Ave., SW
Washington, DC 20201

Email: Public.Affairs@oig.hhs.gov