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Medicare and Some Enrollees Paid Substantially More When Stelara Was Covered Under Part D Versus Part B

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REPORT HIGHLIGHTS

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Why OIG Did This Review

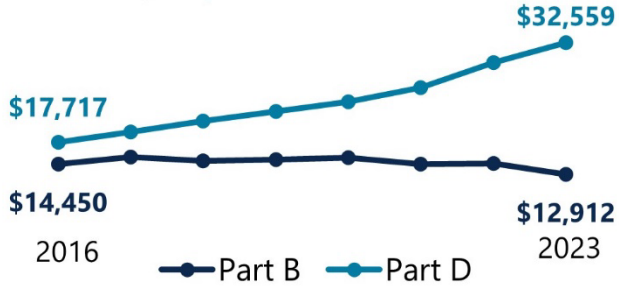
Stelara is a high-cost prescription biologic approved to treat certain autoimmune diseases. Subcutaneous (under-the-skin) versions of Stelara are typically self-injected and covered under Medicare Part D. Prior to 2023, Part B also covered subcutaneous versions of Stelara when the injection was administered by a physician; however, Medicare Administrative Contractors (MACs) now exclude Stelara injections under a policy designed to omit self-administered drugs from Part B coverage. The period during which Stelara was covered under Parts B and D provides a unique opportunity to examine how coverage determinations affect payments made by the Medicare program and costs for its enrollees.

What OIG Found

Medicare and some enrollees paid substantially more when Stelara injections were covered under Part D (i.e., self-administered) versus under Part B (i.e., administered by a physician). However, given recent coverage changes, enrollees who once opted to receive Stelara injections in their doctors' offices (i.e., through Part B) must now obtain Stelara through a pharmacy (i.e., through Part D), where they will potentially face much higher out-of-pocket costs.

In 2021, the annual cost per enrollee for Stelara was 80 percent more under Part D than Part B.

The average Part B cost for a Stelara injection has remained steady while the average Part D cost increased by 84 percent between 2016 and 2023.



Source: OIG analysis of Part B claims and Part D PDE data.
Note: Both graphs depict cost for a 90 mg injection of Stelara. Crohn's disease and ulcerative colitis require six 90 mg doses annually.

What OIG Concludes

Over the past several years, Medicare expenditures for Stelara have increased almost tenfold, from $300 million in 2016 to almost $3 billion in 2023. Our findings illustrate how differences in the methods used to set drug payment amounts under Part B (i.e., manufacturers' sales prices) versus under Part D (i.e., negotiations between plan sponsors, manufacturers, pharmacy benefit managers, and pharmacies) result in widely different payment amounts for the same drugs. As such, Part B and Part D programmatic features—such as payment amounts and available payment supports (e.g., Medigap or LIS)—can have a major effect on expenditures for Medicare and out-of-pocket costs for enrollees, and can also impact where patients choose to obtain the drug.

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 U.S. 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 subcutaneous versions are primarily self-administered but may also be given by a health care professional (see Appendix A for more details). The analysis and discussion within this report focus on the three subcutaneously injected versions. Medicare and its enrollees paid a total of $2.4 billion for Stelara in 2022—$62 million in Part B and $2.3 billion in Part D.

Medicare Coverage Determinations and Payment for Stelara

Medicare Part D. Medicare coverage for prescription drugs is primarily provided under the voluntary Part D benefit. Typically, Stelara would be covered by Part D when the drug is prescribed by a provider and dispensed by a pharmacy for self-injection at home.

Medicare enrollees typically receive drug coverage under Part D in one of two ways: (1) enrolling in a standalone prescription drug plan while maintaining other outpatient coverage under Part B or (2) enrolling in a Medicare Advantage plan (i.e., Part C) with prescription drug coverage (i.e., MA-PD).[2, 3] This evaluation primarily focuses on the cost of Stelara for Part D enrollees in category 1 only (i.e., those with standalone prescription drug plans).[4]

Pharmacy reimbursement for Part D drugs is based on negotiations between plan sponsors (i.e., private companies that offer Part D prescription drug plans), pharmacy benefit managers, drug manufacturers, and pharmacies. A Medicare Part D enrollee's cost-sharing obligations are collectively known as "out-of-pocket costs," and may include deductibles, copayments (fixed payment amounts), and coinsurance amounts (payments based on a percentage of the drug's cost).[5] In 2022, nearly half of Part D enrollees treated with Stelara were eligible for the low-income subsidy (LIS), which helps significantly lower those enrollees' out-of-pocket costs.[6]

Medicare Part B. 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.[7] With certain exceptions prescribed by law, Part B does not cover self-administered drugs, including drugs that are usually self-injected.[8, 9] The infused version of Stelara has been covered under Medicare Part B from the time it

reached the market. However, Part B coverage of the subcutaneous versions has been less straightforward.

