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Medicare Part D and Beneficiaries Could Realize Significant Spending Reductions With Increased Biosimilar Use

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Why OIG Did This Review

Biologics—usually large, complex molecules produced in a living system—are some of the most expensive drugs available, and spending for biologics is growing in Medicare Part D because they treat diseases common among Medicare beneficiaries. Biologics are estimated to cost Part D upwards of \$12 billion annually.

A biosimilar is a lower-cost biologic that is highly similar to an existing biologic approved by the Food and Drug Administration (FDA) (i.e., the biosimilar's "reference product").

Although a limited number of biosimilars are currently available for Part-D-covered reference products, multiple biosimilars for Humira—the best-selling prescription drug in the world—are expected to be available in 2023, thereby presenting an opportunity to significantly decrease Part D drug costs.

How OIG Did This Review

We analyzed biosimilar utilization and spending in Part D from 2015 to 2019. We also calculated multiple estimates to explore how Part D and beneficiary spending in 2019 could have changed with increased utilization of biosimilars.

Lastly, we determined the extent to which Part D plan formularies encouraged the use of biosimilars rather than reference products. Specifically, we examined whether biosimilars were included on Part D plan formularies and, if so, whether they were on a less preferential tier or were subject to different utilization management requirements than their reference products.

Medicare Part D and Beneficiaries Could Realize Significant Spending Reductions With Increased Biosimilar Use

Key Takeaway

Medicare Part D and its beneficiaries could realize significant spending reductions if biosimilar use becomes more widespread, but the lack of biosimilar coverage on Part D formularies may limit increased utilization.

What OIG Found

Since biosimilars were introduced in 2015, use of and spending on these drugs in Part D has steadily increased. However, they are still used far less frequently than their higher-cost reference product alternatives. In 2019, biosimilars' reference products were still prescribed about five times more frequently than biosimilars in Part D.

We estimated that with increased use of biosimilars instead of reference products, Part D and beneficiary spending could have been considerably reduced in 2019. Specifically,

Part D spending on biologics with available biosimilars could have decreased by \$84 million, or 18 percent, if *all* biosimilars had been used as frequently as the most-used biosimilars. Additionally, beneficiaries' out-of-pocket costs for these drugs could have decreased by \$1.8 million, or 12 percent. Although these amounts are modest in the context of overall Part D spending, far greater spending reductions will be possible as additional biosimilars become available.

Biosimilars have the potential to significantly reduce costs for Part D and beneficiaries if their use becomes more widespread, particularly with the expected launches of biosimilars for blockbuster drugs Humira and Enbrel. However, a lack of biosimilar coverage on Part D formularies could limit this wider utilization. In 2019, not all plan formularies covered available biosimilars. Moreover, those formularies that *did* cover biosimilars rarely encouraged their use over reference products through preferential formulary tier placement and utilization management tools.

What OIG Recommends and How the Agency Responded

Without further changes to the Part D program, the impact of limited coverage and promotion of biosimilars on formularies may be magnified as biosimilars for blockbuster drugs become available. To help ensure that Part D and beneficiaries can capitalize on potential savings, we recommend that the Centers for Medicare & Medicaid Services (CMS) encourage plans to increase access to and use of biosimilars in Part D. We also recommend that CMS monitor biosimilar coverage on formularies to identify concerning trends. CMS concurred with our first recommendation and neither concurred nor nonconcurred with our second recommendation.

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BACKGROUND

Objectives

1. To identify trends in biosimilar utilization and spending in the Medicare Part D program for 2015–2019.
 2. To estimate how increased use of biosimilars could have changed Part D spending and beneficiary spending in 2019.
 3. To examine the extent to which Part D formularies were designed to encourage the use of biosimilars rather than reference products in 2019.
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Biological products—usually large, complex molecules produced in a living system—are among the most expensive prescription drugs in the United States. Although less than 2 percent of Americans used biologics in 2018, they accounted for 40 percent of the total spending on prescription drugs.¹ Biologics cost Medicare Part D and beneficiaries nearly \$12 billion in 2019.² Because biologics are often used to treat diseases common among the Medicare population (e.g., rheumatoid arthritis, cancer), Part D spending on biologics likely will continue to rise as more beneficiaries benefit from these expensive drugs.³

A biosimilar is a biological product that is highly similar to and has no clinically meaningful difference from what is known as its “reference product”—i.e., an existing biologic approved by the Food and Drug Administration (FDA).⁴ In 2010, Congress

¹ Scott Gottlieb, M.D., Commissioner of Food and Drugs, remarks as prepared for delivery at the Brookings Institution on the release of the Food and Drug Administration’s (FDA’s) Biosimilars Action Plan, July 18, 2018. Accessed at <https://www.fda.gov/news-events/press-announcements/remarks-fda-commissioner-scott-gottlieb-md-prepared-delivery-brookings-institution-release-fdas> on June 15, 2021.

