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

February 2025 | OEI-BL-19-00501

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

February 2025 | OEI-BL-19-00501

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.

TABLE OF CONTENTS

BACKGROUND

Stelara

Stelara is a high-cost prescription biologic approved to treat certain autoimmune diseases such as psoriasis, psoriatic arthritis, Crohn's disease, and ulcerative colitis.[1] Four versions of Stelara have been approved by the Food and Drug Administration (FDA): one version that must be infused intravenously by a health care professional and three versions that are administered via subcutaneous injection (i.e., under the skin). The injected versions are often self-administered but may also be given by a health care professional (see Appendix A for more details). Hereinafter, "Stelara" refers solely to the subcutaneous injection versions unless otherwise noted.

The cost for a yearly course of Stelara injections under Medicare can exceed $100,000 per patient, depending on the condition being treated. In total, Medicare Part D spent $3 billion for Stelara in 2023. Prior to that year, Stelara was covered under both Medicare Part B and Medicare Part D, depending on the site of service. However, as of November 1, 2022, Medicare coverage is only available through Part D.

Medicare Coverage of Stelara

Medicare Part D Coverage for Self-Administered Injections

Medicare coverage for prescription drugs is primarily provided under the voluntary Part D benefit, either through (1) standalone Medicare drug plans for those enrolled in original fee-for-service Medicare or (2) Medicare Advantage drug plans (MA-PDs) for those enrolled in managed care.[2, 3] Part D drug plans must offer certain minimum prescription drug benefits as specified by Federal law but enrollee cost-sharing, coverage of specific drugs, and other benefit details may vary among plans.[4] Typically, Stelara would be covered by Part D when the drug is prescribed by a provider and dispensed by a pharmacy to be self-administered at home.

Medicare Part B Coverage for Physician-Administered Injections

A limited number of prescription drugs—generally, those that are injected or infused in physicians' offices or hospital outpatient settings—are covered under Medicare Part B.[5] With certain exceptions, Part B does not cover drugs that are "usually" self-administered.[6] According to Centers for Medicare & Medicaid Services (CMS) policy, "usually" means more than 50 percent of the time for all Medicare enrollees who use the drug. The policy goes on to specify that "if a drug is self-administered by more than 50 percent of Medicare [enrollees], the drug is excluded from coverage and the [contractor] may not make any Medicare payment for it."[7] The infused version of Stelara has been covered under Medicare Part B from the time it reached the market. However, Part B coverage of subcutaneous injections has been less straightforward.

Process for Determining Part B Coverage. The authority to determine whether a drug such as Stelara (i.e., one that may be self-administered) meets Part B coverage requirements generally rests with individual Medicare Administrative Contractors (MACs). MACs are private insurers responsible for processing Part A and Part B claims for fee-for-service enrollees in their geographic jurisdictions.[8] According to CMS's Medicare Benefit Policy Manual, "[a]bsent evidence to the contrary, [MACs should] presume that drugs delivered by subcutaneous injection are self-administered by the patient."[9] However, CMS also requires MACs to consider how frequently a drug is administered in each context; whether it is used to treat a chronic or acute condition; and when available, evidence from peer-reviewed medical literature, standards of medical practice, evidence-based practice guidelines, FDA-approved labels, and approved package inserts.[10]

For new drugs, utilization data related to where a drug is administered are often unavailable. Therefore, MACs must rely on the other factors listed above when making initial coverage determinations. After Stelara received FDA approval in 2009, MACs originally allowed for the reimbursement of subcutaneous versions of Stelara under Part B when administered by physicians. For example, in response to OIG's survey, one MAC stated, "[w]hen Stelara was initially reviewed, the frequency of the administration did not support that it was a self-administered drug."

However, after examining public CMS data in early 2020, MACs determined that more than 50 percent of Medicare enrollees were self-administering the drug. The MACs subsequently updated their coverage determinations by placing the subcutaneous versions on their self-administered drug exclusion lists, with effective dates ranging from October 15, 2021, to November 1, 2022.[11] As a result, subcutaneous Stelara is no longer covered under Medicare Part B. For more detail on how CMS and MACs determine coverage eligibility for Stelara and other potentially self-administered prescription drugs under Part B, see Appendix B.

Recent CMS Efforts to Refine Part B Coverage Policy. On August 7, 2023, in light of stakeholder input that current guidance may not adequately address circumstances posed by newly approved drugs, CMS issued a request for information: *Drugs and Biologicals Which Are Not Usually Self-Administered by the Patient, and Complex Drug Administration Coding*.[12] The agency asked stakeholders for feedback on its policies regarding determinations of when a drug is "usually" self-administered. On November 16, 2023, CMS published a final rule stating that the agency received many comments regarding its policies on self-administered drugs. The comments addressed several critical issues, including appeals; FDA labeling; and accommodating patients who are under caregivers' care and/or patients who do not have the ability to self-administer drugs. Ultimately, CMS thanked commentors and stated that the agency looks forward to continued discussion as it works toward potentially developing changes to these policies in future rulemaking; however, the final rule did not include changes to the self-administered drug exclusion list determination process.[13]

Medicare Part C

As previously mentioned, pharmacy coverage for enrollees in Medicare Advantage (MA) plans (i.e., Part C) is provided through Part D. However, MA enrollees may also receive Stelara in their physicians' offices or hospital outpatient settings. In those cases, payment would be made through the medical benefit of Part C rather than Part D.

In recent years, enrollment in MA plans has seen substantial growth. As of 2023, a majority of the Medicare eligible population (51 percent) is now enrolled in MA plans, compared to 39 percent in 2019. The Congressional Budget Office projects that the share of all Medicare beneficiaries enrolled in MA plans will continue to rise and reach 62 percent by 2033.

Methodology

MAC Survey and Interviews. OIG originally surveyed MACs in April 2020 to better understand their practices for determining whether an injectable drug billing code—specifically, code J3357 for Stelara's subcutaneous versions—should be placed on the self-administered drug exclusion list and therefore ineligible for Part B coverage. We analyzed survey responses and supporting documentation to determine their process for reviewing and assessing drug codes to make coverage determinations. In August and September 2024, OIG interviewed MACs to determine whether the contractors had made any changes to their processes since responding to our survey.