The authority to determine whether a drug such as Stelara meets the Part B coverage requirements set by statute and Centers for Medicare & Medicaid Services (CMS) policy, including whether the drug is considered to be "usually self-administered," generally rests with Medicare Administrative Contractors (MACs).[10, 11] MACs are private insurers responsible for processing Part A and Part B claims for Medicare fee-for-service enrollees. For Stelara, the MACs originally allowed for the reimbursement of subcutaneous versions of Stelara under Part B when administered by physicians. However, MACs later updated their coverage determinations and placed the subcutaneous versions of the drug on the self-administered drug exclusion list. As a result, subcutaneous Stelara was no longer covered under Part B, with effective dates ranging by MAC from October 15, 2021, to November 1, 2022.[12]

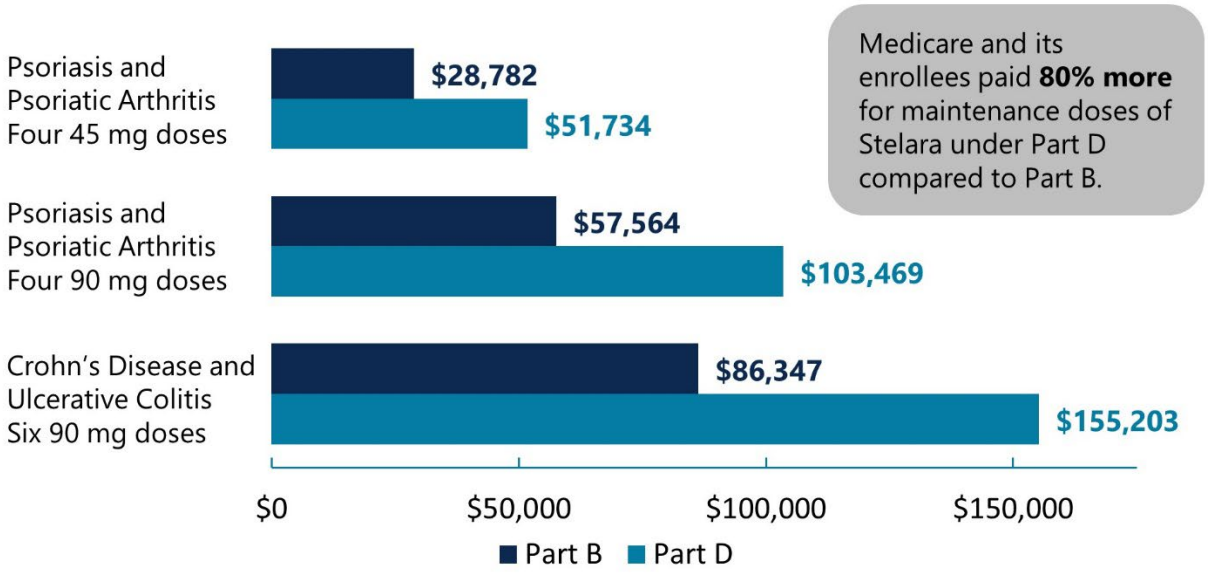
To obtain payment for Part B drugs, providers submit claims to Medicare using Healthcare Common Procedure Coding System (HCPCS) codes.[13] Medicare pays for most Part B drug HCPCS codes at 106 percent of their volume-weighted average sales prices, as reported by manufacturers.[14, 15] Generally, Medicare will pay for 80 percent of the cost for a Part B drug; the enrollee is responsible for the remaining 20 percent in the form of coinsurance.[16] However, more than 8 in 10 people (89 percent) enrolled in Medicare Part B have supplemental insurance such as Medigap, employer coverage, or Medicaid to fully or partially cover their cost-sharing requirements.[17]

FINDINGS

From 2016 to 2021, Stelara was substantially more expensive for Medicare when patients obtained injections under Part D versus Part B