² OIG analysis of the Centers for Medicare & Medicaid Services (CMS) Part D Dashboard for calendar year (CY) 2019 spending. This figure excludes insulin and vaccines. On March 23, 2020, FDA began regulating insulin as a biologic product, allowing for biosimilar and interchangeable versions. Until July 2021, FDA had not approved any insulin biosimilars. FDA, “Insulin Gains New Pathway to Increased Competition,” March 23, 2020. Accessed at <https://www.fda.gov/news-events/press-announcements/insulin-gains-new-pathway-increased-competition> on June 15, 2021. See also FDA, “FDA Approves First Interchangeable Biosimilar Insulin Product for Treatment of Diabetes,” July 28, 2021. Accessed at <https://www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-insulin-product-treatment-diabetes> on October 2, 2021.

³ 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 February 4, 2022.

⁴ 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).

created an abbreviated approval pathway for biosimilars to increase competition and to lower prices for biosimilars in comparison to their reference products. However, in the subsequent 11 years, competition and savings largely have not been realized.⁵

Most Medicare spending on biosimilars and their reference products currently occurs in Part B,⁶ but Part D spending on biosimilars is expected to grow in the coming years. Specifically, biosimilars for two blockbuster drugs covered only under Part D—Humira and Enbrel—have been approved but are not yet available to U.S. consumers.⁷ When biosimilars for these drugs become available—expected in 2023 and 2029, respectively—they present an opportunity to significantly decrease Part D drug costs.^{8,9} Humira and Enbrel accounted for more than \$5 billion in Part D spending and nearly half of Part D spending on biological products in 2019.

This study is part of a larger strategy by the Office of Inspector General (OIG) to address one of the top management and performance challenges facing the Department of Health and Human Services (HHS)—namely, ensuring the financial integrity of HHS programs.¹⁰ More broadly, the objectives of this study align with the Administration’s strategies to reduce U.S. prescription drug spending by increasing access to and utilization of lower-cost biosimilars.¹¹ It also forms a foundation for future work on this topic as Part D spending on biosimilars grows and as the

⁵ 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. 669. Accessed at <https://journalofethics.ama-assn.org/article/why-are-biosimilars-not-living-their-promise-us/2019-08> on June 15, 2021.

⁶ Most biosimilars are typically administered by a physician and therefore billed under Part B, which is Medicare’s medical benefit. Although insulin is primarily billed under Part D, FDA did not regulate insulin as a biologic product—or allow for biosimilar versions—until March 23, 2020. FDA, “Insulin Gains New Pathway to Increased Competition,” March 23, 2020. Accessed at <https://www.fda.gov/news-events/press-announcements/insulin-gains-new-pathway-increased-competition> on June 15, 2021.

⁷ FDA had approved 34 biosimilars as of March 2022; however, some of these biosimilars were not available to consumers because of ongoing patent litigation or patent settlement agreements or because manufacturers had not yet launched them.

⁸ 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. 671. Accessed at <https://journalofethics.ama-assn.org/article/why-are-biosimilars-not-living-their-promise-us/2019-08> on June 15, 2021.

⁹ Eric Sagonowsky, “Sandoz’s Enbrel biosim case turned away at SCOTUS, giving Amgen’s blockbuster 8 more years of free rein,” *Fierce Pharma*, May 17, 2021. Accessed at <https://www.fiercepharma.com/pharma/sandoz-s-enbrel-biosim-case-turned-away-at-supreme-court-giving-amgen-s-blockbuster-many> on August 17, 2021.

¹⁰ OIG, *Top Management and Performance Challenges Facing HHS*, 2020. Accessed at <https://oig.hhs.gov/reports-and-publications/top-challenges/2020/index.asp> on June 15, 2021.

