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DATA BRIEF

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Excluding Noncovered Versions Would Have Substantially Lowered Fourth-Quarter 2025 Part B Payment Amounts for Stelara Biosimilars

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.[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.

What OIG Found

Medicare Part B billing codes for five Stelara biosimilars currently include both covered and noncovered versions. In accordance with CMS policy, these five Stelara biosimilars were each assigned a single billing code that represents both the covered provider-administered and noncovered self-administered versions. A sixth biosimilar has not yet been assigned a dedicated billing code; however, once assigned, the billing code will also include both covered and noncovered versions.

Payment amounts for four Stelara biosimilars included noncovered self-administered versions in the fourth quarter of 2025. Medicare Part B generally pays for qualifying biosimilars using a two-part formula: (1) the biosimilar's volume-weighted average sales price (i.e., ASP portion) and (2) 8 percent of the reference product's ASP (i.e., add-on portion).

- **ASP Portion.** For three biosimilars, CMS included both covered and noncovered versions in the ASP portion of their calculations. For the fourth biosimilar, CMS included only the covered version in its ASP calculation.[2]
- **Add-on Portion.** CMS included the ASPs for the covered and noncovered versions of the reference product (Stelara) in all four biosimilars' add-on calculations—even though the self-administered version of Stelara is not covered under Part B.

ASP data were not available for two of the six biosimilars, meaning their payment amounts were not yet affected.

Excluding noncovered versions would have lowered fourth-quarter 2025 payment amounts for four Stelara biosimilars by 59 to 87 percent—up to $3,765 in savings per vial. Because noncovered versions were included, four Stelara biosimilars had fourth-quarter 2025 payment amounts that were considerably higher than they would have been otherwise. In one case, this resulted in a payment of $5,245 per vial, more than triple that of Stelara ($1,689 per vial).

Conclusion

As required by statute, OIG has identified Part B drug payments that include both covered provider-administered and noncovered self-administered versions, and demonstrated that excluding the noncovered versions would generate savings for Medicare and its enrollees. It is now incumbent upon CMS to use its statutory responsibilities, exercising its discretion as permitted, to remove self-administered versions of Stelara biosimilars from future payment amount calculations.

Primer

Part B Coverage and Payment for Self-Administered Drugs. With certain exceptions, self-administered drugs are not covered under Medicare Part B.[3] However, the billing codes used in setting payments for Part B drugs often include multiple versions of the same drug and, in a small number of cases, some of those versions may be self-administered. Specifically, CMS interprets a relevant statute to require the inclusion of ASPs for noncovered self-administered versions when the agency calculates the payment amount for a billing code if both the covered and noncovered versions of a product are approved by the U.S. Food & Drug Administration (FDA) under the same application number.[4, 5]

Mandated OIG Studies on Noncovered Versions of Part B Drugs. OIG is required to conduct periodic studies to identify 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.[6] In general, for the drugs that OIG identifies, CMS is required to remove 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.[7] In accordance with regulations, any exclusions for these self-administered national drug codes (NDCs) would take effect on the first day of the second quarter after OIG issues a public report.[8]

Stelara. Stelara is a high-cost prescription biologic drug approved to treat certain autoimmune diseases. Both provider-administered and self-administered versions of Stelara have been approved by FDA: one version that must be infused intravenously by a health care provider and three versions that are typically self-administered via subcutaneous injection (i.e., under the skin).[9] CMS assigned two different billing codes for Stelara because FDA approved the provider-administered and self-administered versions under two separate application numbers. In other words, the billing code and therefore the Part B drug payment amount for the provider-administered version of Stelara did not include the self-administered versions. Subsequently, Medicare Administrative Contractors (MACs) determined that the self-administered subcutaneous versions do not meet Part B coverage criteria and placed the associated billing code on their self-administered drug (SAD) exclusion lists.

Stelara Biosimilars. A biosimilar is a biologic that is highly similar to and has no clinically meaningful difference from an existing FDA-approved biologic (i.e., the biosimilar's "reference product").[10] FDA recently approved eight biosimilars for Stelara, encompassing both provider-administered intravenous and self-administered subcutaneous versions.[11] Six of the eight Stelara biosimilars were launched in the U.S. market during the first quarter of 2025 and a seventh was launched in the third quarter. MACs determined that the subcutaneous versions of these biosimilars were noncovered.[12] An eighth biosimilar launched in the fourth quarter of 2025; it has not yet been added to the SAD exclusion list.