Determining Utilization of Stelara in Medicare Part B, Part C, and Part D. MACs used publicly available data from CMS's Medicare Part B and Part D Spending by Drug datasets for years 2014-2018 to determine whether Stelara was usually self-administered. In their analysis, MACs assumed that all Part D utilization represented self-administration. Part D data does not allow for the identification of enrollees who received assistance from a caregiver, family member, or friend in administering Stelara. OIG obtained data from the same sources; made the same assumption for Part D utilization; and replicated the MACs' analysis for years 2019 and 2020.

Given the limitations in the publicly available data, OIG also conducted an independent analysis that included Part C encounter data, i.e., records of when an MA enrollee received Stelara in a doctor's office or hospital outpatient setting. Using Part B claims, Part C (i.e., MA) encounter data, and Part D prescription drug encounter (PDE) data, we calculated the proportions of Medicare enrollees who received Stelara injections from a physician (i.e., Part B and MA office visits) versus when they received it from a pharmacy and self-administered at home (i.e., Part D) for calendar years 2016 through 2022. To do this, we divided the total number of enrollees who received Stelara solely during an office visit (i.e., Part B claims and Part C encounter data) by the total number of enrollees who received Stelara in Medicare overall (i.e., both office visit and pharmacy). We repeated this analysis for enrollees who received Stelara solely from a pharmacy and self-administered at home. A small percentage of

enrollees received Stelara in both types of settings in a given year, i.e., had Stelara injected by a provider and also self-administered. Because CMS has not provided guidance on how to treat enrollees who fit this criterion, we categorized them separately.

Limitations

Because we did not conduct a medical record review, this analysis relied on the accuracy of Part B claims, Part C encounter data, and Part D PDE records for drug utilization. Our analysis assumed that Part D utilization of Stelara solely represented instances in which the drug was obtained from a pharmacy and self-administered. Part D PDE data does not allow for the identification of enrollees who received assistance from a caregiver, family member, or friend when administering Stelara.

Standards

We conducted this study in accordance with the *Quality Standards for Inspection and Evaluation* issued by the Council of the Inspectors General on Integrity and Efficiency.

FINDINGS

MACs did not use complete and timely utilization data when making Part B coverage decisions for Stelara

When revisiting their earlier coverage determinations for Stelara, MACs reported they primarily relied on two publicly available datasets (one for Part B and one for Part D) published by CMS that summarize Medicare spending by drug. However, limitations inherent to these datasets raise questions about their use for this purpose.

The CMS public datasets used by MACs did not account for physician-administered Stelara paid under Medicare Advantage, resulting in an artificially higher proportion of enrollees who self-administer at home. In determining whether a drug such as Stelara is "usually" self-administered and therefore ineligible for Part B coverage, CMS policy states that the criterion applies to all Medicare enrollees who use the drug.[14] However, the publicly available CMS data used by MACs did not include Part C encounter data, meaning that MACs were unable to account for a potentially large segment of the population—MA enrollees who opted to have a physician administer their injections. In other words, using the Part B and Part D data published through CMS's Drug Dashboard resulted in an artificially higher proportion of enrollees who self-administered Stelara because the data (1) did not include MA enrollees who receive Stelara in a professional setting but (2) did include MA enrollees who obtain the drug from a pharmacy. In conducting our own analysis, OIG was able to use Part C encounter data for Stelara to address this limitation. See Exhibit 1.

Exhibit 1: Datasets used by MACs did not include all Medicare enrollees who received Stelara injections in a professional setting

	Physician-Administered		Self-Administered	
Medicare Enrollee Groups	**Part B and Part D**	**MA and MA-PD**	**Part B and Part D**	**MA and MA-PD**
MAC Analysis	✓	✗	✓	✓
OIG Analysis	✓	✓	✓	✓

Source: OIG analysis of CMS's Medicare Part B and Part D Spending by Drug datasets, Medicare Part B claims, Part C encounter data, and Part D PDE claims.

When OIG interviewed MACs in August and September 2024 to determine whether processes had changed since the Stelara decision, some reported they now have additional data sources available, including CMS's Integrated Data Repository and One Program Integrity Business Data Mart (One PI), which contain Part C encounter data along with other Medicare data.[15] However, only one MAC responded that it is currently able to obtain Part C encounter data utilization through these systems. The remaining six MACs said they could not or have not attempted to obtain Part C encounter data through these sources.[16]

Using CMS's public datasets caused MACs to double-count certain enrollees. In 2016, just 374 Medicare enrollees (4 percent) received Stelara in both a professional setting (i.e., physician's office or hospital outpatient department) and a pharmacy. In 2021, over 3,000 enrollees (13 percent) did so. CMS's publicly available Medicare Part B and Part D datasets independently aggregate the number of enrollees who received the drug, meaning that a single patient could appear in both datasets. Therefore, when MACs calculated the proportion of Medicare enrollees self-administering the drug—and those who had Stelara physician-administered—enrollees who did both were double-counted. As previously noted, CMS currently does not provide guidance to the MACs on how to categorize an enrollee when there is evidence of both self- and physician administration.

When OIG spoke to MACs in 2024, two reported having the capability to identify enrollees with evidence of both self-administration and physician administration but noted that they do not do so regularly. All other MACs responded that they have not performed an analysis to assess double-counting enrollees or were unsure of whether their data sources would allow them to do so.

Availability of timely data was also a challenge. CMS updates its Part B and Part D Spending by Drug datasets annually; however, data are on a 1-to-2-year lag. For example, as of November 2024, the latest available data in each dataset are for 2022. When reassessing their determination of Stelara in early 2020, MACs found that Part D accounted for more than 50 percent of the total utilization each year from 2014 through 2018—the most recent data available at that time—and therefore Stelara did not meet the criteria for coverage under Part B. However, as OIG's analysis will show, utilization patterns for drugs such as Stelara may change quickly and using the most current data would lead to better-informed coverage decisions.

According to MACs, the CMS datasets available in 2024 (i.e., the Integrated Data Repository and One PI) provide access to more current data. Even those sources exhibit some degree of data lag, but this may be unavoidable in part due to the maximum period for submission of all Medicare fee-for-service claims being 12 months from the date of service.[17] However, historically, 90 percent of Medicare fee-for-service claims are submitted within 3 months, while MA encounter data submission is less timely with 90 percent of MA encounters submitted within 12 months.[18]

None of CMS's datasets enable MACs to determine conclusively how many enrollees received assistance administering Part D drugs (i.e., administered by caregivers). There may be instances in which patients receive assistance administering a drug that they obtain under Medicare Part D (i.e., from a pharmacy). CMS instructs MACs that when determining if a drug is "usually" self-administered, they should include only the patients themselves and not other individuals such as spouses, friends, or caregivers. (See Appendix B for additional details about CMS guidance on this issue.) However, there is no conclusive way for MACs to identify all enrollees in these circumstances using Medicare data. MACs generally assume that all Part D utilization (i.e., Part D PDE claims) represents self-administration. For the same reason, OIG also could not identify how many enrollees had their Part D-covered Stelara injections administered by caregivers, and we assumed self-administration for all Part D utilization.