¹¹ 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. Executive Order No. 14036, 86 Fed. Reg. 36987 (July 14, 2021).

biosimilar market matures. Additional OIG work will examine biosimilar utilization and spending in Part B.¹²

Biological Products

Spending for biological products—which are usually large, complex molecules produced in a living system, such as a microorganism, plant cell, or animal cell—is growing.¹³ Recent analysis indicates that biologic spending has grown more than twice as quickly as overall drug spending since 2015 and totaled \$211 billion in 2019.¹⁴ List prices for Humira and Enbrel—two biologics that accounted for nearly half of the \$12 billion in Part D biologic spending—doubled between 2012 and 2017.¹⁵ Because biologics are used to treat diseases common among Medicare beneficiaries (e.g., rheumatoid arthritis), Part D spending on biologics will continue to increase as additional beneficiaries benefit from these expensive therapies.¹⁶

Biosimilars

A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing biologic (known as the biosimilar’s “reference product”) that has already been approved by the FDA. In 2010, Congress passed the Biologics Price Competition and Innovation Act (BPCIA) as part of the Patient Protection and Affordable Care Act, creating an abbreviated approval pathway for biosimilars to introduce competition and lower prices for these drug products.¹⁷ Under the BPCIA, FDA may approve a biosimilar once the drug 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

¹² OIG, *Biosimilar Trends in Medicare Part B*, OEI-05-22-00140. Accessed at <https://oig.hhs.gov/reports-and-publications/workplan/summary/wp-summary-0000659.asp> on February 16, 2022.

¹³ FDA, “Biological Product Definitions.” Accessed at <https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf> on June 15, 2021.

¹⁴ IQVIA, “Biosimilars in the United States 2020-2024: Competition, Savings, and Sustainability,” October 2020.

¹⁵ Nathan E. Wineinger, Yunyue Zhang, and Eric J. Topol, “Trends in Prices of Popular Brand-Name Prescription Drugs in the United States,” *JAMA Network Open*, May 31, 2019, pp. 4–5.

¹⁶ 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 February 4, 2022.

¹⁷ P.L. No. 111–148, Title VII, §§ 7001–7003.

the biosimilar. The first biosimilar—Zarxio—was approved under the BPCIA by FDA in 2015.¹⁸

As of March 2022, 20 of the 34 FDA-approved biosimilars were available in the United States.¹⁹ Ongoing patent litigation and patent dispute settlements prevented many of the remaining biosimilars from launching in the U.S. market.²⁰ For example, as a result of patent dispute settlements, manufacturers of multiple FDA-approved biosimilars for the blockbuster reference product Humira are not expected to launch their products in the United States until 2023.²¹ Similarly, approved biosimilars for another blockbuster drug, Enbrel, are not expected to launch until 2029.²²

A biosimilar can be deemed “interchangeable” if the manufacturer can demonstrate that the biosimilar produces the same clinical result as its reference product in any given patient.²³ The interchangeability designation allows pharmacists to substitute an interchangeable biosimilar for its reference product without involving the prescriber.²⁴ Meeting the BPCIA-established threshold for interchangeability requires additional data, such as results of clinical trials in which patients are switched from the reference product to the biosimilar.^{25, 26} As of November 2021, only two biosimilars—one for an insulin product and one for Humira—had been deemed

¹⁸ 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 <http://jhoonline.com/2016-first-annual-oncology-guide-to-new-fda-approvals/16744-zarxio-filgrastim-sndz-first-biosimilar-approved-in-the-united-states> on June 15, 2021.

¹⁹ FDA, “Biosimilar Product Information: FDA-Approved Biosimilar Products,” July 2021. Accessed at <https://www.fda.gov/drugs/biosimilars/biosimilar-product-information> on August 2, 2021.

²⁰ 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 June 15, 2021.

²¹ *Ibid*, p. 671.

²² Eric Sagonowsky, “Sandoz's Enbrel biosim case turned away at SCOTUS, giving Amgen's blockbuster 8 more years of free rein,” *Fierce Pharma*, May 17, 2021. Accessed at <https://www.fiercepharma.com/pharma/sandoz-s-enbrel-biosim-case-turned-away-at-supreme-court-giving-amgen-s-blockbuster-many> on August 17, 2021.

²³ 42 U.S.C. § 262(k)(4).