Part B Payment Amount Calculation for Biosimilars. Part B generally pays for biosimilars using a two-part formula: (1) the biosimilar's volume-weighted ASP (i.e., ASP portion) and (2) 6 or 8 percent of the reference product's ASP (i.e., add-on portion). The add-on percentage was increased from 6 to 8 percent for qualifying biosimilars for a 5-year period starting October 1, 2022. Biosimilars qualify for this increased 8-percent add-on if they have a lower ASP than their reference product.[13]

According to CMS, if a billing code for a biosimilar includes both covered and noncovered versions, the agency will also include both the covered and noncovered versions of the reference product in the add-on portion of the biosimilar's payment calculation.

FINDINGS

Medicare Part B billing codes for five Stelara biosimilars include both covered and noncovered versions

Unlike the Stelara reference product, six of the eight Stelara biosimilars have both covered provider-administered and noncovered self-administered versions approved under the same FDA application number. In accordance with CMS policy, five of these six biosimilars were each assigned a single billing code that represents both versions of the drug (see Exhibit 1). The sixth has not yet been assigned a dedicated billing code; however, once assigned, the billing code will also include both versions.

Exhibit 1: Five of the eight Stelara biosimilars were each assigned a single billing code representing covered and noncovered versions

	Drug Name	Application Number(s)	Billing Code(s)
Part B billing codes for these **5 Stelara biosimilars** include noncovered self-administered versions.	Otulfi	BLA761379	Q9999
	Selarsdi	BLA761343	Q9998
	Yesintek	BLA761406	Q5100
	Steqeyma	BLA761338	Q5099
	Imuldosa	BLA761364	Q5098
Once assigned, the billing code for **1 additional Stelara biosimilar** will include noncovered self-administered versions.	Starjemza	BLA761419	*Not yet assigned*
	Wezlana	BLA761331 (Intravenous) BLA761285 (Subcutaneous)	Q5138 (Intravenous) Q5137 (Subcutaneous)
	Pyzchiva	BLA761425 (Intravenous) BLA761373 (Subcutaneous)	Q9997 (Intravenous) Q9996 (Subcutaneous)

Source: OIG analysis of FDA's NDC Directory, CMS's second-quarter 2025 ASP file, and MACs' SAD exclusion lists.

Payment amounts for four Stelara biosimilars included noncovered self-administered versions in the fourth quarter of 2025

As previously described, Medicare Part B generally pays for qualifying biosimilars using a two-part formula: (1) the biosimilar's volume-weighted ASP (i.e., ASP portion) and (2) 8 percent of the reference product's ASP (i.e., add-on portion). In the fourth quarter of 2025, the ASP-based payment amounts for four of the five Stelara biosimilars discussed above were calculated using both covered and noncovered versions. All four qualified for the 8-percent add-on because their ASPs were below those of the reference product. CMS did not calculate ASP-based payment amounts for the fifth product (Imuldosa) because ASP data were not yet available.

ASP Portion. The volume-weighted ASPs for four Stelara biosimilars were first calculated for the fourth quarter of 2025. For three of these, CMS included both covered and noncovered versions in the ASP portion of their calculations. For the fourth, CMS included only the covered version in its ASP calculation (see Exhibit 2).[14]

Add-on Portion. According to CMS, if a billing code for a biosimilar includes both covered and noncovered versions, the agency will also include both the covered and noncovered versions of the reference product in the add-on portion of the biosimilar's payment calculation. In other words, because the four biosimilars cited above were each assigned a single billing code representing both versions of the drug, CMS included the ASPs for both versions of the reference product (Stelara) in each biosimilar's add-on calculation—even though the self-administered version of Stelara has its own unique billing code that specifically is not covered under Part B.[15]

Combining sales data for both the covered physician-administered and the noncovered self-administered versions of Stelara resulted in an add-on payment of $1,357 per vial during the fourth quarter of 2025.[16] This amount is more than 10 times greater than the $127 per vial add-on had CMS included only the covered physician-administered version of Stelara in the calculation.

Exhibit 2: For four Stelara biosimilars, CMS included noncovered versions in the ASP and/or add-on portion of fourth-quarter payment amounts; payments for the fifth biosimilar will include noncovered versions when ASP data is available

Drug Name	Billing Code	ASP Portion Included Noncovered Versions	Add-on Portion Included Noncovered Versions
Otulfi	Q9999	✓	✓
Selarsdi	Q9998	✓	✓
Yesintek	Q5100	✓	✓
Steqeyma	Q5099	⊘	✓
Imuldosa	Q5098	*ASP data not available*	*ASP data not available*