From 2016 through 2021, the average Part B cost of Stelara (which is reflective of manufacturer-submitted sales data) remained relatively steady, fluctuating between approximately $14,400 and $15,500 for a typical 90 mg injection. During that same period, the average Part D cost (which is based on negotiations between Part D plans, pharmacy benefit managers, manufacturers, and pharmacies) for a single Stelara injection continually increased, rising from $17,700 to $25,900.[a, 18] As a result, in 2021, Medicare was paying 80 percent more, on average, for the same drug being used to treat the same conditions when it was obtained under Part D (i.e., through a pharmacy) instead of Part B (i.e., administered in a physician's office).[19] Furthermore, depending on the condition being treated, patients require four to six maintenance doses of Stelara each year, meaning these higher per-injection costs caused Medicare to pay tens of thousands of dollars in additional annual costs for every enrollee who received Stelara under Part D.[20] See Exhibit 1.

Exhibit 1: Annual costs for Stelara were substantially more under Part D (i.e., self-injected at home) than under Part B (i.e., received in doctors' offices).



Source: OIG analysis of 2021 Medicare Part B and Part D PDE claims data.

[a] OIG work previously found that post-point-of-sale rebates paid by manufacturers sometimes lower the costs incurred by Part D plans by a significant margin. However, in the case of Stelara, post-point-of-sale rebates did not substantially close the gap between Part B and Part D costs (i.e., the gap was reduced by less than one-third for years 2016-2021). Furthermore, because enrollee out-of-pocket cost is calculated on the basis of the drug price at the point of sale, rebates and other price concessions received after the point of sale have no effect on the amounts paid by enrollees at the pharmacy counter.

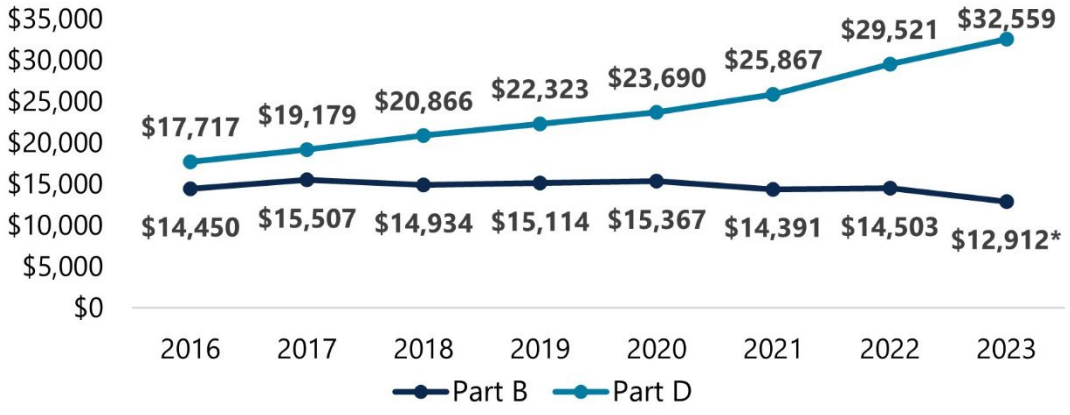
As MACs stopped covering Stelara under Part B, the cost of Stelara in Part D rose and total Medicare expenditures increased substantially

In spring of 2020, MACs re-examined the subcutaneous versions of Stelara and determined they 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.[21] Each MAC has now placed subcutaneous versions of Stelara on their published self-administered drug exclusion list with effective dates between October 15, 2021, and November 1, 2022. For more information on how the MACs conducted their assessment and the decision to apply the self-administered drug exclusion to subcutaneous Stelara, see OIG's related report OEI-BL-19-00501 (forthcoming).

The changes to Stelara coverage under Part B helped drive an increase in the number of enrollees with standalone plans receiving the drug under Part D. In 2022, more than 11,000 enrollees with standalone plans obtained their Stelara through Part D, compared to approximately 9,000 in 2021 and fewer than 8,000 in 2020. In contrast, the number of enrollees who had their Stelara paid under Part B fell from around 6,500 to under 2,000 over the same period.

The increase in the number of enrollees receiving Stelara under Part D coincided with rising per-injection costs for the drug in Part D, while the Part B cost remained steady. In 2022, Medicare Part D paid an average of almost $30,000 per 90 mg injection for Stelara, up 14 percent from the previous year (the average Part B cost, however, remained steady). In 2023, with Stelara excluded from Part B coverage in all MAC jurisdictions, the average Part D cost jumped to nearly $33,000 per 90 mg injection. See Exhibit 2.

