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Biosimilars Have Lowered Costs for Medicare Part B and Enrollees, but Opportunities for Substantial Spending Reductions Still Exist

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Report In Brief
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Why OIG Did This Review

Biologic drugs (biologics)—usually large, complex molecules produced in a living system—are some of the most expensive drugs available. They are estimated to cost Medicare Part B and its enrollees upwards of $32 billion annually.

A biosimilar is a biologic that is highly similar to and has no clinically meaningful difference from an existing Food and Drug Administration-approved biologic (i.e., the biosimilar's "reference product"), and biosimilars are often less expensive.

This study identifies opportunities to reduce spending for Part B and its enrollees by increasing use of lower-cost biosimilars, which aligns with OIG and Department of Health and Human Services goals. It provides insights into the impact of biosimilar market entry on Part B costs and how biosimilar use in Part B has developed under existing payment policies. It also estimates potential spending reductions that could be achieved through greater use of biosimilars or under a least costly alternative (LCA) payment policy.

How OIG Did This Review

We analyzed quarterly biosimilar and reference product prices; use; and program and enrollee costs in Medicare Part B from 2015 to 2021. We used this information to calculate estimates of how Part B and enrollee spending could have changed if biosimilars that were more affordable than their reference products had been used more frequently, or if biosimilars and their reference products had been paid using an LCA policy.

Key Takeaway

Biosimilar competition has already led to lower costs for the Medicare Part B program and enrollees. However, opportunities exist to further reduce Part B and enrollee spending through increased use of more affordable biosimilars or with the implementation of different payment policies.

What OIG Found

Biosimilar competition has led to decreases in costs for both biosimilars and their reference products. However, many biosimilars remain more affordable than their reference products and could be more widely used. We estimated that with increased use of these more affordable biosimilars instead of reference products, Part B and enrollee spending could have been reduced in 2021. Specifically, Part B and enrollee spending on these biologics could have decreased by $179 million, or 4 percent, if more affordable biosimilars had been used as frequently as the most-used biosimilars.

A different approach to Part B payment policies for biologics could have resulted in even greater spending reductions. One type of alternative payment policy that could help address the high costs of biologics for Part B and its enrollees is an LCA policy—under which payment would be based on the lowest-cost drug, regardless of which one was administered. We estimated that an LCA policy for biosimilars and their reference products would have reduced Part B and enrollee spending on these biologics by $419 million—or 9 percent—in 2021, even without an increase in the use of more affordable biosimilars.

What OIG Recommends

To reduce Part B and enrollee spending on biologics, we recommend that the Centers for Medicare & Medicaid Services (CMS) pursue one or more payment changes that could further realize savings from biosimilars for Part B and enrollees, which could include seeking additional legislative authority. CMS did not explicitly concur or nonconcur with our recommendation, but stated that it is committed to taking action, as appropriate, within its authority.

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BACKGROUND

OBJECTIVES

1. To identify trends in biosimilar and reference product average sales prices (ASPs); use; and program and enrollee costs in the Medicare Part B program for 2015-2021.
2. To estimate how increased use of biosimilars could have changed Part B and enrollee spending in 2021.
3. To examine the extent to which applying a least costly alternative (LCA) payment policy could have changed Part B and enrollee spending in 2021.

Biologic drugs (hereinafter referred to as biologics) are usually large, complex molecules produced in a living system, such as a microorganism, plant cell, or animal cell—and they are among the most costly prescription drugs for Medicare and its enrollees. Biologics treat cancers; autoimmune diseases such as ulcerative colitis; anemia due to chronic kidney disease; and neutropenia, in which the body makes too few white blood cells as a result of chemotherapy. Because biologics are infusions or injections commonly administered by a provider in a physician's office or hospital outpatient department, they are most often paid for by Medicare under Part B.[1, 2, 3, 4] Biologics cost Medicare Part B upwards of $32 billion annually—and accounted for more than 80 percent of all Part B drug spending in 2020.[5] In that same year, seven biologics each had Part B spending over $1 billion.[6]

Biosimilars are biologics that are highly similar to and have no clinically meaningful differences from an existing biologic (known as a reference product)—and they are often less expensive.[7, 8] In 2010, Congress created an abbreviated approval pathway for biosimilars to increase competition and lower biologic prices.[9] However, OIG has previously found that biosimilars were not always included on Medicare Part D plan formularies and were used far less frequently than their reference products.[10] Further, in Medicare Part B, the lack of financial incentives for providers to use more affordable biosimilars may have limited their adoption.[11] Several changes to biosimilar payment have already been made, and additional changes have been proposed, to further encourage biosimilar use and reduce Part B and enrollee spending on biologics.[12]

Biosimilar Availability and Barriers to Greater Use

Although the Food and Drug Administration (FDA) had approved 33 biosimilars as of December 2021 (the end of the period reviewed for this evaluation), only 21 were available in the United States.[13] Ongoing patent litigation and patent dispute settlements prevented many of the remaining biosimilars from launching in the U.S. market.[14] For example, as a result of patent dispute settlements, manufacturers of multiple FDA-approved biosimilars for the reference product Humira delayed launch of their products in the United States until 2023—despite FDA approving the first Humira biosimilar in 2016.[15] To address these ongoing patent delays, in 2021, the Secretary of the Department of Health and Human Services (the Department) directed FDA to work with the Federal Trade Commission and the U.S. Patent and Trademark Office to develop solutions to ensure that manufacturers cannot unfairly use the patent system to discourage competition.[16]

Biosimilar and Reference Product Drug Groups in this study

- Bevacizumab
- Epoetin Alfa
- Filgrastim
- Infliximab
- Pegfilgrastim
- Rituximab
- Trastuzumab

The 21 biosimilars that were available in 2021 were approved as alternatives to 7 reference products in Part B. Throughout this report, we refer to available biosimilars and their reference product, collectively, as a **drug group**. See Appendix A for a list of all biosimilars covered under Part B in 2021 and their reference products.

A number of barriers have potentially contributed to limited use of the FDA-approved biosimilars that are already available in the United States. Research indicates that low biosimilar use, particularly in Part B, may be attributed to the lack of financial incentives for providers to use more affordable biosimilars.[17] Furthermore, research shows that many prescribers and patients are not well informed about—and sometimes not even aware of—biosimilar alternatives.[18, 19] Some prescribers are hesitant to switch patients already successfully using a reference product to its biosimilar, even when they have a high degree of confidence in the biosimilar's safety and effectiveness.[20]

Part B Payment for Biologics

Under Part B, providers purchase outpatient prescription drugs and biologics (Part B drugs) and then submit claims to Medicare for payment after administering those drugs to patients. Payment for most Part B drugs is based on ASP—which reflects the average price manufacturers charged to physicians, hospitals, and other purchasers—plus an add-on payment.[21] Individual providers' expenditures to purchase these drugs vary and may be higher or lower than that average price. The Medicare program pays providers 80 percent of the total payment amount, while enrollees typically pay the remaining 20 percent of this amount as coinsurance.[22]

HCPCS codes. Providers submit claims for Part B outpatient prescription drugs using the drug's Healthcare Common Procedure Code System (HCPCS) code.[23] Each HCPCS code is based on the drug name and the amount of the drug (e.g., in milliliters or milligrams) that represents one billing unit.