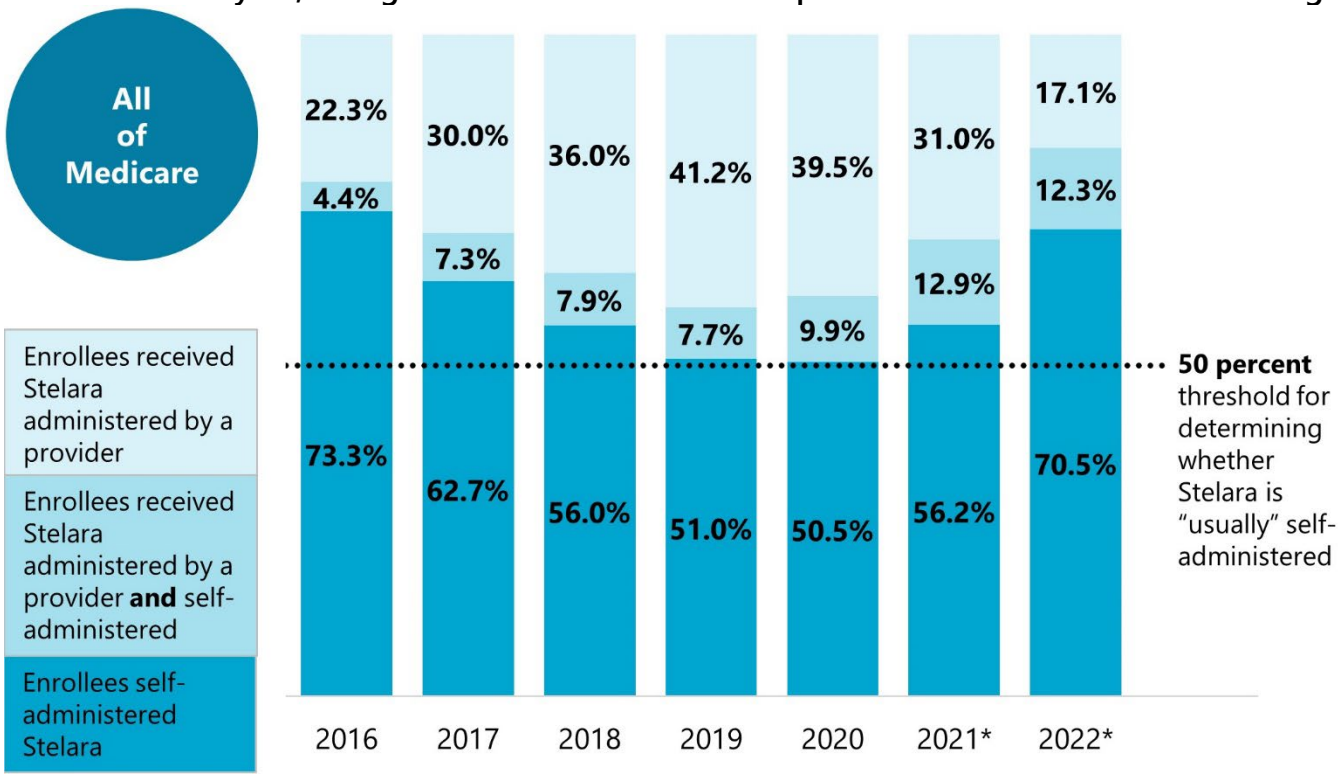
OIG analysis of more complete and timely data shows that Stelara was trending toward—and came very close to meeting—the utilization threshold for Part B coverage between 2016 and 2020

Medicare policy generally requires that a drug not be covered under Part B if it is self-administered by more than 50 percent of all enrollees who receive it.[19] Given the limitations in the data used by MACs when making coverage determinations, OIG re-analyzed Stelara claims and determined that (1) even with substantial growth in the number of enrollees who opted for physician administration, the coverage decision made by the MACs appears to align with current guidelines, but (2) the MAC analysis still overestimated the rate of self-administration by several percentage points. Because these data limitations are not unique to Stelara, the overestimation of self-administration rates could result in an inaccurate coverage determination for other drugs that are sometimes self-administered and sometimes physician-administered.

In 2019 and 2020, the proportion of enrollees who solely obtained Stelara under Part D came within a single point of the 50-percent Part B coverage threshold

From 2016 to 2022, the percentage of enrollees who self-administered Stelara (i.e., paid under Part D) never fell below 50 percent. However, as utilization patterns for the drug shifted, the percentage of enrollees who solely self-administered the drug fell to 51.0 and 50.5 percent in 2019 and 2020, respectively, down from a high of 73.3 percent in 2016. See Exhibit 2. As noted previously, the MACs' analyses—and OIG's—assumed that all utilization under Part D represented self-administration of Stelara because Medicare PDE claims data do not capture whether the enrollee self-injected the drug independently or received help from a caregiver.