Exhibit 2: The average Part B cost for a 90 mg Stelara injection remained steady between 2016 and 2023. Over that same period, the average Part D cost increased by 84 percent.

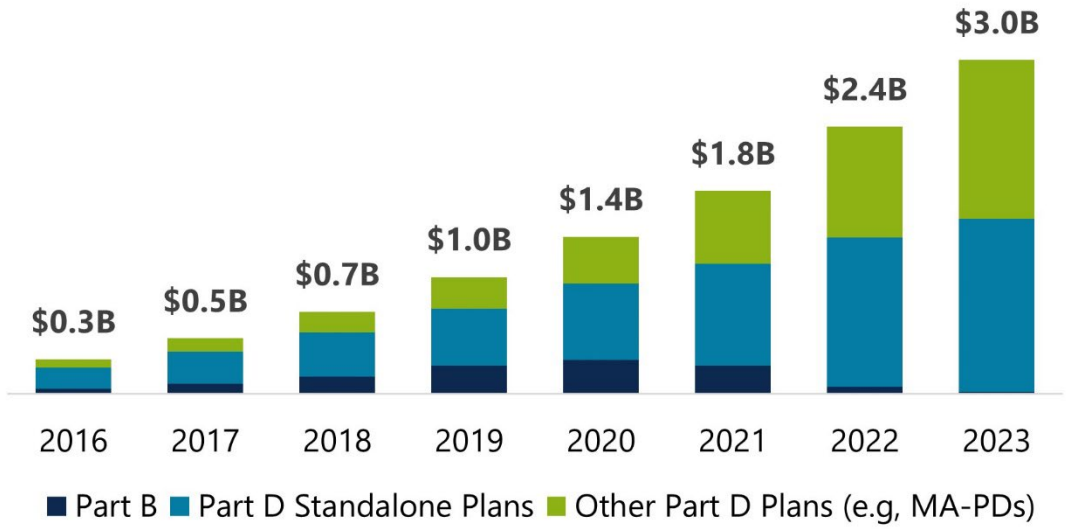


Source: OIG analysis of Medicare Part B and Part D PDE claims data.
*Note: Despite Part B coverage ending among all MACs by November 2022, a small number of Part B claims were still processed and paid in 2023.

The combination of an increasing number of enrollees receiving Stelara under Part D and higher costs for the drug led to a $1.2 billion increase in Medicare expenditures from 2021 to 2023

In 2021, Medicare expenditures for Stelara totaled almost $1.8 billion—$255 million in Part B, $909 million in Part D standalone prescription drug plans, and $655 million in other Part D plans (e.g., Medicare Advantage prescription drug plans)—to treat nearly 22,000 enrollees. In 2022, as MACs began implementing the Part B coverage change, Medicare spending rose to $2.4 billion for Stelara—$62 million in Part B, $1.3 billion in Part D for standalone prescription drug plans, and $991 million in other Part D plans—to treat a similar number of enrollees. In 2023, Medicare expenditures reached $3 billion now that Part B coverage for Stelara has ended. See Exhibit 3.

Exhibit 3: Annual Medicare expenditures for Stelara have been steadily growing, with recent increases of about $500 million year to year.



Source: OIG analysis of Medicare Part B and Part D PDE claims data.

In August 2023, HHS announced that Stelara is 1 of 10 high-expenditure drugs covered under Part D without generic or biosimilar competition selected for the first cycle of Medicare drug price negotiations. Negotiations with participating drug companies are ongoing in 2024, and any negotiated prices will become effective beginning in 2026.[22] However, on October 31, 2023, FDA approved Wezlana as the first biosimilar of Stelara.[23] FDA subsequently approved two additional biosimilars of Stelara—Selarsdi and Pyzchiva—in April and June of 2024, respectively.[24, 25] The potential for new biosimilar competition may mean Stelara would not be subject to Medicare Part D drug price negotiations.

Enrollees who once opted to receive Stelara injections in their doctors' offices (i.e., Part B) must now obtain Stelara through a pharmacy (i.e., Part D), leading to higher out-of-pocket costs for many enrollees

In 2021, prior to Stelara being placed on the self-administered drug exclusion list, out-of-pocket costs under Part B were minimal as long as the enrollee had supplemental insurance. According to recent data, 89 percent of Part B enrollees have some type of supplemental insurance such as Medigap to assist with the 20-percent patient coinsurance generally required for Part B claims.[26] Most Medigap plans cover 100 percent of Part B coinsurance for physician-administered drugs.[27] As a result, these enrollees typically would owe nothing for Stelara injections administered in their doctors' offices once any deductible for their supplemental insurance was met.