Each reference product and biosimilar has its own HCPCS code.[24] For example, a reference product with three biosimilars would result in four unique HCPCS codes. In contrast, brand and generic versions of small molecule drugs (e.g., antibiotics and pain medications) are grouped under the same HCPCS code.[25]

ASP. To determine the ASP for each HCPCS code, the Centers for Medicare & Medicaid Services (CMS) uses manufacturer-reported information about prices charged to providers. Manufacturers must report average quarterly pricing and sales volume data to CMS, minus any price concessions such as volume discounts and rebates.[26, 27] CMS then calculates ASP based on the volume-weighted average price of each drug's HCPCS code.[28, 29] The actual prices manufacturers charge to providers can vary, meaning that a provider's cost to purchase a drug may be more or less than the drug's ASP.

ASP payment. Provider payment for Part B drugs includes the ASP of the drug as well as an add-on payment. For our study timeframe (2015-2021), Medicare paid reference product claims using the reference product's ASP plus a 6-percent add-on, as it does for most Part B drugs.[30, 31] In contrast, to encourage biosimilar use, Medicare paid biosimilar claims the biosimilar's ASP plus an add-on equal to 6 percent of its reference product's ASP.[32] Because reference products often have a higher ASP than their biosimilars, this policy ensures that providers receive the same add-on payment whether they administer a biosimilar or its reference product, removing what might otherwise be a disincentive to prescribe a less expensive biosimilar.[33] However, the Department noted that the single add-on policy has not provided sufficient incentive for providers to change prescribing patterns and maximize savings.[34]

ASP reflects the prices manufacturers charge for drugs and **ASP payments** represent the *cost* of drugs to Medicare Part B.

First, CMS uses manufacturer-submitted pricing information to calculate the ASP for each HCPCS code.

Then, providers receive an **ASP payment** based on the drug's **ASP** *plus* an add-on amount.

Providers receive the ASP-based payment regardless of the actual amount they paid to purchase the drug.[35] As a result, providers choosing among clinically comparable options may be incentivized to use the drug that has the largest difference between their actual purchase price and the ASP-based Medicare payment amount, rather than to use the lowest-priced drug. To address this concern, stakeholders have proposed

eliminating separate payment calculations for reference products and their biosimilars.[36]

Methodology in Brief

This study analyzed trends in biosimilar and reference product prices and use rates in the fee-for-service Medicare Part B program from 2015 to 2021. Additionally, we calculated estimates to explore how Part B and enrollee spending in CY 2021 could have changed with (1) increased use of more affordable biosimilars; and (2) an LCA payment policy, which both the Department and OIG have recommended for Congressional consideration. Our review included only biosimilars and reference products that were available on the U.S. market and covered by Part B in our analysis period; we did not assess why other FDA-approved biosimilars were not available on the U.S. market.

Limitations

Changes in Part B spending and enrollee spending are estimates. They do not represent the exact changes in Part B or enrollee spending that would have resulted from increased biosimilar use or an LCA policy in 2021. For example, the estimates do not account for how increases in biosimilar use could have affected ASPs for biosimilars and reference products. This study also does not assess whether the increased use rates used to estimate spending reductions were achievable. Furthermore, this report does not include a dynamic analysis of how changes in payment policy could impact manufacturer prices or provider incentives. Finally, this report does not include an analysis of additional factors—such as prescriber preference—that impact the extent of biosimilar use. The study does not account for the effects of sequestration on Medicare payment amounts or estimated changes in Medicare spending.[37, 38]

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

Biosimilar competition has already led to decreases in costs for the Part B program and enrollees, but opportunities exist to leverage biosimilars to further reduce spending. After the introduction of biosimilar alternatives, both reference product and biosimilar prices fell, reducing overall costs for Part B and enrollees. However, many biosimilars remained more affordable than their reference products and could be more widely used. Had those more affordable biosimilars been used as frequently as the most-used biosimilars, Part B and enrollee spending on these biologics could have been reduced by $179 million in 2021. Applying an LCA payment policy would have reduced Part B and enrollee spending by $419 million in 2021, even without an increase in the use of more affordable biosimilars.

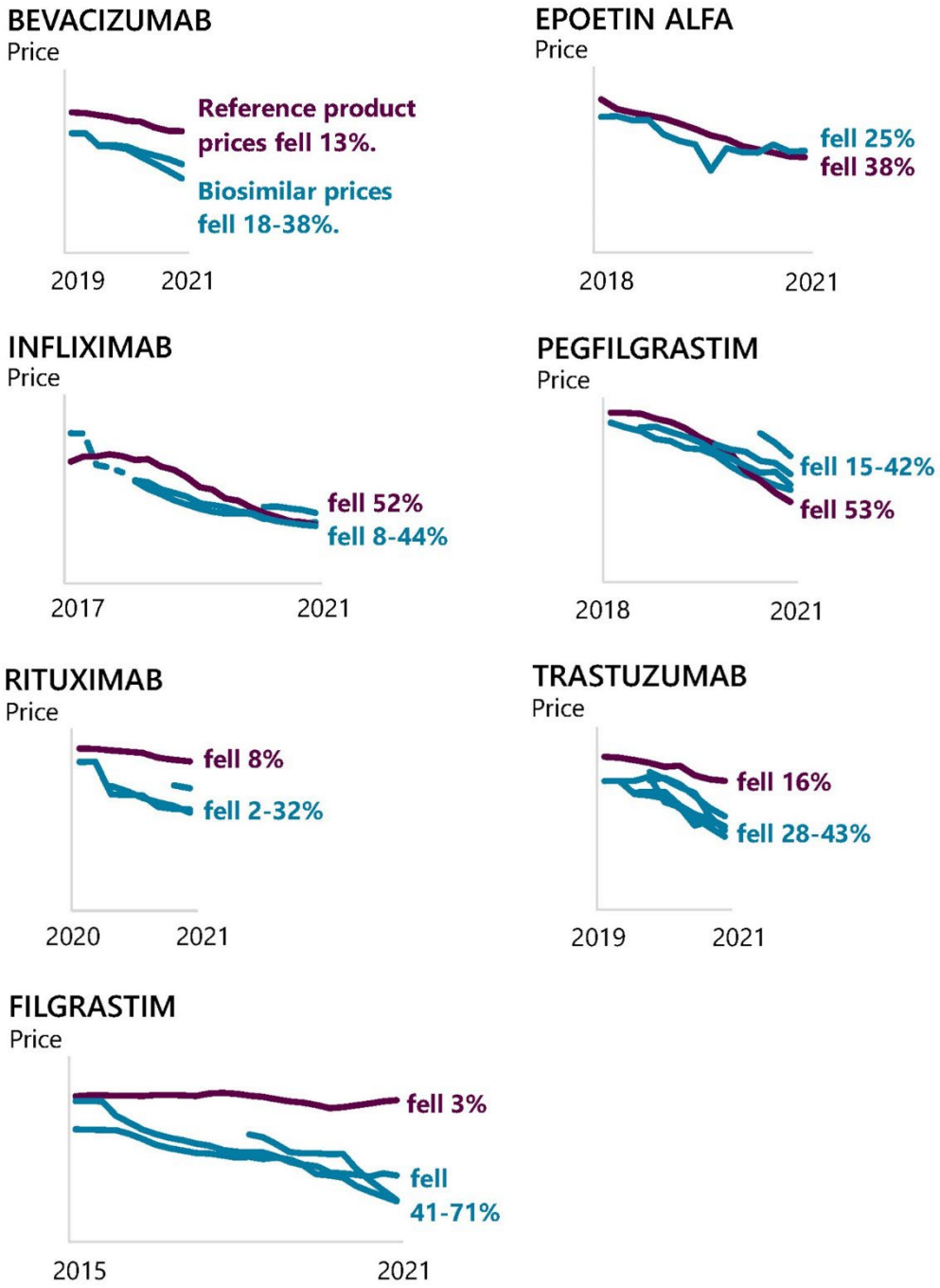
Biosimilar competition has led to lower costs for the Part B program and enrollees

From 2015 to 2021, the availability of biosimilar competitors for biologic reference products led to price decreases for both types of drugs, which has reduced overall costs for the Part B program and enrollees. When they were first introduced, nearly all biosimilars had a lower price, as measured by ASP, than their reference products. In most cases, both biosimilar and reference product prices fell after the first biosimilar alternative became available, reversing the trend of reference product price increases up to that point. Only the filgrastim reference product did not follow this pattern; its price remained fairly constant over time, even as prices for its biosimilars decreased. Because Part B payment for drugs is based on ASP, these price decreases lowered program and enrollee costs for both biosimilars and reference products.