²⁴ Forty-seven States have passed laws allowing pharmacists to substitute interchangeable biosimilars for their reference products unless a prescriber indicates that the prescription should be dispensed as written. Cardinal Health, “Biosimilar Interchangeability Laws by State,” July 2021. Accessed at <https://www.cardinalhealth.com/content/dam/corp/web/documents/publication/Cardinal-Health-Biosimilar-Interchangeability-Laws-by-State.pdf> on September 27, 2021.

²⁵ 42 U.S.C. § 262(k)(4)(B).

²⁶ 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. 669. Accessed at <https://journalofethics.ama-assn.org/article/why-are-biosimilars-not-living-their-promise-us/2019-08> on June 15, 2021.

“interchangeable.”^{27, 28, 29} Without interchangeability status, currently a prescriber must proactively write or approve a prescription for a biosimilar.

In 2019, eight biosimilars were available and approved as alternatives to four reference products in Part D. These biosimilars can be self-administered or administered by a caregiver. They treat autoimmune diseases like ulcerative colitis; anemia due to chronic kidney disease; and neutropenia, when the body makes too few white blood cells as a result of chemotherapy. Part D and beneficiary spending on these biosimilars and their reference products was about \$466 million.³⁰ Exhibit 1 lists the biosimilars covered under Part D in 2019 and their reference products.

Exhibit 1: Eight Biosimilars for Four Reference Products Were Covered Under Part D in 2019

Drug Group	Biosimilar	Approval Date	Reference Product(s)
Filgrastims	Zarxio	March 2015	Neupogen
	Nivestym	July 2018	
	Granix	August 2012 ³¹	
Infliximabs	Inflectra	April 2016	Remicade
	Renflexis	May 2017	
Pegfilgrastims	Fulphila	June 2018	Neulasta
	Udenyca	November 2018	
Epoetin alfas	Retacrit	May 2018	Epogen/Procrit

Source: OIG research, 2021.

²⁷ An interchangeable product is a biosimilar product that meets additional requirements. FDA, “Biological Product Definitions.” Accessed at <https://www.fda.gov/files/drugs/published/Biological-Product-Definitions.pdf> on June 15, 2021.

²⁸ FDA, “FDA Approves First Interchangeable Biosimilar Insulin Product for Treatment of Diabetes,” July 28, 2021. Accessed at <https://www.fda.gov/news-events/press-announcements/fda-approves-first-interchangeable-biosimilar-insulin-product-treatment-diabetes> on July 29, 2021.

²⁹ FDA, “FDA Approves Cyltezo, the First Interchangeable Biosimilar to Humira,” October 18, 2021. Accessed at <https://www.fda.gov/news-events/press-announcements/fda-approves-cyltezo-first-interchangeable-biosimilar-humira> on October 18, 2021.

³⁰ OIG analysis of the CMS Medicare Part D Drug Spending Dashboard. Dashboard available at <https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/Information-on-Prescription-Drugs/MedicarePartD>.

³¹ 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.

A number of barriers potentially limit the use of available biosimilars. Research shows that many prescribers and patients are not well informed about—and sometimes not even aware of—biosimilar alternatives.^{32, 33} Furthermore, some prescribers are hesitant to switch patients who are already successfully using a reference product to its biosimilar—even when the prescribers have a high degree of confidence in the biosimilar’s safety and effectiveness.³⁴ Industry stakeholders argue that confusion among prescribers, patients, and plans results in part from differences in FDA naming conventions for biosimilars and their reference products that may make biosimilars appear inferior.^{35, 36, 37} Additional research indicates that low biosimilar use, particularly in Part D, may be attributed to a variety of causes, such as formulary exclusion, unfavorable formulary tier placement, and rebates for preferential formulary treatment of reference products.^{38, 39, 40}

Part D Drug Coverage and Formulary Design

Part D sponsors contract with the Centers for Medicare & Medicaid Services (CMS) to administer the Part D benefit through prescription drug plans. Each plan has a formulary, or a list of covered drugs. CMS reviews the formularies submitted by plan sponsors to ensure they align with best practices and provide sufficient access to

³² 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.

³³ Ira Jacobs et al., “Patient attitudes and understanding about biosimilars: an international cross-sectional survey,” *Patient Preference and Adherence*, May 26, 2016.

³⁴ NORC, “Understanding Stakeholder Perception of Biosimilars,” April 2021. Accessed at <https://www.norc.org/Research/Projects/Pages/understanding-stakeholder-perception-of-biosimilars.aspx> on October 5, 2021.