Exhibit 2: From 2016 to 2020, the proportion of Medicare enrollees receiving Stelara solely through pharmacies for self-administration decreased each year, though it never fell below the 50 percent threshold for Part B coverage



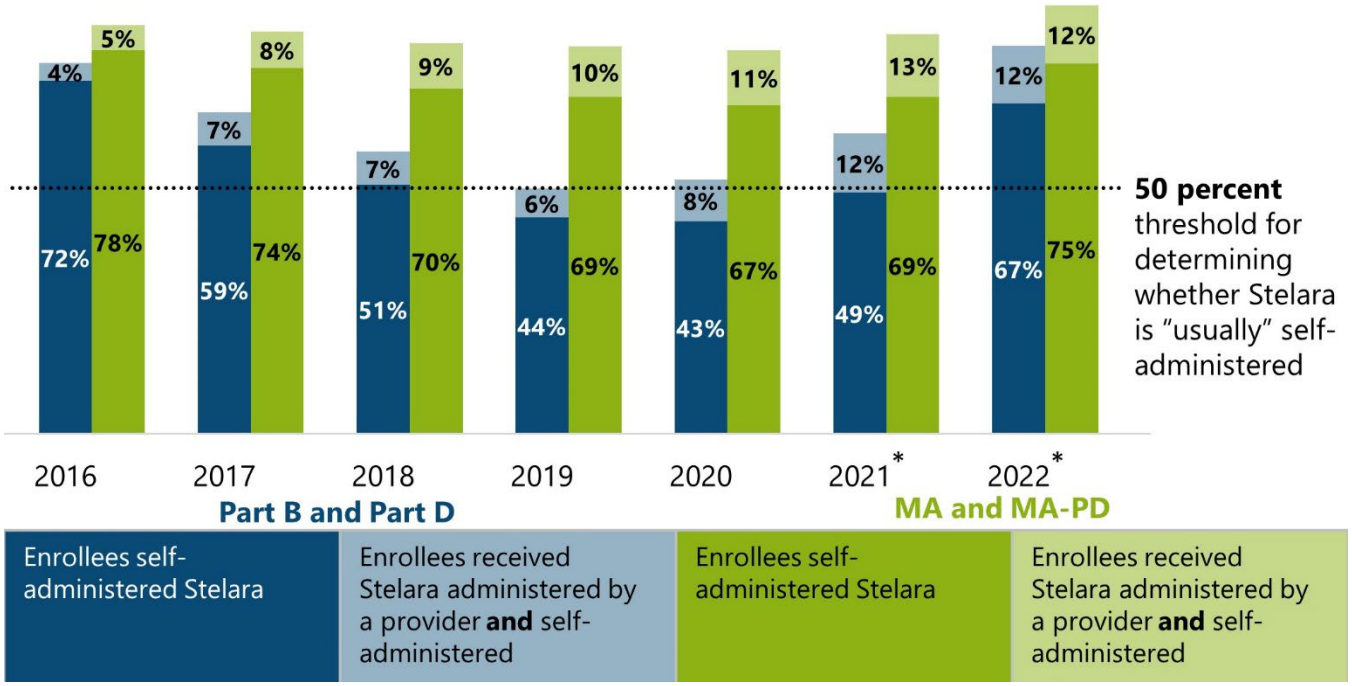
Source: OIG analysis of Medicare Part B claims, Part C encounter data, and Part D PDE claims.
*Note: MACs placed the subcutaneous versions of Stelara on their self-administered drug exclusion lists and no longer covered those versions under Part B, with effective dates between October 15, 2021, and November 1, 2022.
Note: CMS currently does not provide guidance to the MACs on how to categorize an enrollee when there is evidence of both self- and physician administration when making coverage determinations.

Although a majority of enrollees consistently chose to self-administer (i.e., under Part D) during the period under review, the percentage who instead opted to have Stelara administered by their doctors (i.e., paid through either Part B or Part C) saw a steady and dramatic increase from 2016 through 2020. In 2016, more than 8,500 enrollees received Stelara under Medicare, with 22 percent getting injections solely in doctors' offices or hospital outpatient departments. Within 3 years, the proportion of enrollees choosing the physician-administered route nearly doubled. Specifically, 41 percent of the approximately 18,500 enrollees with a Stelara claim in 2019 had all of their injections administered by a health care professional, with another 8 percent receiving the drug both through a doctor and through a pharmacy at various points of the year.

The growth trend began to reverse after 2020, the year MACs announced that subcutaneous versions of Stelara would be placed on the self-administered drug exclusion list—with effective dates between October 15, 2021, and November 1, 2022—thus ending coverage under Part B.

Individuals enrolled in original Medicare were less likely to obtain Stelara through a pharmacy to self-administer than were those with MA plans. Between 2016 and 2022, enrollees with original Medicare Part B plus standalone Part D plans were less likely to obtain Stelara from a pharmacy and self-administer at home than were MA enrollees. For example, 44 percent of original Medicare enrollees received Stelara solely through pharmacies in 2019, with another 6 percent having claims through both pharmacies and physicians. In contrast, that same year, 69 percent of MA enrollees received their Stelara solely through a pharmacy, with an additional 10 percent having both pharmacy and physician-administered claims. See Exhibit 3.

Exhibit 3: In 2019 and 2020, less than 50 percent of enrollees with original Medicare Part B and standalone Part D drug plans solely obtained Stelara through a pharmacy for self-administration at home, compared to two-thirds of MA enrollees for the same years



Source: OIG analysis of Medicare Part B claims, Part C encounter data, and Part D PDE claims.
*Note: MACs placed the subcutaneous versions of Stelara on their self-administered drug exclusion lists and no longer covered those versions under Part B, with effective dates between October 15, 2021, and November 1, 2022.

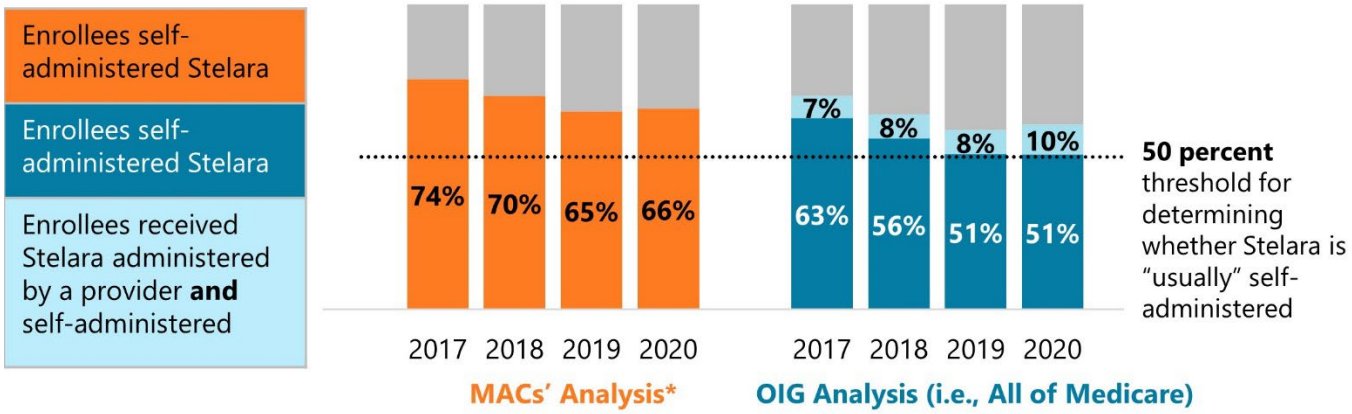
The difference in what enrollees pay for Stelara under Part D versus Part B may explain why more enrollees in original Medicare opted to have the drug administered by a Part B physician. OIG previously found that when Stelara was being covered under Part B and administered by physicians in their offices, it was costing the Medicare program and some original Medicare enrollees far less than when it was being covered under Part D and enrollees were self-administering the drug at home (see OEI-BL-19-00500). For example, from 2016–2022, Medicare paid between $3,000 and $15,000 more under Part D than under Part B for a typical 90 mg dose of Stelara.