While biosimilar prices generally remained lower, for some drug groups reference product price decreases were substantial enough that the reference products cost less than some of their biosimilars at the end of 2021. See Exhibit 1 on the next page for an illustration of the changes in biosimilar and reference product prices after the introduction of biosimilar competitors.

Without these reductions in reference product prices after the introduction of biosimilar competitors, the Part B program and enrollees could have spent much more. For example, if the price for the pegfilgrastim reference product had remained stable at its 2018 Q3 level—just as the first biosimilar was introduced—the Part B program and enrollees would have spent an additional $264 million on this drug in 2021.

Exhibit 1: The prices for both biosimilars and reference products fell once biosimilar alternatives were introduced.



Notes: We analyzed biosimilar prices starting in the first quarter with a published biosimilar ASP payment. Because CMS calculates quarterly ASP using manufacturer price and volume information from two quarters prior, the first published ASP payment reflects the initial prices manufacturers charged for biosimilars.

When necessary, we adjusted ASP to reflect a standardized quantity for the drug group. See standardizing quantity administered and ASP in the detailed methodology for more information.

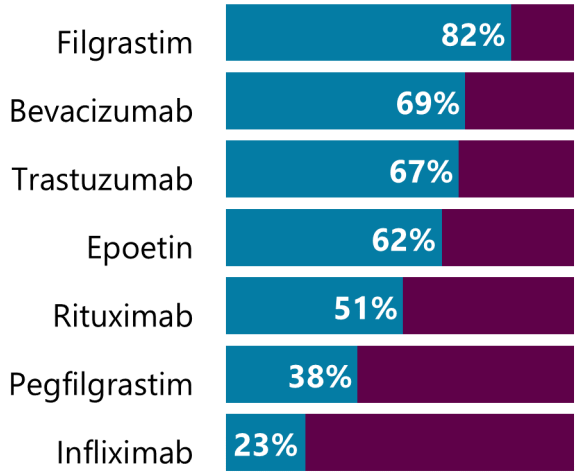
The dotted line for infliximab reflects that prior to 2018, two infliximab biosimilars shared an ASP payment.

Source: OIG analysis of CMS's ASP Drug Pricing Files from 2015-2021.

Use of biosimilars in Medicare Part B has grown significantly, and opportunities remain for even greater use

The overall use rate of available biosimilars in the Part B program grew from just 18 percent in 2015 to 62 percent in 2021. Biosimilars for filgrastim—which include the first approved biosimilar, Zarxio—were the most widely adopted, accounting for 82 percent of all filgrastim administered in the fourth quarter of 2021.[39] However, other biosimilars were used less than 70 percent of the time, including two that were used less than half of the time.

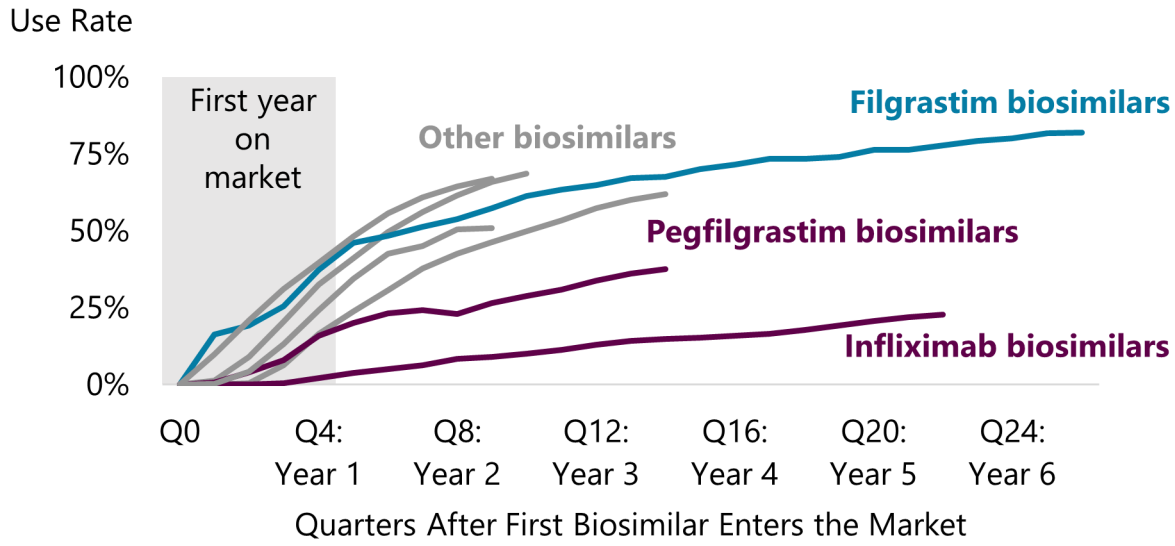
Exhibit 2: The range of biosimilar use rates in the fourth quarter of 2021 highlights opportunities for increased biosimilar use.



Source: OIG analysis of Part B claims from 2021.

Some, but not all, biosimilars may be on track to reach use rates similar to those of filgrastim. Within a year of its first biosimilar becoming available, filgrastim biosimilar use reached 37 percent. Biosimilars for most other reference products had similar, although slightly lower, use rates after a similar amount of time on the market, and their use continued to grow. In contrast, two biosimilars (pegfilgrastim and infliximab) with use rates of less than 16 percent a year after their introduction still had much lower use rates than other biosimilars at the end of 2021. See Exhibit 3 on the next page for an illustration of biosimilar use rates over time.

Exhibit 3: Many biosimilars appear on track to reach use rates similar to the most widely used biosimilars, but rates for the two least-used biosimilars have grown more slowly, despite their being on the market longer than most other biosimilars.



Note: We analyzed the share of biosimilars administered starting in the quarter in which a biosimilar alternative first became available on the U.S. market.

Source: OIG analysis of Part B claims from 2015-2021.

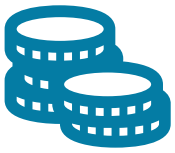
Both prescriber preferences and market dynamics likely affect the extent to which different biosimilars have been adopted. For example, the slower adoption rates for biosimilar infliximabs seen above may be the result of prescribers' hesitancy to switch patients to a biosimilar for the chronic conditions these biologics treat.[40] For pegfilgrastim biosimilars, slower adoption could be related to the substantial reductions in the reference product's cost after biosimilars entered the market. As noted above, the pegfilgrastim reference product was more affordable than all of its biosimilars by the end of 2021.

