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

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.