Some Part D enrollees also faced substantially higher out-of-pocket costs for the drug. These cost differences likely influenced where patients chose to obtain the drug—with certain enrollees having strong incentives to prefer having their physicians administer their injections due to lower cost-sharing under Medicare Part B.

Missing data for Medicare Advantage enrollees led MACs to overestimate self-administered Stelara usage by as much as 16 percentage points

As described above, when MACs reevaluated their Medicare Part B coverage policy for Stelara in 2020, they used publicly available Medicare Part B and Part D utilization data to determine the number of enrollees who received the drug in pharmacies compared to physicians' offices and hospital outpatient departments. The Part D data used for pharmacies includes all enrollees (i.e., those in original Medicare as well as those with MA). However, for professional settings, MACs used only Part B data (i.e., those with original Medicare) because utilization data related to office visits for MA enrollees (i.e., Part C) are not publicly available from CMS. As a result, the undercounting of these MA enrollees inflated MAC calculations of the overall proportion who opted to self-administer Stelara by 4-16 percentage points, depending on whether enrollees who obtained Stelara in multiple settings are included in the self-administered or physician-administered category. See Exhibit 4. As noted earlier, despite these discrepancies, the coverage decision made by the MACs appears to align with current guidelines; however, the over-estimation of self-administration rates could result in an inaccurate coverage determination for similar drugs in the future.

Exhibit 4: Because of data limitations, MACs' analysis overestimated the number of enrollees who self-administered Stelara by several percentage points



Source: OIG analysis of CMS's Medicare Part B and Part D Spending by Drug datasets, Medicare Part B claims, Part C encounter data, and Part D PDE claims.

*Note: MACs provided a record of analysis using CMS's Medicare Part B and Part D Spending by Drug datasets for years 2014-2018. OIG performed analysis for years 2019 and 2020 using the same datasets and methodology. Given the limitations in the publicly available data used by the MACs, OIG also conducted an independent analysis that included Part C encounter data. When comparing the numbers presented in this exhibit, the difference between the MAC's and OIG's analysis (i.e., 4-15 percentage points) does not match the range presented in text (i.e., 4-16 percentage points) due to rounding.

CONCLUSION AND RECOMMENDATIONS

It is critically important that MACs make Part B coverage determinations for drugs such as Stelara using complete and timely data, as these decisions can have major cost implications for both Medicare and its enrollees. For example, in 2022, Medicare paid an average of almost $15,000 for a typical 90 mg injection of Stelara under Part B (i.e., physician-administered) and nearly $30,000 for that same injection under Part D (i.e., self-administered). Some enrollees also faced substantially higher out-of-pocket costs for Stelara through Part D. Further, coverage determinations influence where patients receive their injections (at home or in a professional setting), which may have health and quality of care implications for some enrollees.

However, our findings illustrate some important limitations in the utilization data that MACs use to determine whether a drug is "usually" self-administered. Most notably, MACs are not using—and most MACs report they cannot readily obtain—MA encounter data (i.e., Part C utilization data on physician administration in managed care) in their analysis. However, MA utilization through pharmacies (i.e., Part D) is being included. OIG's analysis demonstrated that including the "missing" MA enrollees increased the calculated rate of Stelara use in physicians' offices by up to 16 percentage points. While our analysis is specific to Stelara, the underlying data limitations we identified would apply to the growing number of injectable drugs that are sometimes self-administered and sometimes administered by physicians.

Accurate coverage determinations for Part B drugs are critical, both for the health of the people served by the program and in terms of cost to Medicare and its enrollees. OIG appreciates CMS's recent efforts to engage with stakeholders regarding potential changes to coverage policies in future rulemaking. In the interim, given the importance of the data-related issues identified in this report, we recommend that CMS:

Assist MACs in obtaining more complete and timely utilization data with which to make coverage determinations

CMS should assist MACs in obtaining complete utilization data for MA enrollees—specifically when these enrollees receive drugs administered by a physician in a doctor's office or hospital outpatient setting—to ensure that MAC calculations make appropriate comparisons. As demonstrated by our analysis, excluding MA enrollees can skew the calculations of utilization rates by several percentage points. Additionally, CMS should assist MACs in obtaining more timely data related to utilization in both Part B and Part D. As illustrated in this report, utilization patterns may shift quickly, meaning that improved availability of current data could lead to more informed decisions.

Provide guidance on how MACs should account for enrollees who receive injections in both home and professional settings when performing their comparisons

CMS should also instruct MACs on how to categorize an enrollee who has evidence of both self- and physician administration.

AGENCY COMMENTS AND OIG RESPONSE

CMS concurred with our first recommendation to assist MACs in obtaining more complete and timely utilization data with which to make coverage determinations. CMS stated that it will work with MACs regarding additional available data sources to assist the contractors in obtaining more complete and timely data with which to make coverage determinations.

In response to our second recommendation—that CMS provide guidance on how MACs should account for enrollees who receive injections in both home and professional settings when performing their comparisons—CMS neither concurred nor nonconcurred. Instead, CMS stated that its Calendar Year 2024 Physician Fee Schedule proposed rule included a request for information regarding drugs and biologicals which are not usually self-administered by the patient and that the agency will take OIG's findings and recommendations into consideration as it works toward potentially developing changes to these policies in the future. OIG requests that CMS clarify in its Final Management Decision its concurrence or nonconcurrence with our second recommendation and the steps it is taking to implement it.

Given the importance of correct coverage determinations for the program and its enrollees, OIG appreciates CMS's commitment to ensuring that MACs have complete and timely data. OIG looks forward to continued engagement with CMS as the agency addresses broader considerations related to coverage policies for Part B drugs.