Greater use of more affordable biosimilars could have reduced Part B and enrollees' spending

In recent years, the Department has noted the importance of biosimilars for reducing drug costs and has directed the Center for Medicare and Medicaid Innovation (CMMI) to continue investigating options to improve biosimilar adoption.[41, 42]

We estimated that with greater use of more affordable biosimilars, Part B and enrollee spending could have been notably reduced in 2021. Specifically, if the five biosimilars that cost less than their reference products for all or part of 2021—epoetin alfa, infliximab, bevacizumab, rituximab, and trastuzumab—had been used at the same rate as the most widely used biosimilar, filgrastim, spending by Part B and its enrollees could have been reduced by $179 million. This amounts to 4 percent of the $4.4 billion that Part B spent on these biosimilars and their reference products in 2021. Enrollees' portion of this spending reduction would have been $36 million. This is an estimate of the scale of spending reductions that could result from policies designed to increase use of biosimilars in Part B when they are more affordable. Such policies include a provision of the Inflation Reduction Act (IRA) that, starting in October 2022, required a 2-percentage-point increase to providers' add-on payment for biosimilars with ASP less than that for their reference products for a five-year period.[43]

Part B spending could have been reduced by $179 million with greater use of more affordable biosimilars.



An enrollee's yearly spending on rituximab could have been reduced by $1,219 by using a biosimilar.

The largest spending reductions would have come from increased use of rituximab biosimilars, which cost about one-quarter less than their reference product. For enrollees, the typical yearly supply of rituximab cost $4,267 for the reference product, but $3,048 for the biosimilar. By using a biosimilar, an enrollee's spending could have been reduced by $1,219.[44]

A least costly alternative payment policy could have resulted in even greater spending reductions

OIG has previously recommended that CMS consider seeking legislative authority to implement LCA policies for certain clinically comparable Part B drugs.[45] The Department has also noted that Congress could consider the use of an LCA policy for biosimilars and their reference products in Medicare.[46] Under an LCA policy, reimbursement for a given reference product and its biosimilars would be 106 percent of the ASP of the least costly of those biologics, regardless of which biologic a provider administered. An LCA policy could reduce Part B and enrollee spending while more directly encouraging price competition among these biologics.[47]

We estimated that Part B and enrollee spending on these biologics in 2021 could have been reduced by $419 million under an LCA policy. This amounts to 9 percent of the $4.4 billion that Part B spent on these biosimilars and their reference products in 2021. Enrollees' portion of this spending reduction would have been $84 million. Lower-cost biosimilars would have driven most of the spending reductions, but in some cases a reference product would have been the least costly option. For example, the reference products for both pegfilgrastim and epoetin alfa had the lowest cost in three out of four quarters.

Part B spending could have been reduced by $419 million under an LCA policy.

Policymakers would need to consider this potential spending reduction alongside concerns about an LCA policy's broader effects. Stakeholders raised concerns with a previous LCA policy for drugs to treat prostate cancer, contending that the policy pushed providers to make treatment decisions based on which drug was most affordable, rather than which drug they considered the most appropriate treatment for their patient.[48] While biosimilars have no clinically meaningful differences from their reference products, research has shown that providers' comfort and familiarity with biosimilars varies, particularly when it comes to switching patients successfully established on a reference product to its biosimilar. Furthermore, while an LCA policy could immediately reduce spending, some stakeholders worry that this short-term price competition could disincentivize future biosimilar development.[49]

CONCLUSION AND RECOMMENDATION

Lowering drug spending remains a top priority for the Department, particularly for biologics, which are among the most expensive drugs on the U.S. market. Our findings demonstrate that there are opportunities for greater use of more affordable biosimilars in Medicare Part B, which could directly lead to spending reductions for the program and enrollees.

Alternative payment approaches could even more substantially reduce Part B and enrollee spending and promote price competition. For example, we estimated that an LCA policy could have reduced Part B and enrollee spending by $419 million in 2021. Under an LCA policy, payment for biosimilars and their reference products would be based on the lowest-cost drug, regardless of which one was administered. Since 2012, OIG has recommended that CMS consider seeking legislative authority to implement LCA policies for certain clinically comparable Part B drugs.[50] While an LCA policy for biosimilars and reference products in Part B could reduce spending and promote competition, implementation of such a policy would need to account for potential access concerns and implications for future biosimilar development.

OIG acknowledges that multiple agencies within and outside HHS are taking steps to lower drug spending. For example, FDA is engaging with the Federal Trade Commission and the U.S. Patent and Trademark Office to prevent manufacturers from using strategies to delay the entry of biosimilar competition. Additionally, OIG recognizes that CMS is actively working to implement IRA provisions to lower drug costs. As of October 2022, CMS had already implemented the IRA's temporary increase in Part B add-on payments for more affordable biosimilars, which strengthens providers' financial incentives to use biosimilars. However, the Department also noted that stakeholders have suggested further actions to encourage biosimilar adoption.[51] CMS stated that it regularly monitors biosimilar pricing and use trends in Part B to assess the impact of the IRA and the launches of additional biosimilar competitors. CMS also noted that CMMI's recently completed Oncology Care Model led to higher rates of biosimilar use among participating providers, and that it plans to determine the extent to which its newly launched Enhancing Oncology Model similarly encourages biosimilar use by incentivizing providers to prescribe lower-cost oncology drugs.[52, 53] CMS should also pursue additional opportunities it identifies to leverage biosimilars to lower drug spending for Medicare and its enrollees.

We recommend that CMS:

Pursue one or more payment changes that could further realize savings from biosimilars for Part B and enrollees

As CMS monitors the evolving biosimilar landscape in the Part B program, it should pursue one or more payment changes for biosimilars and their reference products to reduce Part B and enrollee spending. CMS should use what it learns from its regular monitoring of biosimilar pricing and use trends and evaluation of its oncology care models to determine the most appropriate payment changes to pursue. For example, CMS could determine that additional CMMI models encouraging biosimilar use beyond oncology care are needed. CMS could also determine that other approaches, such as seeking legislative authority to change payment policies, would be more conducive to realizing further savings from biosimilars for Part B and enrollees. Additional legislative authority could allow CMS to institute an LCA policy—as modeled for biosimilars and reference products in this report, and consistent with OIG's longstanding recommendation—or another method of eliminating separate payments for biosimilars and their reference products.

AGENCY COMMENTS AND OIG RESPONSE

CMS did not explicitly concur or nonconcur with our recommendation for it to pursue one or more payment changes that could further realize savings from biosimilars for Part B and enrollees. Instead, CMS stated that it is committed to taking action within its authority to increase access to and use of biosimilars, and that it is currently conducting research to determine how additional demonstration projects could be used to address this issue. OIG supports this effort and looks forward to future updates from CMS on its progress.

In its response, CMS also noted that Section 1847A of the Social Security Act establishes how Medicare pays for Part B drugs, and that CMS's payment policies for drugs must be consistent with the Act. OIG recognizes that CMS's current legislative authority to change payment policy for Part B drugs is limited. Nonetheless, if CMS determines that payment policy changes beyond its current authority are the most effective way to realize further savings from biosimilars for Part B and enrollees, OIG encourages CMS to seek additional legislative authority.

DETAILED METHODOLOGY

Data Sources

Product information for biosimilars and reference products. We used FDA's Biosimilar Product Information; FDA's Purple Book; manufacturer and industry press releases; and First Databank to identify all biosimilars and reference products available as of January 1, 2021, and their National Drug Codes (NDCs).[54] FDA's Biosimilar Product Information lists all FDA-approved biosimilars, and the Purple Book lists all biologics, including biosimilars and their reference products.[55, 56] Manufacturer and industry press releases include information about when FDA-approved biosimilars become available in the United States. The First Databank database links drugs' proprietary names with their NDCs.