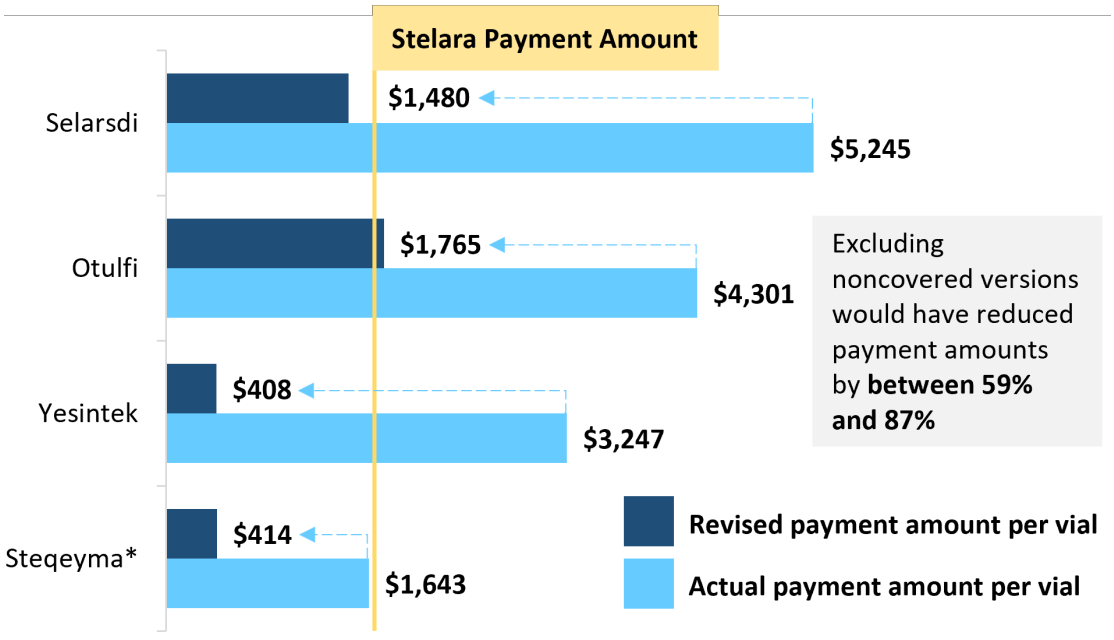
Source: OIG analysis of FDA's NDC Directory and CMS's second-quarter 2025 ASP file.

Excluding noncovered versions would have lowered fourth-quarter 2025 payment amounts for four Stelara biosimilars by 59 to 87 percent—up to $3,765 in savings per vial

Biosimilars provide an opportunity to significantly decrease costs for Medicare Part B and its enrollees. However, because noncovered versions were included, the four affected Stelara biosimilars had payment amounts that were considerably higher than they would have been otherwise (see Exhibit 3). Specifically, excluding noncovered self-administered versions would have reduced the payment amounts for Stelara biosimilars by 59 to 87 percent in the fourth quarter of 2025. For example, with noncovered versions removed, Selarsdi would have been paid at $1,480 per vial instead of $5,245 (a 72-percent decrease). This difference in payment ($3,765) reflects a $2,536 decrease in the ASP portion and another $1,230 decrease in the 8-percent add-on portion.[17, 18]

Further, for three of the four Stelara biosimilars, Part B payment amounts actually exceeded those of the reference product. In the case of Selarsdi, the Medicare payment amount ($5,245 per vial) was more than triple that of Stelara ($1,689 per vial).

Exhibit 3: Fourth-quarter payment amounts would have been substantially reduced had CMS excluded noncovered versions



Source: OIG analysis of FDA's NDC Directory and CMS's second-quarter 2025 ASP file.
* CMS included only the covered version in its ASP calculation.

CONCLUSION

Payment policies for biosimilars should further CMS's goal of lowering drug costs for the Medicare program and its enrollees. However, in the case of Stelara biosimilars, the inclusion of higher-cost noncovered versions when setting Part B payment amounts runs counter to this goal.

Specifically, our analysis has shown that excluding noncovered self-administered versions of four Stelara biosimilars from Medicare Part B drug payment calculations —including both the ASP and the add-on portions—would have lowered costs for Medicare and its enrollees by between 59 and 87 percent—up to $3,765 in savings per vial—during the fourth quarter of 2025. Even more concerning, the resulting payment amounts for three of the four Stelara biosimilars exceeded those of the reference product itself.

As required by statute, OIG has identified Part B drug payments that include both covered provider-administered and noncovered self-administered versions and demonstrated that excluding the noncovered versions would generate savings for Medicare and its enrollees. It is now incumbent upon CMS to use its statutory responsibilities, exercising its discretion as permitted, to remove self-administered versions from the payment amount calculations for (1) the four Stelara biosimilars identified in this report whose payment amounts were affected in the fourth quarter of 2025 and (2) the two additional Stelara biosimilars for which ASP-based payment amounts have yet to be calculated due to data availability, but whose future payments amounts will be affected given that their billing codes include or will include both covered and noncovered versions.