In contrast, an enrollee who self-administered Stelara at home under Part D paid an average of nearly $6,000 out of pocket if they did not receive any type of financial assistance (e.g., LIS, support from State pharmaceutical assistance programs, charities, group health plans, etc.). These individuals who did not receive financial assistance accounted for 22 percent of Part D enrollees. Comparatively, the Part D enrollees who received the LIS paid an average of $10 for Stelara. Enrollees with the other types of financial support paid an average of $400 to $1,100.[28]

In 2021, the cost differences described above provided significant incentives for non-LIS enrollees to receive Stelara in their doctors' offices under Part B. Specifically, more than half of enrollees not eligible for the LIS received at least one of their Stelara injections in an office setting. In contrast, only 1 in 10 Medicare enrollees with both Part B and Part D who were eligible for the LIS received a Stelara injection in their doctors' offices.

However, once Part B coverage for Stelara fully ended (i.e., the self-administered drug exclusion was fully implemented in all MAC jurisdictions) at the close of 2022, non-LIS enrollees no longer had this option, and they subsequently would have faced thousands of dollars in additional out-of-pocket costs to continue treatment with Stelara.

The Part B coverage change would likely have had a similar effect on many of the enrollees who received Stelara in their doctors' offices and were not enrolled in a Part D drug plan. In 2021, there were 572 enrollees who received Stelara injections that had Part B coverage but not Part D. The Medicare Payment Advisory Commission estimated that in 2022, half of Medicare enrollees without a Part D plan had no prescription drug coverage or coverage less generous than Part D.[29]

The Inflation Reduction Act (IRA) will cap future Part D out-of-pocket spending, but many enrollees will still face greater out-of-pocket costs than under Part B. In 2024, the IRA eliminates the 5-percent enrollee coinsurance in catastrophic coverage, capping out-of-pocket costs at approximately $3,250. Starting in 2024, Medicare Part D also will expand eligibility criteria for the low-income subsidy program that helps eligible enrollees with their out-of-pocket costs (i.e., coinsurance or copayments). In 2025 and beyond, the IRA will further reduce out-of-pocket costs, capping them at $2,000.[30] Even this reduced out-of-pocket maximum will be more than what most enrollees with supplemental insurance would have been responsible for paying in Part B.

Furthermore, Part D plan sponsors may receive compensation after the point of sale—often in the form of rebates—that alters the final price they pay for Part D drugs. However, because enrollee out-of-pocket cost is calculated on the basis of the drug price at the point of sale, rebates and other price concessions received after the point of sale do not affect enrollees' out-of-pocket costs.

CONCLUSION

Over the past several years, Medicare expenditures for Stelara have increased almost tenfold, from $300 million in 2016 to almost $3 billion in 2023. Our findings illustrate how differences in Part B versus Part D payment amounts for the same drug—as well as decisions regarding coverage under Medicare Part B and Part D—can significantly affect both expenditures for the program and out-of-pocket costs for enrollees receiving high-cost drugs such as Stelara.

OIG found that when Stelara was being covered under Part B and administered by physicians in their offices, it was costing the Medicare program and most enrollees far less than when it was being covered under Part D and enrollees were self-administering the drug at home. In addition, 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. Nevertheless, now that subcutaneous versions of Stelara are excluded from Part B coverage because they are self-administered and covered under Part D, enrollees who had previously opted to receive their injections under Part B no longer have that option. Subsequently, these enrollees may face thousands of dollars in additional out-of-pocket costs to continue treatment with Stelara.

HHS has the stated goal to protect and strengthen equitable access to high-quality and affordable healthcare.[31] One component of that is examining ways to reduce the cost of prescription drugs for Medicare enrollees, both within its existing authority and by pursuing legislative changes where appropriate. For example, in August 2023, HHS announced that Stelara is 1 of 10 high-expenditure drugs without generic or biosimilar competition selected for the first cycle of Medicare Part D drug price negotiations. For this first cycle, any negotiated prices will become effective beginning in 2026. However, new biosimilar competition through the recent approvals of Wezlana, Selarsdi, and Pyzchiva may potentially mean that Stelara would not be subject to Medicare Part D drug price negotiations. OIG's analysis of Medicare payments for Stelara provides information to CMS and stakeholders as they consider ways to reduce the cost of drugs to the program and its enrollees while protecting access to vital medications.