Biosimilars and reference products covered by Part B. We used CMS's HCPCS/NDC crosswalks from 2015 to 2021 to identify the HCPCS for biosimilars and reference products that may be covered by Part B. CMS's crosswalks link drugs' NDCs with HCPCS codes used in Part B claims.[57, 58]

Part B prescription drug data. To determine biosimilar use and Part B and enrollee spending, we used National Claims History (NCH) records from CMS's physician office and hospital outpatient prospective payment system files.[59] NCH records include the HCPCS code associated with each drug; the amount of the drug administered; and total Part B and enrollee payment for each Part B claim.

Average sales price data. We used publicly available ASP payment information from CMS to identify quarterly payment amounts for each biosimilar and reference product HCPCS code.

Data Analysis

Identifying biosimilars and reference products. Using FDA's Biosimilar Product Information and Purple Book, we identified all biosimilars approved for use as of January 1, 2021, and their reference products. We used First Databank to identify all NDCs associated with these biosimilars and reference products. In total, we identified 148 NDCs for 7 reference products and 21 biosimilars covered by Part B. We then used CMS's quarterly HCPCS/NDC crosswalks from 2015-2021 to identify the unique HCPCS codes billed in the hospital outpatient and physician office settings for each biosimilar and reference product.

Biosimilar drug group(s). We considered all biosimilars approved for the same reference product to belong to one biosimilar drug group. Biosimilar drug group(s) included multiple biosimilar HCPCS codes, with different manufacturers, proprietary names, and strengths. We analyzed average costs for each biosimilar drug group to

avoid making assumptions about provider practices that are beyond the scope of this study (e.g., which biosimilar brand would be administered).

Standardizing quantity administered and ASP. In some instances, the biosimilars and reference product in one drug group had HCPCS codes based on different quantities (e.g., the reference product's HCPCS code was for 6 mg while the biosimilars' HCPCS codes were for 0.5 mg). To account for these differences in our analysis, we adjusted the quantity administered and ASP to reflect a standardized quantity for each drug group.

For example, to standardize the quantity administered if the reference product's HCPCS code was for 6 mg and the biosimilars' for 0.5 mg, we multiplied the reference product's quantity by 12. To standardize the price, we divided the reference product's ASP by 12.

Analysis of biologic prices over time. To analyze trends for biosimilar and reference product prices over time, we used CMS's ASP payment data, published quarterly, for our analysis period. To calculate **price** from ASP payments, we subtracted the add-on amount from the ASP payment.

Analysis of biosimilar use over time. To calculate Part B biosimilar use over time, we identified NCH records for biosimilar and reference product HCPCS codes from January 1, 2015, to December 31, 2021.[60]

To calculate **biosimilar use rates for each drug group** (as seen on page 2 and in Appendix A), we first determined the total quantity administered for each biosimilar and reference product in our analysis. For each drug group, we then divided the total quantity administered across all biosimilars by the total quantity administered for the entire drug group (including the reference product). We performed this calculation for each quarter and each calendar year from 2015 to 2021.

2021 spending. We calculated Part B and enrollee spending for 2021 by quarter and summed each quarter to get total annual spending.

To calculate **Part B spending**, we summed the amount for both physician office and hospital outpatient claims. For physician office claims, we summed the "line allowed charge amount" variable. For hospital outpatient claims, we summed the enrollee deductible, coinsurance, and Part B payment amounts.

To estimate **enrollee spending**, we calculated 20 percent of the Part B spending amount, which represents the typical coinsurance in Medicare Part B.

Average enrollee spending per typical administration. To provide an example of potential spending reductions for enrollees, we chose to calculate the differences for one biologic, rituximab. Rituximab biosimilars cost about one-quarter less than their reference product. We used average enrollee spending and the typical yearly quantity administered for rituximab. We first identified the average enrollee spending for the biosimilars and the reference product separately by dividing the total enrollee

spending by the total quantity administered. Next, to identify the yearly quantity most typically administered, we used the median quantity administered for rituximab. Finally, we multiplied this average spending by the median yearly quantity administered.

Spending reduction with greater biosimilar use. We estimated potential spending reductions that Part B and enrollees could have realized if more affordable biosimilars had been used at the same use rate as the most widely used biosimilar group in 2021 instead of their reference products. First, using the previously calculated **biosimilar use rates**, we identified which biosimilar group had the highest use rate in each quarter; this was the filgrastim drug group for all four quarters in 2021. Next, we calculated the needed **change in quantity** administered for the other drug groups to achieve this same highest use rate. We subtracted the 2021 actual biosimilar quantity administered from what the quantity administered would have been at the highest use rate.

We calculated the **cost difference** between biosimilars and their reference product. First, we calculated a single volume-weighted **average cost** for each biosimilar drug group. Then we calculated the **cost difference** between this biosimilar average cost and the reference product's cost.

We calculated the total **potential reduced cost** had biosimilars been used at the highest use rate. We multiplied the **change in quantity** by the **cost difference**. To calculate reduced costs specific to enrollees, we calculated 20 percent of the total potential reduced cost.

Spending reduction under an LCA policy. We calculated an estimate for changes in Part B and enrollee spending if biosimilars and reference products had been paid under an LCA policy in 2021.

To do so, we identified the **least costly option** in each drug group as the biologic (reference product or biosimilar) with the lowest price in each quarter and calculated the 6-percent add-on amount.

To estimate the change in Part B and enrollee spending, we multiplied each drug group's total quarterly use by its calculated LCA payment amount. We then calculated the difference between this and the actual 2021 quarterly spending for each drug group. The total difference between actual spending and the estimated spending amounts represents the potential reductions in Part B and enrollee spending under an LCA policy. To estimate changes in enrollee spending, we calculated 20 percent of the change in total spending.

APPENDICES

Appendix A: Biosimilars and Reference Products Covered Under Part B in 2021

Drug Group	Biosimilar	FDA Approval Date	Reference Product(s)
Filgrastim	Granix Zarxio Nivestym	August 2012[61] March 2015 July 2018	Neupogen
Bevacizumab	Mvasi Zirabev	September 2017 June 2019	Avastin
Trastuzumab	Ogivri Herzuma Ontruzant Trazimera Kanjinti	December 2017 December 2018 January 2019 March 2019 June 2019	Herceptin
Epoetin Alfa	Retacrit	May 2018	Epogen/Procrit
Rituximab	Truxima Ruxience Riabni	November 2018 July 2019 December 2020	Rituxan
Pegfilgrastim	Fulphila Udenyca Ziextenzo Nyvepria	June 2018 November 2018 November 2019 June 2020	Neulasta
Infliximab	Inflectra Renflexis Avsola	April 2016 May 2017 December 2019	Remicade

Source: OIG research, 2023.

Appendix B: Agency Comments

Following this page are the official comments from CMS.

DATE: September 14, 2023

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: *Biosimilars Have Lowered Costs for Medicare Part B and Enrollees, But Opportunities for Substantial Spending Reductions Still Exist* OEI-05-22-00140

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 is committed to ensuring that Medicare beneficiaries have access to high quality and affordable health care, while at the same time working to preserve the Medicare Trust Funds.

Recognizing that Medicare payment policy can play a role in promoting use of biosimilar and generic drugs, CMS is committed to continuing to use its authority to promote competition, support increased utilization of biosimilars and generic drugs when clinically appropriate, reduce the federal government's spending on drugs, encourage price transparency, and achieve greater equity in drug access and affordability for beneficiaries.