³⁵ Biospace, “In an Attempt at Clarity, FDA Makes the Biosimilar Naming Convention Even More Confusing,” March 8, 2019. Accessed at <https://www.biospace.com/article/fda-abandons-biosimilar-naming-convention/> on October 30, 2019.

³⁶ Biosimilars Council, “Naming Advocacy.” Accessed at <https://www.biosimilarscouncil.org/advocacy/> on October 28, 2019.

³⁷ Biosimilars’ nonproprietary names follow a standard naming convention: the reference product’s nonproprietary name plus a four-letter suffix (e.g., pegfilgrastim-jmdb).

³⁸ 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. 671. Accessed at <https://journalofethics.ama-assn.org/article/why-are-biosimilars-not-living-their-promise-us/2019-08> on June 15, 2021.

³⁹ Jinoos Yazdany et al., “Out-of-Pocket Costs for Infliximab and Its Biosimilar for Rheumatoid Arthritis Under Medicare Part D,” *JAMA*, Vol. 320, No. 9, September 2018, pp. 931-933. Accessed at <https://jamanetwork.com/journals/jama/fullarticle/2698912> on June 15, 2021.

⁴⁰ Biosimilars Council, *Failure to Launch: Barriers to Biosimilar Market Adoption*, September 2019. Accessed at <https://www.biosimilarscouncil.org/wp-content/uploads/2019/09/AAM-Biosimilars-Council-Failure-to-Launch-2-web.pdf> on June 15, 2021. p. 6.

a range of drugs.⁴¹ At a minimum, formularies must cover commonly needed drugs and generally must offer at least two different drugs in each drug class and category.⁴² Formularies allow Part D plans to negotiate lower drug prices with manufacturers in exchange for giving the drugs preferential tier placement on a plan's formulary.⁴³

Tier Placement

Part D plan formularies organize the drugs they cover into tiers with different beneficiary cost-sharing requirements.⁴⁴ Beneficiaries typically pay less for drugs on lower formulary tiers and more for drugs on higher formulary tiers.⁴⁵ Part D plans can use preferential tier placement to encourage utilization of certain drugs. Many Part D plans use five-tier formularies that include one specialty tier for very high-priced drugs.^{46, 47}

Utilization management tools

In addition to using formulary tier placement to control costs and utilization of specific drugs, Part D plans may implement utilization management tools. These tools include prior authorization and step therapy. Prior authorization requires prescribers to obtain approval from the Part D plan before it will cover a specific drug.

⁴¹ CMS, *Medicare Prescription Drug Benefit Manual*, ch. 6, § 30.2.7. Accessed at <https://www.cms.gov/Medicare/Prescription-Drug-Coverage/PrescriptionDrugCovContra/Downloads/Part-D-Benefits-Manual-Chapter-6.pdf> on June 15, 2021.

⁴² 42 CFR § 423.120(b)(2).

⁴³ Health Affairs, Prescription Drug Pricing, September 2017, p. 1. Accessed at https://www.healthaffairs.org/doi/10.1377/hpb20171409.000177/full/hpb_2017_09_14_formularies.pdf on June 15, 2021.

⁴⁴ Beneficiaries can request coverage for drugs not included on their plan's formulary by submitting formulary exception requests—with provider documentation—to their Part D plan. CMS, *Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance*, §§ 40.5.2, 40.5.3. Accessed at <https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf> on August 16, 2021.

⁴⁵ According to CMS, tier 1 should be the lowest cost-sharing tier available to beneficiaries, and any subsequent tiers should be higher cost-sharing tiers in ascending order. CMS, *Medicare Prescription Drug Benefit Manual*, ch. 6, § 30.2.7.

⁴⁶ MedPAC, "Chapter 14: The Medicare prescription drug program (Part D): Status report," *Report to the Congress: Medicare Payment Policy*, March 2019. Accessed at https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar19_medpac_ch14_sec.pdf on February 4, 2022.

⁴⁷ In 2022, Part D plan sponsors may establish a second, "preferred" specialty tier on their formularies. 42 CFR § 423.104(d)(2)(iv)(D). CMS gave sponsors flexibility to determine which drugs are placed on the two specialty tiers. For example, CMS noted that the second specialty tier may impact Part D drug costs by allowing sponsors to encourage use of biosimilars on the preferred specialty tier or by giving them additional negotiating power with brand drug manufacturers. 86 Fed. Reg. 6077 (January 19, 2021).

