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Medicare Contractors Did Not Use Complete and Timely Utilization Data When Making Part B Coverage Determinations for Stelara

Why OIG Did This Review

- Stelara is a high-cost prescription biologic approved to treat certain autoimmune diseases. A yearly course of Stelara injections under Medicare can exceed \$100,000 per patient.
- Subcutaneous (under the skin) injections of Stelara are covered under Medicare Part D as a self-administered drug. Prior to 2023, Stelara injections were also covered under Part B when administered by a physician. Medicare Administrative Contractors (MACs) now exclude Stelara injections from Part B because their analysis showed that less than 50 percent of enrollees had the drug administered in a physician's office—50 percent is the threshold for determining Part B coverage.
- It is critical that MACs have complete and timely utilization data when determining Part B coverage. As [OIG work](#) has shown, removing Part B coverage of Stelara had substantial financial impacts on Medicare and some enrollees because Medicare Part D paid much more per dose for Stelara than Part B.

What OIG Found

MACs' challenges with utilization data when determining Part B coverage could lead to excluding drugs from Part B coverage inappropriately, potentially leading to higher costs to Medicare and its enrollees.

- **MACs face challenges with utilization data when following Centers for Medicare & Medicaid Services' (CMS's) coverage guidance for drugs such as Stelara.**
 - Because of data limitations, MACs did not include certain Medicare Advantage (MA) enrollees—and double-counted other enrollees—when determining whether Stelara is usually self-administered.
 - Medicare data do not allow MACs to conclusively determine how many enrollees received assistance in administering Part D drugs (i.e., administered by caregivers rather than by the enrollees themselves).
- **Using more complete and timely data revealed that Stelara was trending toward—and came very close to meeting—the utilization threshold for Part B coverage as described under CMS guidelines.**
- **Missing data led MACs to overestimate self-administered Stelara use by up to 16 percentage points.**

What OIG Recommends

Because the types of data limitations that impact Part B coverage determinations are not unique to Stelara and affect coverage determinations for similar drugs, CMS should (1) assist MACs in obtaining more complete and timely utilization data; and (2) provide guidance on how MACs should account for enrollees who receive injections in both home and professional settings.

CMS concurred with our first recommendation. CMS neither concurred nor nonconcurred with our second recommendation, but stated that the agency will take OIG's findings and recommendations into consideration as it works toward potentially developing changes to coverage determination policies in the future.