CMS continues to monitor the evolving biosimilar landscape in the Medicare Part B program. Executive Order 14036 requires CMS to "prepare for Medicare and Medicaid coverage of interchangeable biological products, and for payment models to support increased utilization of generic drugs and biosimilars," and CMS is committed to continuing to act within our statutory authority to achieve these goals.[1] It is important to note that Section 1847A of the Social Security Act establishes how Medicare pays for drugs covered under the Part B benefit. It is also important to note that factors outside of coverage and payment policy may affect provider and beneficiary preferences for a reference product versus the biosimilars. For example, prescribers or beneficiaries may prefer the more familiar reference product when a biosimilar first enters the market. In addition, the price of a biosimilar may fall below the price of the reference product even when taking the reference product's rebate into consideration, which may drive uptake and increased market share for the biosimilar. CMS will continue to research and pursue strategies within our statutory authority to address both cost and market competition concerns.

[1] Please see Executive Order 14036 (July 9, 2021) "Promoting Competition in the American Economy", Section 5(p)(viii). https://www.govinfo.gov/content/pkg/FR-2021-07-14/pdf/2021-15069.pdf

In addition, as noted by OIG, the Inflation Reduction Act of 2022 (IRA) instituted various changes to the Part B program, including with respect to the allocation of financial responsibility for prescription drug costs between manufacturers, beneficiaries, and the Medicare program. As of October 2022, CMS had already implemented the IRA's temporary increase in Part B add-on payments for certain biosimilars. The temporary add-on payment may increase access to biosimilars, as well as encourage competition between biosimilars and reference biological products, which may, over time, lower drug costs and lead to savings for beneficiaries and Medicare.

OIG's recommendation and CMS' response is below.

OIG Recommendation

CMS should pursue one or more payment changes that could further realize savings from biosimilars for Part B and enrollees.

CMS Response

Within our authority, CMS is committed to taking action, as appropriate, to increase access to and use of biosimilars.

As discussed above, any changes that CMS might make to the payment policies for drugs and biologicals covered under Part B must be consistent with the requirements of Section 1847A of the Social Security Act. In addition, while a multitude of policy and operational considerations influence whether CMS implements a demonstration project, CMS is currently conducting the research necessary to determine how demonstration projects could be used to test ways to lower beneficiary and program spending on drugs and incentivize the use of biosimilar and generic drugs.[2] CMS will continue to explore options to address this issue.

CMS thanks OIG for their efforts on this issue and looks forward to working with OIG on this and other issues in the future.

[2] https://innovation.cms.gov/strategic-direction-whitepaper

ACKNOWLEDGMENTS AND CONTACT

Acknowledgments

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This report was prepared under the direction of Laura Kordish, Regional Inspector General for Evaluation and Inspections in the Chicago regional office; Adam Freeman, Deputy Regional Inspector General; and Hilary Slover, Assistant Regional Inspector General.

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ENDNOTES

[1] The Medicare Payment Advisory Commission (MedPAC), "Chapter 14: The Medicare prescription drug program (Part D): Status report," *Report to the Congress: Medicare Payment Policy*, March 2018. Accessed at https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar18_medpac_ch14_sec.pdf on April 15, 2023. Part D covers drugs, including biosimilars, that can be administered at home by an enrollee or caregiver.

[2] Biosimilars reviewed in this study also include erythropoietin-stimulating agents—drugs statutorily covered under Part B for dialysis patients even when self-administered. Section 1861(s)(2)(O) of the Social Security Act (hereafter "the Act").

[3] 42 CFR § 414.900(b).

[4] The Centers for Medicare & Medicaid Services (CMS), "Chapter 15: Covered Medical and Other Health Services," *Medicare Benefit Policy Manual*, May 2022, p. 51. Accessed at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/downloads/bp102c15.pdf on April 15, 2023.

[5] OIG analysis of CMS's Part B Dashboard for calendar year (CY) 2020 spending. Accessed at https://data.cms.gov/summary-statistics-on-use-and-payments/medicare-medicaid-spending-by-drug/medicare-part-b-spending-by-drug on April 15, 2023.

[6] Ibid.

[7] A reference product is the single biological product, already approved by FDA, against which a proposed biosimilar product is compared. 42 U.S.C. § 262(i)(4).

[8] Biosimilars can also be deemed as "interchangeable" by FDA if the manufacturer can also demonstrate that the biosimilar produces the same clinical result as the reference product in any given patient. This designation primarily affects biosimilar use in the pharmacy setting, as in most States, pharmacists can substitute an interchangeable biosimilar for its reference product without involving the prescriber. Only four biosimilars had been deemed interchangeable as of July 2023. 42 U.S.C. § 262(k)(4).

[9] The Biologics Price Competition and Innovation Act (BPCIA), part of the Patient Protection and Affordable Care Act, created an abbreviated approval pathway for biosimilars to introduce competition and lower prices for biologics. Under the BPCIA, the FDA may approve a biosimilar once its manufacturer demonstrates that the biosimilar is "highly similar" to the reference product and that there are no "clinically meaningful differences" between the reference product and the biosimilar. P.L. 111–148, Title VII, §§ 7001-7003, and 42 U.S.C. § 262(i).

[10] OIG, *Medicare Part D and Beneficiaries Could Realize Significant Spending Reductions With Increased Biosimilar Use*, OEI-05-20-00480, March 2022.

[11] Assistant Secretary for Planning and Evaluation (ASPE), *Medicare Part B Drugs: Trends in Spending and Utilization: 2006-2017*, November 2020, p. 17. Accessed at https://aspe.hhs.gov/sites/default/files/private/pdf/264416/Part-B-Drugs-Trends-Issue-Brief.pdf on April 15, 2023.

[12] HHS, *Comprehensive Plan for Addressing High Drug Prices: A Report in Response to the Executive Order on Competition in the American Economy*, September 9, 2021. Accessed at https://aspe.hhs.gov/reports/comprehensive-plan-addressing-high-drug-prices on July 19, 2023.

[13] FDA, Biosimilar Product Information: FDA-Approved Biosimilar Products, December 2022. Accessed at https://www.fda.gov/drugs/biosimilars/biosimilar-product-information on May 22, 2023.

[14] Mike Z. Zhai, Ameet Sarpatwari, and Aaron Kesselheim, "Why Are Biosimilars Not Living up to Their Promise in the US?," *AMA Journal of Ethics*, August 2019, p. 670. Accessed at https://journalofethics.ama-assn.org/article/why-are-biosimilars-not-living-their-promise-us/2019-08 on April 15, 2023.

[15] Ibid., p. 671.

[16] HHS, *Comprehensive Plan for Addressing High Drug Prices: A Report in Response to the Executive Order on Competition in the American Economy*, September 9, 2021, p. 10. Accessed at https://aspe.hhs.gov/reports/comprehensive-plan-addressing-high-drug-prices on July 19, 2023.

[17] ASPE, *Medicare Part B Drugs: Trends in Spending and Utilization: 2006-2017*, November 2020, p. 17. Accessed at https://aspe.hhs.gov/sites/default/files/private/pdf/264416/Part-B-Drugs-Trends-Issue-Brief.pdf on April 15, 2023.

[18] John W. Cook, et al., "Academic oncology clinicians' understanding of biosimilars and information needed before prescribing," *Therapeutic Advances in Medical Oncology*, vol. 22, Jan. 6, 2019.