METHODOLOGY

Data Analysis

Determining Average Cost of Subcutaneous Stelara

To determine the average cost per injection of subcutaneous versions of Stelara, we first summed the expenditures for the drug and divided by the total number of units in both Part B and Part D (standalone prescription drug plans only) to get the average cost per unit (i.e., 1 mg). We then multiplied the cost per unit by the units in a typical injection (i.e., 45 mg or 90 mg). We also calculated the total average cost per enrollee who receives the recommended number of maintenance doses of Stelara in a calendar year.

Part D plan sponsors or pharmacy benefit managers frequently receive compensation after the point of sale—often in the form of rebates—that alters the final price they pay for Part D drugs. OIG examined Direct and Indirect Remuneration (DIR) data, including rebates, for years 2016 through 2022. However, our findings did not include details regarding price reductions when reporting Part D costs for Stelara because rebate information is confidential. Furthermore, because enrollee out-of-pocket cost is calculated on the basis of the drug price at the point of sale, rebates and other price concessions received after the point of sale do not affect out-of-pocket costs.

We categorized enrollees by two disease categories: one for Crohn's disease and ulcerative colitis, and the other for psoriasis and psoriatic arthritis, because the two groups have different schedules for maintenance doses of Stelara at 8- and 12-week intervals, respectively. Therefore, patients being treated for Crohn's disease and/or ulcerative colitis would receive six maintenance injections in a given year, while those being treated for psoriasis or psoriatic arthritis would receive only four injections. For patients being treated for Crohn's disease and ulcerative colitis, the recommended dose is a 90 mg injection six times per year. For enrollees being treated for psoriasis and/or psoriatic arthritis, the recommended dose is dependent on the patient's weight, with those weighing less than or equal to 220 pounds receiving a 45 mg injection four times per year and those weighing more getting a 90 mg injection four times per year. We then multiplied the average cost per injection of Stelara (i.e., 45 mg or 90 mg) by the number of recommended maintenance doses (i.e., four or six).

Determining average out-of-pocket costs per enrollee. We also calculated the average out-of-pocket costs for enrollees when they received Stelara injections under Part B (i.e., in doctors' offices) versus when they received Stelara under Part D (i.e., from a pharmacy and self-injected at home). In Part B, enrollees are responsible for 20 percent of the drug cost. We analyzed average beneficiary out-of-pocket spending for two groups of Part D enrollees: (1) enrollees who received any form of

financial assistance (e.g., the low-income subsidy; support from charities or group health plans; etc.) and (2) beneficiaries who received no Part D financial assistance. We calculated 2021 average beneficiary out-of-pocket spending for each of the financial assistance groups by dividing the summed patient costs for each group (as reported in the PDE data) by the number of beneficiaries in each group who received Stelara.

We also examined the proportion of Medicare enrollees who received Stelara injections in their doctors' offices (i.e., under Part B) on the basis of whether they were eligible for the Part D LIS (i.e., received financial assistance). To do this, we divided the total number of enrollees who received Stelara in a doctor's office by the total number of enrollees in each group (i.e., eligible for the LIS or not eligible for the LIS).

Determining annual Medicare expenditures. To determine how much Medicare spent on Stelara annually, we calculated total expenditures in Part B and Part D—including both standalone plans and other plans (e.g., Medicare Advantage prescription drug plans)—for calendar years 2016–2023.

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.

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.

APPENDICES

Appendix A: Stelara Approvals and Treatment Regimen

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-injected by the patient at home after proper training in subcutaneous injection techniques.[32] 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.[33] See Exhibit A-1 for Stelara treatment regimen by indication.

Exhibit A-1: Stelara Treatment Regimen by Indication

Indication	Initial Dosage Type	Second Dosage Type and Timeframe	Maintenance Dosage Type and Timeframe
Psoriasis	Subcutaneous injection	Subcutaneous injection 4 weeks after initial	Subcutaneous injection Every 12 weeks
Psoriatic Arthritis	Subcutaneous injection	Subcutaneous injection 4 weeks after initial	Subcutaneous injection Every 12 weeks
Crohn's Disease	Intravenous infusion	Subcutaneous injection 8 weeks after initial	Subcutaneous injection Every 8 weeks
Ulcerative Colitis	Intravenous infusion	Subcutaneous injection 8 weeks after initial	Subcutaneous injection Every 8 weeks

Source: FDA-approved label for Stelara.