METHODOLOGY

Medicare sets payment amounts for Part B drugs using Healthcare Common Procedure Coding System (HCPCS) codes. Because more than one NDC may meet the definition of a HCPCS code, CMS must first "crosswalk" manufacturers' NDCs to their corresponding HCPCS codes.

Using FDA's NDC Directory and prescription drug packaging and labeling information, and MACs' SAD exclusion lists, we identified all biological license application numbers and NDCs assigned to each Stelara biosimilar in our review and then determined whether each NDC represents a version of the drug that is typically self-administered.

We used CMS's ASP files to identify each HCPCS code assigned to a Stelara biosimilar. We then determined whether these HCPCS codes were crosswalked to both provider-administered and self-administered NDCs. For the HCPCS codes that were crosswalked to both versions, 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 for the fourth quarter of 2025.

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)(3) of the Social Security Act (the Act) as amended by section 405 of the Consolidated Appropriations Act, 2021.

[2] Medicare Part B payment limits could be affected by incomplete data due to manufacturer noncompliance with ASP reporting requirements.

[3] Medicare Part B does cover a small number of self-administered drugs, including certain oral anti-cancer drugs, blood clotting factors, and inhalation and infusion drugs used with durable medical equipment. See Section 1861(s)(2) of the Social Security Act (the Act), 42 CFR § 414.900(b), and the *Medicare Benefit Policy Manual*, ch. 15 § 50.2.

[4] A drug's average sales price (ASP) is a manufacturer's sales of a drug to all purchasers in the United States in a calendar quarter (net of most discounts) divided by the total number of units of the drug sold by the manufacturer in that same quarter. Section 1847A(c) of the Act.

[5] 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. In interpreting the Act, CMS determined that (1) all versions of a product listed under the same FDA application number must be considered the same drug or biological, for payments made under Part B, and (2) for a product marketed under the same application number, labeling that indicates that a version may be used primarily when the drug is not covered under Part B (e.g., the version is for self-administration only) cannot be used as a basis to exclude that version from a payment amount calculation. CMS's interpretation is supported by *Allergan, Inc. v. Sylvia Mathews Burwell*, Case No. 13-00264, 2016 U.S. Dist. LEXIS 43550 (D.D.C. March 30, 2016). See Sections 1847A(b)(4)(A) and 1847A(b)(5) of the Act. Also, see CMS, *Update to Information Regarding Medicare Payment and Coding for Drugs and Biologics*, May 18, 2007, https://www.cms.gov/Medicare/Coding/MedHCPCSGenInfo/Downloads/051807_coding_annoucement.pdf, accessed on April 1, 2025.

[6] 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; and OIG, *Update: Xolair Prefilled Syringes Likely Meet Part B Coverage Criteria* (OEI-BL-24-00440), December 2024.

[7] Section 1847A(g)(1)-(2) of the Act and 42 CFR § 414.904(d)(4)(i)–(ii) & (iv).

[8] 42 CFR § 414.904(d)(4)(i).

[9] FDA, Label, Highlights of Prescribing Information, Stelara (Ustekinumab) injection, for subcutaneous or intravenous use. Accessed at https://www.accessdata.fda.gov/drugsatfda_docs/label/2025/125261s171,761044s019lbl.pdf on November 25, 2025.

[10] FDA, "Biosimilars Basics for Patients." Accessed at https://www.fda.gov/drugs/biosimilars/biosimilars-basics-patients on November 25, 2025.

[11] For more information, see biosimilar product information published by FDA at https://www.fda.gov/drugs/biosimilars/biosimilar-product-information. Accessed on November 25, 2025.

[12] For example, see CMS, *Self-Administered Drug Exclusion List: (SAD List) A52800*. Accessed at

https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=52800 on November 26, 2025.

[13] Inflation Reduction Act, P.L. 117-169, § 11403.

[14] Medicare Part B payment limits could be affected by incomplete data due to manufacturer noncompliance with ASP reporting requirements.

[15] The authority to determine whether a drug such as Stelara meets the Part B coverage requirements set by statute and CMS policy, including whether the drug is "usually self-administered," generally rests with Medicare Administrative Contractors (MACs). See Section 1861(s)(2) of the Act, 42 CFR § 414.900, and the Medicare Benefit Policy Manual, ch. 15 § 50.2. For Stelara, MACs placed the subcutaneous versions of the drug on the self-administered drug exclusion list, with effective dates ranging by MAC from October 15, 2021, to November 1, 2022.

[16] The intravenous versions of Stelara and its eight biosimilars are packaged in a single-dose 130 mg vial and administered using weight-based dosing, ranging from 2 to 4 vials (260 to 520 mg) as a single intravenous infusion.

[17] Payment differences do not equal the total due to rounding.

[18] Medicare enrollees are responsible for covering 20 percent of these increased costs through coinsurance.

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