[19] Ira Jacobs, et al., "Patient attitudes and understanding about biosimilars: an international cross-sectional survey," *Patient Preference and Adherence*, May 26, 2016.

[20] Before switching their patients to a biosimilar, these providers may want additional real-world evidence about patient switches or further guidance from FDA. NORC, *Understanding Stakeholder Perception of Biosimilars*, April 2021. Accessed at https://www.norc.org/content/dam/norc-org/pdfs/20210405_AV%20-%20NORC%20Biosimilars%20Final%20Report.pdf on June 15, 2023.

[21] Sections 1847A(b)-(c) of the Act.

[22] Medicare, *Part B (Medical Insurance) Costs*. Accessed at https://www.medicare.gov/basics/costs/medicare-costs on April 6, 2023.

[23] HCPCS is a standardized coding system that represents medical procedures, supplies, products, and services. The codes facilitate the processing of health insurance claims by Medicare and other insurers.

[24] Prior to 2018, CMS assigned one HCPCS code to all biosimilars with the same reference biologic. 82 Fed. Reg. 52976-53371, 53186 (November 15, 2017).

[25] ASPE, *Medicare Part B Drugs: Trends in Spending and Utilization, 2006-2017*, November 20, 2020, p. 5. Accessed at https://aspe.hhs.gov/sites/default/files/private/pdf/264416/Part-B-Drugs-Trends-Issue-Brief.pdf on April 15, 2023.

[26] Sections 1847A(b)(6) and 1847A(c)(3) of the Act. Drugs assigned to the same HCPCS code may have come in multiple strengths and volumes.

[27] Section 1927(b)(3) of the Act. Section 1847A(f)(2) of the Act requires manufacturers without a Medicaid drug rebate agreement to report average sales price information to CMS for calendar quarters beginning on January 1, 2022. See also 42 CFR § 414.804.

[28] There is a two-quarter lag between the sales quarter for which manufacturers submit pricing and sales volume information and the effective date of the ASP-based payment amount. For example, CMS uses the first calendar-quarter pricing and sales volume information submitted by manufacturers to calculate ASP for the third calendar-quarter ASP payment amounts.

[29] Before sufficient data exist to calculate ASP—such as during the first few quarters after a new biosimilar enters the market—CMS pays providers the drug's wholesale acquisition cost (WAC) plus 3 percent. See MedPAC, *Part B Drugs Payment Systems*, November 2021. Accessed at https://www.medpac.gov/wp-content/uploads/2021/11/medpac_payment_basics_21_partb_final_sec.pdf on June 18, 2023.

[30] Typically, providers receive 106 percent of ASP (i.e., 100 percent of the ASP plus a 6-percent add-on) for most Part B drugs administered in a physician's office as well as for some high-cost drugs—such as reference products—administered in hospital outpatient departments. Drugs administered in a hospital outpatient department are considered separately payable when they exceed a threshold for per-drug, per-day costs (greater than $130 in CY 2021). 85 Fed. Reg. 85866-86305, 86032 (December 29, 2020).

[31] From 2018 to 2022, payment was generally lower for Part B drugs—including reference products and older biosimilars—administered at hospitals participating in the 340B Drug Pricing Program. However, the Supreme Court recently ruled that the Federal government had improperly reduced payment rates for 340B hospitals in CY 2018 and CY 2019. As a result, CMS will return to paying for all 340B drugs at the default rate for CY 2023 (generally ASP + 6 percent) and will develop a plan to compensate providers for the reduced payments from 2018-2022. 87 Fed. Reg. 71748-72310, 71973-71976 (November 23, 2022). See also STAT, "Supreme Court sides with hospitals on Medicare drug pay dispute," June 15, 2022. Accessed at

https://www.statnews.com/2022/06/15/supreme-court-sides-with-hospitals-on-medicare-drug-pay-dispute/ on April 15, 2023.

[32] As of October 2022, the add-on payment for qualifying biosimilars temporarily increased from 6 to 8 percent of the reference product's ASP. Biosimilars qualify for this increased add-on for a 5-year period if they have a lower ASP than their reference product. Inflation Reduction Act, P.L. 117-169, § 11403.

[33] According to The Pew Charitable Trusts, by paying the same add-on rate for reference products and their biosimilars, CMS offered providers equal financial incentives when providers are choosing between a reference product and its biosimilar. The Pew Charitable Trusts, *Can Biosimilar Drugs Lower Medicare Part B Spending?*, January 2017. Accessed at https://www.pewtrusts.org/-/media/assets/2017/01/leveraging-biosimilars-to-lower-medicare-part-b.pdf on April 15, 2023.

[34] HHS, *Comprehensive Plan for Addressing High Drug Prices: A Report in Response to the Executive Order on Competition in the American Economy*, September 9, 2021, pp. 14-15. Accessed at https://aspe.hhs.gov/reports/comprehensive-plan-addressing-high-drug-prices on July 19, 2023.

[35] Due to the two-quarter lag between the sales quarter for which manufacturers submit pricing and sales volume information and the effective ASP payment amount, the payment providers receive in any given quarter is based on the manufacturer's average prices from two quarters prior.

[36] The Department noted that Congress could consider a single payment limit applicable to the reference product and all biosimilar product(s) to encourage price competition and drive down ASPs. See HHS, *Comprehensive Plan for Addressing High Drug Prices: A Report in Response to the Executive Order on Competition in the American Economy*, September 9, 2021, pp. 14-15. Accessed at https://aspe.hhs.gov/reports/comprehensive-plan-addressing-high-drug-prices on July 19, 2023. MedPAC has proposed a similar idea. See MedPAC, "Addressing the high prices of drugs covered under Medicare Part B," April 13, 2023, p. 8. Accessed at https://www.medpac.gov/wp-content/uploads/2022/07/Tab-B-Part-B-drugs-April-2023-SEC.pdf on May 18, 2023.

[37] The sequestration implemented by the Budget Control Act of 2011 and the American Taxpayer Relief Act of 2012 reduces Medicare payments to providers—but not enrollee payments—by 2 percent. With this mandatory 2-percent reduction in the Federal payment, providers effectively receive a payment of ASP plus 4.3 percent. CMS Medicare FFS Provider e-News, "Mandatory Payment Reductions in the Medicare Fee-for-Service (FFS) Program—'Sequestration,'" March 8, 2013. Accessed at https://www.cms.gov/Outreach-and-Education/Outreach/FFSProvPartProg/Downloads/2013-03-08-standalone.pdf on April 15, 2023.

[38] Sequestration was suspended during part of our analysis period, from May 1, 2020, through December 31, 2021. CMS, "Medicare FFS Claims: 2% Payment Adjustment (Sequestration) Suspended Through December," April 16, 2021. Accessed at https://www.cms.gov/outreach-and-educationoutreachffsprovpartprogprovider-partnership-email-archive/2021-04-16-mlnc#_Toc69394754 on April 4, 2023.

[39] Lisa A. Raedler, "Zarxio (Filgrastim-sndz): First Biosimilar Approved in the United States," *Journal of Hematology Oncology Pharmacy*, June 2020, vol. 10, no. 3. Accessed at https://jhoponline.com/2016-first-annual-oncology-guide-to-new-fda-approvals/16744-zarxio-filgrastim-sndz-first-biosimilar-approved-in-the-united-states on April 15, 2023.