As of September 2023, 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.

ACKNOWLEDGMENTS AND CONTACT

Acknowledgments

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ENDNOTES

[1] Specifically, Stelara is indicated for the treatment of (1) patients 6 years and older with active psoriatic arthritis; (2) patients 6 years and 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] Centers for Medicare & Medicaid Services (CMS). *How to get prescription drug coverage*. Accessed at https://www.medicare.gov/drug-coverage-part-d/how-to-get-prescription-drug-coverage on February 1, 2024.

[3] A small proportion of Medicare-eligible enrollees may enroll in other insurance plans with drug coverage such as Medicare Cost plans, Programs of All-inclusive Care for the Elderly (PACE) plans, or demonstration/pilot programs.

[4] Enrollees must have Medicare Part A (Hospital Insurance) and/or Medicare Part B (Medical Insurance) to join a separate Medicare standalone prescription drug plan.

[5] In some cases, enrollees may receive financial support for these costs from various sources, such as additional insurance or charity care.

[6] 42 CFR § 423.34.

[7] Section 1831 et seq. of the Social Security Act (the Act), 42 CFR Part 414.

[8] 42 CFR § 414.900(b) and the Medicare Benefit Policy Manual, ch. 15, § 50.

[9] 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.

[10] Section 1861(s)(2) of the Act and 42 CFR § 414.900.

[11] OIG has also conducted an evaluation examining how Medicare Administrative Contractors make Part B coverage determinations for injectable drugs such as Stelara as required by statute and instructed in CMS policy and guidance. See OEI-BL-19-00501 (forthcoming).

[12] 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, LLC published an effective date of June 6, 2022. CGS Administrators, LLC published an effective date of November 1, 2022.

[13] HCPCS codes provide a standardized system for describing specific items and services provided in the delivery of health care. In the case of prescription drugs, each HCPCS code defines the drug's name and the amount of the drug represented by one unit of the HCPCS code but does not specify manufacturer or package size information.

[14] Section 1847A of the Act. Part B claims dated on or after April 1, 2013, incur a 2-percent reduction in payment in accordance with the Budget Control Act of 2011 and the American Taxpayer Relief Act of 2012 (i.e., sequestration). This mandatory payment reduction is applied after the enrollee's coinsurance has been determined. However, the sequestration payment reduction was suspended from May 1, 2020, through March 31, 2022; the sequestration reduction was then set to 1 percent from April 1, 2022, through June 30, 2022. The sequestration of payment reductions ended as of July 1, 2022, when cuts of 2 percent were reimposed. (See the Coronavirus Aid, Relief, and Economic Security (CARES) Act (P.L. No. 116-136) as amended by the Consolidated Appropriations Act, 2021 (P.L. 116-260); the Act to Prevent Across-the-Board Direct Spending Cuts, and for Other Purposes (P.L. No. 117-7); and the Protecting Medicare and American Farmers from Sequester Cuts Act (P.L. 117-71).)

[15] Section 1847A(c) of the Act defines Average Sales Price (ASP).

[16] In 2021, more than 8 in 10 enrollees in traditional Medicare (89%) had some type of supplement insurance to cover some or all of Medicare Part B cost-sharing requirements. Kaiser Family Foundation, *A Snapshot of Sources of Supplemental Coverage Among Medicare Beneficiaries*. Accessed at https://www.kff.org/medicare/issue-brief/a-snapshot-of-sources-of-coverage-among-medicare-beneficiaries/ on July 7, 2024. Types of supplemental insurance include employer-sponsored insurance, Medicare supplemental insurance (Medigap), and Medicaid.

[17] Supplemental insurance helps protect beneficiaries from incurring high medical expenses; however, high-cost Part B drugs may still financially affect individual patients through higher premiums as insurers redistribute costs across enrollees.

[18] Part D plan sponsors or pharmacy benefit managers frequently receive compensation after the point of sale that alters the final price they pay for Part D drugs. Manufacturer rebates—post-sale price concessions received by sponsors or pharmacy benefit managers—comprise a significant portion of this compensation. Rebates can significantly reduce Part D sponsors' net spending for drugs; however, because rebates are paid to plans after a prescription has been picked up by the enrollee, they do not directly lower enrollee cost-sharing. Similarly, prior OIG work showed that in the case of drugs used to treat hepatitis C, the large rebates offered by manufacturers had limited effects on total Medicare expenditures because their high costs pushed enrollees into catastrophic coverage, where Medicare, and not Part D sponsors, was responsible for payment. Given Stelara's similarly high costs, Medicare would likely not have benefited significantly from any rebates.