For the full text of CMS's comments, see the Agency Comments appendix at the end of the report.

APPENDICES

Appendix A: Stelara Approvals and Product Versions

Stelara was initially approved by FDA in September 2009 to treat moderate-to-severe plaque psoriasis. Four years later, FDA approved Stelara to treat psoriatic arthritis, and in September 2016, Crohn's disease. Most recently, in October 2019, Stelara was approved for ulcerative colitis.

Originally, the manufacturer of Stelara, Janssen Biotech, marketed only subcutaneous versions of the drug. According to the manufacturer, these versions may be self-administered by the patient at home after proper training in subcutaneous injection techniques.[20] In September 2016, Janssen also began marketing an infused version of Stelara specifically for Crohn's disease. The initial infusion of Stelara for Crohn's disease must be administered by a health care professional. According to the manufacturer, patients suffering from Crohn's should only receive a single infusion of Stelara and then would be prescribed the subcutaneous version for maintenance doses. The recently approved treatment regimen for ulcerative colitis is the same as that for Crohn's disease.[21]

As of March 2024, Janssen Biotech manufactures four versions of Stelara. The three subcutaneous versions include a 45 mg single dose vial, a 45 mg single dose prefilled syringe, and a 90 mg single-dose prefilled syringe. The fourth product is a 130 mg single use vial for intravenous infusion.

Appendix B: Medicare Part B Coverage Determinations

A limited number of prescription drugs—generally, those that are injected or infused in physicians' offices or hospital outpatient settings—are covered under Medicare Part B.[22] With certain exceptions, Part B does not cover self-administered drugs, including drugs that are primarily self-injected.[23] 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.

Under Medicare rules, infused Stelara would be considered a Part B-covered drug as it can only be administered by a health care professional. However, Part B coverage determinations for subcutaneous versions of Stelara that, for various reasons, are injected by a health care professional (i.e., rather than self-administered by the patient) are governed by a more complex set of rules.

Private insurers, known as Medicare Administrative Contractors (MACs), process Part A and Part B claims for Medicare fee-for-service enrollees. CMS instructs MACs to follow guidelines in the Medicare Benefit Policy Manual when applying exclusions for drugs that are usually self-administered by the patient. MACs develop and publish self-administered drug exclusion lists of drugs that should not be paid under Part B—even when administered by a physician. Each individual MAC is responsible for making its own coverage determination on each drug.

According to the Medicare Benefit Policy Manual, "[a]bsent evidence to the contrary, [MACs should] presume that drugs delivered by subcutaneous injection are self-administered by the patient."[24] However, MACs may consider the type of condition (i.e., acute vs. chronic) and frequency of administration in reaching this determination. The Medicare Benefit Policy Manual also states:

> [Part B] covers drugs that are furnished "incident to" a physician's service provided that the drugs are not usually self-administered by the patients who take them…[f]or the purposes of applying this exclusion, the term "usually" means more than 50 percent of the time for all Medicare [enrollees] who use the drug.[25]

In other words, if a drug is self-administered by more than half of the Medicare enrollees who use it, then the drug should not be covered under Part B and Part B should make no payment for the drug, even in instances in which it was actually physician-administered.

There may be instances in which patients are physically unable to self-administer a drug. CMS instructs MACs that when determining self-administration, they should include only the patients themselves and not other individuals such as spouses, friends, or caregivers.[26] Guidance states: "In evaluating whether [enrollees] as a collective whole self-administer, individual [enrollees] who do not have the capacity to self-administer any drug due to a condition other than the condition for which they are taking the drug in question are not considered. For example, an individual afflicted with paraplegia or advanced dementia would not have the capacity to self-

administer any injectable drug, so such individuals would not be included in the population upon which the determination for self-administration by the patient was based. Note that some individuals afflicted with a less severe stage of an otherwise debilitating condition would be included in the population upon which the determination for "self-administered by the patient" was based; for example, an early onset of dementia."[27]

Additionally, CMS has instructed MACs to use peer-reviewed medical literature, standards of medical practice, evidence-based practice guidelines, FDA-approved labels, and package inserts when making a determination as to whether a drug is usually self-administered.[28] However, CMS has noted that the fact that the FDA label for a drug includes instructions for self-administration is not, by itself, a determining factor that a drug is subject to exclusion from Part B coverage.[29]

MACs' Initial Review and Assessment of Stelara. Because utilization data was not readily available when the HCPCS codes for Stelara were established in 2009, MACs had to rely on other factors outlined in CMS guidance such as the frequency of administration of Stelara; whether Stelara treats acute conditions; and evidence from peer-reviewed medical literature, standards of medical practice, evidence-based practice guidelines, FDA-approved labels, and approved package inserts. For example, in response to OIG's survey, one MAC stated that "[w]hen Stelara was initially reviewed, the frequency of administration did not support that it was a self-administered drug. We did not make a determination of its inclusion to the [self-administered drug exclusion] list until we had sufficient data to support that it was being used as a self-administered drug by more than 50 [percent] of Medicare [enrollees]."

MACs' Updated Review and Assessment of Stelara. In early 2020, MACs conducted analysis using publicly available Medicare Part B and Part D utilization data related to the subcutaneous versions of Stelara.[30, 31] The MACs found that more than 50 percent of Medicare enrollees were self-administering the drug each year from 2014 through 2018.

In addition to the results of their utilization analysis, all of the MACs reported reviewing and considering other factors—outlined in CMS's Medicare Benefit Policy Manual. The other factors included:

- **Acute Condition.** Every MAC reported that it considered whether the conditions Stelara is approved to treat are acute or chronic. For example, one MAC responded that its review of the FDA-approved labeling for Stelara identified that the drug is indicated for chronic (i.e., non-acute) conditions. CMS guidance states that "[i]f the condition [is chronic or] longer term, it would be more likely that the patient would self-administer the drug."[32]

- **Frequency of Administration.** Every MAC reported that it reviewed and considered the frequency of administration for Stelara. For example, one MAC stated that "the frequency [of administration], considered in isolation, makes it

less likely that Stelara is a self-administered drug...[; however,] Stelara is likely self-administered when the criteria...are considered as a whole."

