HHS Office of Inspector General
HIGHLIGHTS

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

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.