[40] Some possible explanations for slower adoption of infliximab biosimilars include (1) that infliximab is used to treat chronic conditions (e.g., Crohn's disease, ulcerative colitis, psoriasis) and prescribers may be hesitant to switch patients to a biosimilar when those patients are stable on the reference product, and (2) that certain practitioners who treat these chronic conditions may be less familiar with biosimilars (e.g., advanced practice providers treating inflammatory bowel disease (IBD)). See Alice J. Chen, et al., "Uptake of Infliximab Biosimilars Among the Medicare Population," *JAMA Internal Medicine*, July 20, 2020. Accessed at https://jamanetwork.com/journals/jamainternalmedicine/fullarticle/2768650 on April 14, 2023. See also Nana Bernasko and Kofi Clarke, "Why Is There Low Utilization of Biosimilars in Inflammatory Bowel Disease Patients by Gastroenterology Advanced Practice Providers?," *Crohn's & Colitis,* vol. 3, no. 4, October 2021. Accessed at https://academic.oup.com/crohnscolitis360/article/3/4/otab004/6196016 on April 14, 2023.

[41] CMMI has explored payment and service delivery models that feature (1) innovative payments that incentivize the use of biosimilars, (2) sharing savings from biosimilar use with providers, and (3) bundled payments for episodes of care that incentivize the use of biosimilars. HHS, *Comprehensive Plan for Addressing High Drug Prices: A Report in Response to the*

Executive Order on Competition in the American Economy, September 9, 2021, pp. 16-17. Accessed at https://aspe.hhs.gov/reports/comprehensive-plan-addressing-high-drug-prices on July 19, 2023.

[42] HHS, *A Report in Response to the Executive Order on Lowering Prescription Drug Costs for Americans*, 2023, p. 10. Accessed at https://innovation.cms.gov/data-and-reports/2023/eo-rx-drug-cost-response-report on February 2, 2023.

[43] Inflation Reduction Act, P.L. 117-169, § 11403.

[44] These figures represent 20 percent of total Part B spending for the typical annual amount administered and serve as an estimation of enrollee spending. Actual spending may be lesser or greater depending on enrollees' deductibles and supplemental insurance. For example, people with Medicare who have supplemental coverage may not be responsible for paying the full cost-sharing amount for outpatient prescription drugs. However, in 2018, nearly one in five enrollees with traditional Medicare did not have supplemental coverage and would have been responsible for the full cost-sharing for their outpatient prescription drugs. Kaiser Family Foundation, *A Snapshot of Sources of Coverage Among Medicare Beneficiaries in 2018*. Accessed at https://www.kff.org/medicare/issue-brief/a-snapshot-of-sources-of-coverage-among-medicare-beneficiaries-in-2018/ on April 14, 2023.

[45] OIG, *OIG's Top Unimplemented Recommendations: Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs*, 2022, p. 7. Accessed at https://oig.hhs.gov/reports-and-publications/compendium/files/compendium2022.pdf on April 15, 2023.

[46] HHS, *Comprehensive Plan for Addressing High Drug Prices: A Report in Response to the Executive Order on Competition in the American Economy*, September 9, 2021, pp. 14-15. Accessed at https://aspe.hhs.gov/reports/comprehensive-plan-addressing-high-drug-prices on July 19, 2023.

[47] Nitzan Arad, et al., Duke-Robert J. Margolis Center for Health Policy, *Originator Biologics and Biosimilars: Payment Policy Solutions to Increase Price Competition While Maintaining Market Sustainability in Medicare Part B*, October 2021, p. 7. Accessed at https://healthpolicy.duke.edu/publications/originator-biologics-and-biosimilars-payment-policy-solutions-increase-price#:~:text=Payment%20reforms%20are%20needed%20to%20increase%20price%20competition,rates%20and%20least%20costly%20alternative%20%28LCA%29%20payment%20policies on April 14, 2023.

[48] "Coalition urges CMS to drop LCA policy for prostate cancer drugs," *Urology Times*, November 16, 2006. Accessed at https://www.urologytimes.com/view/coalition-urges-cms-drop-lca-policy-prostate-cancer-drugs on April 14, 2023.

[49] Nitzan Arad, et al., Duke-Robert J. Margolis Center for Health Policy, *Originator Biologics and Biosimilars: Payment Policy Solutions to Increase Price Competition While Maintaining Market Sustainability in Medicare Part B*, October 2021, p. 7. Accessed at https://healthpolicy.duke.edu/publications/originator-biologics-and-biosimilars-payment-policy-solutions-increase-price#:~:text=Payment%20reforms%20are%20needed%20to%20increase%20price%20competition,rates%20and%20least%20costly%20alternative%20%28LCA%29%20payment%20policies on April 14, 2023.

[50] OIG, *OIG's Top Unimplemented Recommendations: Solutions To Reduce Fraud, Waste, and Abuse in HHS Programs*, 2022, p. 7. Accessed at https://oig.hhs.gov/reports-and-publications/compendium/files/compendium2022.pdf on February 22, 2023.

[51] HHS, *A Report in Response to the Executive Order on Lowering Prescription Drug Costs for Americans*, 2023, p. 17. Accessed at https://innovation.cms.gov/data-and-reports/2023/eo-rx-drug-cost-response-report on February 2, 2023.

[52] Abt, Evaluation of the Oncology Care Model, p. 30. Accessed at https://innovation.cms.gov/data-and-reports/2023/ocm-evaluation-pp1-9 on July 20, 2023.

[53] CMS, Enhancing Oncology Model. Accessed at https://innovation.cms.gov/innovation-models/enhancing-oncology-model on July 19, 2023.

[54] NDCs are numeric codes that uniquely identify a drug, its manufacturer, and its package size.

[55] FDA, Biosimilar Product Information: FDA-Approved Biosimilar Products. Accessed at https://www.fda.gov/drugs/biosimilars/biosimilar-product-information on April 14, 2023.

[56] FDA, *Purple Book: Lists of Licensed Biological Products with Reference Product Exclusivity and Biosimilarity or Interchangeability Evaluations*. Accessed at https://www.fda.gov/drugs/therapeutic-biologics-applications-bla/purple-book-lists-licensed-biological-products-reference-product-exclusivity-and-biosimilarity-or on April 14, 2023.

[57] Our analysis did not include Not Otherwise Classified codes. Providers may use these codes when billing for drugs and biologics in some instances, but they do not uniquely identify records for specific biosimilars and their reference products.

[58] This excludes claims for biologics used during the treatment of end-stage renal disease (ESRD). ESRD is not paid on the basis of ASP, as of January 1, 2011, and is instead paid under a bundled rate. CMS, Medicare Claims Processing Manual, August 6, 2021, p. 5. Accessed at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c08.pdf on March 7, 2023.

[59] We excluded claims not paid on the basis of ASPs. This includes claims from critical access hospitals (CAHs); certain hospitals in Maryland; hospitals located outside one of the 50 States, the District of Columbia, and Puerto Rico; and hospitals of the Indian Health Service. 42 CFR § 419.20(b). Accessed at https://www.ecfr.gov/current/title-42/chapter-IV/subchapter-B/part-419/subpart-B/section-419.20 on March 7, 2023.

[60] We excluded from our analysis claims from hospitals that are not paid for Part B drugs on the basis of ASP. These include CAHs; Maryland waiver hospitals; hospitals outside the 50 States, D.C., or Puerto Rico; and hospitals of the Indian Health Service. 42 CFR § 419.20(b).

[61] Although Granix was approved under a Biologic License Application before the BPCIA created an abbreviated approval pathway for biosimilars, it is considered a filgrastim biosimilar alternative.