- **Evidentiary Criteria.** Every MAC reported that it reviewed the FDA-approved label and/or package insert for Stelara. Only two MACs reported that they reviewed and considered additional evidentiary criteria from medical literature, standards of medical practice, or evidence-based practice guidelines. For example, one MAC reported that it reviewed practice guidelines from the American College of Rheumatology and National Psoriasis Foundation. The other MAC reviewed resources and education for self-administration, available on the manufacturer's website for Stelara, which demonstrated that "self-administered use is acceptable and common practice."

On the basis of their analyses, MACs concluded that Stelara did not meet the criteria for coverage under Part B. On April 7, 2020, MACs unanimously agreed to delay the implementation of a coverage change for Stelara due to the COVID-19 public health emergency. Each MAC has now placed subcutaneous versions of Stelara (HCPCS code J3357) on its published self-administered drug exclusion list with effective dates between October 15, 2021, and November 1, 2022, effectively removing Part B coverage.

Appendix C: Agency Comments

Following this page are the official comments from CMS.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Centers for Medicare & Medicaid Services

Administrator
Washington, DC 20201

DATE: January 16, 2025

TO: Ann Maxwell
Deputy Inspector General for Evaluation and Inspections
Office of Inspector General

FROM: Chiquita Brooks-LaSure
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: Medicare Contractors Did Not Use Complete and Timely Utilization Data When Making Part B Coverage Determinations for Stelara (OEI-BL-19-00501)

The Centers for Medicare & Medicaid Services (CMS) appreciates the opportunity to review and comment on the Office of Inspector General's (OIG) draft report.

CMS serves the public as a trusted partner and steward, dedicated to advancing health equity, expanding coverage, and improving health outcomes. As such, CMS strives to maximize the affordability and availability of drugs for individuals with Medicare while protecting taxpayer dollars.

Section 1861(s)(2)(A) of the Social Security Act allows Medicare to pay for services and supplies, including drugs and biologicals (hereafter, drugs) that are not usually self-administered by the patient, which are furnished as ''incident to'' a physician's professional service. Section 112 of the Benefits, Improvements & Protection Act of 2000 (BIPA) (Pub. L. 106–554, December 21, 2000) amended the above-referenced sections 1861(s)(2)(A) and 1861(s)(2)(B) of the Act, which formerly referred to drugs ''which cannot be self-administered,'' to read, ''which are not usually self- administered.'' Drugs that are ''usually self-administered'' are thus statutorily excluded from coverage and payment under Part B under the ''incident to'' benefit.

CMS has provided definitions and other guidance for Medicare Administrative Contractors (MACs) regarding determinations on drugs that are ''not usually self-administered by the patient'' in Chapter 15, Section 50.2 of the Medicare Benefit Policy Manual. Chapter 15 also describes the evidentiary criteria that MACs should use in determining whether a drug is usually self-administered. The guidance directs MACs to publish a description of the process they use to make that determination, and to publish a list of the drugs that are subject to the self-administered exclusion on their website. The guidance also requires that this list include the data and rationale that led to the determinations. This list is referred to as the ''self-administered drug (SAD) list,'' and each MAC maintains their own version of the list, which is applicable to that MAC's area of jurisdiction. While the lists are often similar between MACs, they are not identical. Drugs that are put on a SAD list are excluded from Part B coverage, but in those situations, they are almost always covered by Medicare Part D prescription drug coverage.

The Calendar Year 2024 Physician Fee Schedule proposed rule (88 FR 52387) included a request for information regarding drugs and biologicals which are not usually self-administered by the

patient. CMS appreciated the comments related to these policies and for sharing the desire to improve health equity and healthcare access for Medicare enrollees. CMS plans to consider all comments and looks forward to continued discussions with interested parties as we work toward potentially developing changes to these policies in the future.

Similarly, we appreciate the OIG's work on this area and look forward to working collaboratively on this and other issues in the future.

The OIG's recommendations and CMS' responses are below.

OIG Recommendation

The OIG recommends that CMS assist MACs in obtaining more complete and timely utilization data with which to make coverage determinations.

CMS Response

CMS concurs with this recommendation. As stated in the OIG's report there are additional data sources available, outside of the publicly available drug dashboard that was reportedly used by most MACs when making their coverage determinations. CMS will work with the MACs regarding the available data sources to assist in obtaining more complete and timely utilization data with which to make coverage determinations.

OIG Recommendation

The OIG recommends that CMS provide guidance on how MACs should account for enrollees who receive injections in both home and professional settings when performing their comparisons.

CMS Response

Guidance on how MACs should account for enrollees who receive injections in both home and professional settings when performing their comparisons may be appropriate for notice and comment rulemaking. CMS included a request for information regarding drugs and biologicals which are not usually self-administered by the patient in the Calendar Year 2024 Physician Fee Schedule proposed rule. CMS will take OIG's findings and recommendations into consideration as we work toward potentially developing these policies in the future.

ABOUT THE OFFICE OF INSPECTOR GENERAL

Office of Inspector General
https://oig.hhs.gov

The mission of the Office of Inspector General (OIG) is to provide objective oversight to promote the economy, efficiency, effectiveness, and integrity of the Department of Health and Human Services (HHS) programs, as well as the health and welfare of the people they serve. Established by Public Law No. 95-452, as amended, OIG carries out its mission through audits, investigations, and evaluations conducted by the following operating components:

The Office of Audit Services. OAS provides auditing services for HHS, either by conducting audits with its own audit resources or by overseeing audit work done by others. The audits examine the performance of HHS programs, funding recipients, and contractors in carrying out their respective responsibilities and provide independent assessments of HHS programs and operations to reduce waste, abuse, and mismanagement.

The Office of Evaluation and Inspections. OEI's national evaluations provide HHS, Congress, and the public with timely, useful, and reliable information on significant issues. To promote impact, OEI reports also provide practical recommendations for improving program operations.

The Office of Investigations. OI's criminal, civil, and administrative investigations of fraud and misconduct related to HHS programs and operations often lead to criminal convictions, administrative sanctions, and civil monetary penalties. OI's nationwide network of investigators collaborates with the Department of Justice and other Federal, State, and local law enforcement authorities. OI works with public health entities to minimize adverse patient impacts following enforcement operations. OI also provides security and protection for the Secretary and other senior HHS officials.

The Office of Counsel to the Inspector General. OCIG provides legal advice to OIG on HHS programs and OIG's internal operations. The law office also imposes exclusions and civil monetary penalties, monitors Corporate Integrity Agreements, and represents HHS's interests in False Claims Act cases. In addition, OCIG publishes advisory opinions, compliance program guidance documents, fraud alerts, and other resources regarding compliance considerations, the anti-kickback statute, and other OIG enforcement authorities.