[19] Even taking into account the additional costs related to in-office Stelara administration, the cost to Medicare was still significantly less in Part B than in Part D. For example, in 2021, physicians were reimbursed between $12.89 and $18.08, depending on the MAC locality, for administering a subcutaneous injection (Current Procedural Terminology (CPT) code 96372) of Stelara. That same year, payment rates for established patient office visits ranged from $20-$30 for visits less than 10 minutes to $167-$238 for visits lasting longer than 40 minutes (CPT codes 99211-99215).

[20] In a given year, an enrollee with Crohn's disease and/or ulcerative colitis will typically receive six maintenance doses of 90 mg Stelara (i.e., one injection every 8 weeks). For enrollees being treated for psoriasis and/or psoriatic arthritis, the recommended dose is dependent on the patient's weight, with those weighing less than or equal to 220 pounds receiving a 45 mg injection four times per year and those weighing more getting a 90 mg injection four times per year (i.e., one injection every 12 weeks). See 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] MACs informed OIG that the unanimous decision to delay the implementation of a coverage change for Stelara due to the COVID-19 public health emergency was made by a MAC workgroup (i.e., with representation from all MACs) that collaboratively discusses whether drugs should be considered self-administered.

[22] CMS. *Medicare Drug Price Negotiation Program: Selected Drugs for Initial Price Applicability Year 2026*. Accessed at https://www.cms.gov/files/document/fact-sheet-medicare-selected-drug-negotiation-list-ipay-2026.pdf on September 12, 2023.

[23] FDA. *FDA Approves Interchangeable Biosimilar for Multiple Inflammatory Diseases*. Accessed at https://www.fda.gov/news-events/press-announcements/fda-approves-interchangeable-biosimilar-multiple-inflammatory-diseases on February 7, 2024. Amgen Inc., *Wezlana (ustekinumab-auub) [label]*. FDA website. Accessed at https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761285s000,761331s000lbl.pdf on July 9, 2024.

[24] Teva Pharmaceuticals. *Selarsdi (ustekinumab-aekn) [label]*. FDA website. Accessed at https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761343s000lbl.pdf on July 9, 2024.

[25] Sandoz Inc. *Pyzchiva (ustekinumab-ttwe) [label]*. FDA website. Revised July 4, 2024. Accessed at https://www.accessdata.fda.gov/drugsatfda_docs/label/2024/761373Orig1s000;761425Orig1s000correctedlbl.pdf on July 9, 2024.

[26] Kaiser Family Foundation. *A Snapshot of Sources of Supplemental Coverage Among Medicare Beneficiaries*. Accessed at https://www.kff.org/medicare/issue-brief/a-snapshot-of-sources-of-coverage-among-medicare-beneficiaries/ on November 7, 2023.

[27] Some Medigap supplemental insurance plan types may only cover part of the Part B coinsurance for physician-administered drugs. For example, plans K and L will pay 50 percent and 75 percent, respectively, of the Part B coinsurance before the enrollee meets their out-of-pocket yearly limit and Part B deductible. After an enrollee has met their

out-of-pocket yearly limit and Part B deductible, the plans will pay 100 percent of the enrollee's Part B coinsurance for physician-administered drugs. See https://www.medicare.gov/health-drug-plans/medigap/basics/compare-plan-benefits for the different benefits Medigap policies cover.

[28] Enrollees may receive support from third parties that pay on behalf of the enrollee, including State pharmaceutical assistance programs, charities, and group health plans.

[29] Medicare Payment Advisory Commission. "Chapter 14: The Medicare prescription drug program (Part D): Status report." *Report to the Congress: Medicare Payment Policy*. March 2020.

[30] CMS. *Inflation Reduction Act: CMS Implementation Timeline*. Accessed at https://www.cms.gov/files/document/10522-inflation-reduction-act-timeline.pdf on November 17, 2023.

[31] U.S. Department of Health and Human Services. *Strategic Goal 1: Protect and Strengthen Equitable Access to High Quality and Affordable Healthcare*. Accessed at https://www.hhs.gov/about/strategic-plan/2022-2026/goal-1/index.html on April 17, 2024.

[32] 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.

[33] 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.