ENDNOTES

[1] Specifically, Stelara is indicated for the treatment of (1) patients 6 years and older with active psoriatic arthritis; (2) patients 6 years or older with moderate to severe plaque psoriasis who are candidates for phototherapy or systemic therapy; (3) adult patients with moderately to severely active Crohn's disease; and (4) adult patients with moderately to severely active ulcerative colitis.

[2] A standalone Medicare prescription drug plan adds drug coverage to Original Medicare (Parts A and B), some Medicare Cost Plans, some private fee-for-service plans, and medical savings account plans. An enrollee must have Medicare Part A (i.e., hospital insurance) and/or Medicare Part B (i.e., medical insurance) to join a standalone Medicare prescription drug plan. See https://www.medicare.gov/drug-coverage-part-d/how-to-get-prescription-drug-coverage for more details.

[3] A Medicare Advantage prescription drug (i.e., MA-PD) plan is a Medicare Advantage plan that includes prescription drug coverage. Most MA plans (but not all) offer prescription drug coverage.

[4] Social Security Act § 1860D-2.

[5] Social Security Act §§ 1861(s)(2) and 1832.

[6] 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) regarding coverage of drugs and biologicals that are "not usually self-administered." Also, see 42 CFR § 414.900(b) and the Medicare Benefit Policy Manual, ch. 15 § 50. At Section 50.2 of the same manual, CMS describes how contractors can determine whether a drug is "usually self-administered."

[7] Medicare Benefit Policy Manual, ch. 15, § 50.2(C).

[8] There are 12 A/B MAC jurisdictions in the United States. However, there are only seven unique MACs because five are responsible for two jurisdictions. The seven MACs are (1) CGS Administrators, LLC; (2) First Coast Service Options, Inc.; (3) National Government Services, Inc.; (4) Noridian Healthcare Solutions, LLC; (5) Novitas Solutions, Inc.; (6) Palmetto GBA, LLC; and (7) Wisconsin Physicians Service Government Health Administrators.

[9] Medicare Benefit Policy Manual, ch. 15, § 50.2(C).

[10] Medicare Benefit Policy Manual, ch. 15, § 50.2(A)-(F).

[11] Three MACs—National Government Services, Inc.; Noridian Healthcare Solutions, LLC; and Palmetto GBA, LLC—published Stelara on their self-administered drug exclusion list with an effective date of October 15, 2021. Wisconsin Physicians Service Government Health Administrators published an effective date of November 15, 2021. First Coast Service Options, Inc. and Novitas Solutions, Inc. published an effective date of June 6, 2022. CGS Administrators, LLC published an effective date of November 1, 2022.

[12] 88 FR 52262, 52387 (August 7, 2023).

[13] 88 FR 78818, 79045-79046 (November 16, 2023).

[14] Medicare Benefit Policy Manual, ch. 15, § 50.2(C).

[15] CMS's One Program Integrity Business Data Mart provides access to current and historical Medicare and Medicaid data from the Integrated Data Repository (IDR). The IDR is a high-volume data warehouse integrating Parts A, B, C, D, and DME claims, and enrollee and provider data sources, along with ancillary data such as contract information, risk scores, and many other types. For more information, see https://www.cms.gov/files/document/dasg-leaflet-one-pi.pdf.

[16] According to CMS, the lone MAC that reported being able to obtain Part C encounter data at the time of OIG's interviews notified the agency that subsequent to our interview, the contractor shared the data with the other MACs and offered to do so on an ongoing basis.

[17] Section 6404 of the Patient Protection and Affordable Care Act (the Affordable Care Act) reduced the maximum period for submission of all Medicare fee-for-service claims to no more than 12 months, or 1 calendar year, after the data of service.

[18] CMS. *Preliminary Medicare COVID-19 Data Snapshot.* Accessed at https://www.cms.gov/files/document/medicare-covid-19-data-snapshot-fact-sheet-september2020.pdf on November 4, 2024.

[19] Social Security Act § 1861(s)(2) and Medicare Benefit Policy Manual, ch. 15, § 50.2(C).

[20] Janssen Pharmaceutical Companies. *Stelara (ustekinumab) [label]*. FDA website. Revised March 2024. Accessed at https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/125261s163lbl.pdf on April 17, 2024.

[21] Janssen Pharmaceutical Companies. *Stelara (ustekinumab) [label]*. FDA website. Revised March 2024. Accessed at https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/125261s163lbl.pdf on April 17, 2024.

[22] Social Security Act §§ 1861(s)(2) and 1832.

[23] 42 CFR § 414.900(b) and the Medicare Benefit Policy Manual, ch. 15, § 50.

[24] Medicare Benefit Policy Manual, ch. 15, § 50.2(C)(3).

[25] Medicare Benefit Policy Manual, ch. 15, §§ 50 and 50.2(C). Medicare payment contractors are required to perform this analysis across all indications of the drug.

[26] Medicare Benefit Policy Manual, ch. 15, § 50.2(E).

[27] Medicare Benefit Policy Manual, ch. 15, § 50.2(E).

[28] Medicare Benefit Policy Manual, ch. 15, § 50.2(F).

[29] Medicare Benefit Policy Manual, ch. 15, § 50.2(F).

[30] CMS's Medicare Part B by Drug dataset presents information on spending for drugs administered in doctors' offices and other outpatient settings by physicians and other health care providers to Medicare Part B enrollees. This dataset is based on information gathered from CMS administrative claims data for Medicare beneficiaries enrolled in the Part B program available from the CMS Chronic Condition Data Warehouse. The data are summarized from 100% final-action Part B institutional and non-institutional claims and limited to drugs identified on the Medicare Average Sale Price drug pricing data available publicly.

[31] CMS's Medicare Part D Spending by Drug dataset presents information on spending for drugs prescribed to Medicare beneficiaries enrolled in Part D by physicians and other health care providers. Drugs prescribed in the Medicare Part D program are drugs patients generally administer themselves. This dataset is based on information gathered from CMS administrative claims data for Medicare beneficiaries enrolled in the Part D program available from the CMS Chronic Condition Data Warehouse. The data are summarized from 100% final-action Part D prescription drug claims.

[32] Medicare Benefit Policy Manual, ch. 15, § 50.2(C)(3)(A).

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