Step therapy typically requires beneficiaries to first try a less expensive drug before moving to a more expensive drug.

Drug rebates

Part D plan sponsors may negotiate rebates from drug manufacturers in exchange for encouraging greater utilization of a manufacturer's drug. For example, manufacturers may offer rebates to plan sponsors in exchange for placing their drugs on preferred formulary tiers with lower beneficiary cost-sharing or for exclusive coverage of their drugs.^{48, 49} In some cases, a manufacturer's rebates for biologic reference products may be high enough that they reduce the cost of these products so much that the biosimilars—despite their typically lower list price—are more expensive for the Part D plan than their reference products.⁵⁰ However, manufacturer rebates generally do not directly lower Part D drug costs for beneficiaries.

Beneficiary cost-sharing

Beneficiaries' cost-sharing obligations shift over the course of the annual Part D benefit. As their drug spending increases, beneficiaries move through the phases of the standard Part D drug benefit—deductible, initial coverage, coverage gap, and catastrophic coverage. Cost-sharing amounts for beneficiaries, known as "out-of-pocket costs," vary from one phase to another. Beneficiaries pay for all drug costs until they meet their Part D plan's deductible. During the initial coverage and coverage gap phases, beneficiaries pay copayments (fixed payment amounts) and coinsurance amounts (payments based on a percentage of the drug's cost). Beneficiaries then pay no more than 5-percent coinsurance during catastrophic coverage.

Contributions from other sources can reduce beneficiaries' out-of-pocket costs. Beneficiaries who meet certain income and asset thresholds may qualify for reduced cost-sharing under Medicare's Low-Income Subsidy (LIS) program. In some cases, beneficiaries may receive financial assistance from other sources, such as charities or other government healthcare programs.

Recent legal and policy changes to the Part D drug benefit have decreased beneficiary cost-sharing for biosimilars; however, these changes affect only select Part D coverage phases or beneficiaries. Beginning in 2019, biosimilar manufacturers provided

⁴⁸ Congressional Research Service, "Negotiation of Drug Prices in Medicare Part D," October 2019, p. 1. Accessed at <https://crsreports.congress.gov/product/pdf/IF/IF11318> on June 15, 2021.

⁴⁹ MedPAC, "Chapter 14: The Medicare prescription drug program (Part D): Status Report," *Report to the Congress: Medicare Payment Policy*, March 2020, p. 431. Accessed at https://www.medpac.gov/wp-content/uploads/import_data/scrape_files/docs/default-source/reports/mar20_medpac_ch14_sec.pdf on February 4, 2022.

⁵⁰ Jinoos Yazdany, "Failure to Launch: Biosimilar Sales Continue to Fall Flat in the United States," *Arthritis Rheumatology*, Vol. 72, No. 6, pp. 870-873, September 2019.

beneficiaries with a 70-percent discount on biosimilars in the coverage gap by participating in the Medicare Coverage Gap Program.^{51, 52} Prior to this, when beneficiaries were in the coverage gap, they received the 70-percent manufacturer discount only on biologics (i.e., reference products and biologics without biosimilar competitors).⁵³ Additionally, CMS finalized a rule in 2018 that reduced cost-sharing for LIS beneficiaries, allowing biosimilars to be covered at the copayment level for generic drugs rather than for brand-name drugs for these beneficiaries.⁵⁴ As a result, LIS beneficiaries paid very little—between \$0 and \$3.40—for biosimilar drugs in 2019.⁵⁵

Methodology

This study analyzed trends in biosimilar utilization and spending in Part D using information about prescription drug costs and beneficiary spending from calendar years (CYs) 2015 to 2019. We calculated multiple estimates to explore how Part D and beneficiary spending in CY 2019 could have changed had there been increased biosimilar use.

This study also analyzed 2019 Part D plan formularies to examine how formulary coverage, placement, and utilization management requirements for biosimilars compared to those for their reference products.

Data Analysis

Analysis of total utilization and spending over time. To analyze total Part D biosimilar utilization and spending over time, we identified all Prescription Drug Event (PDE) records for biosimilars and reference products from January 1, 2015,

⁵¹ The Bipartisan Budget Act of 2018 required that manufacturers provide a 70-percent discount for biosimilars. Section 53116 of Bipartisan Budget Act of 2018, P.L. No. 115-123 (February 9, 2018). See also Kaiser Family Foundation, “Closing the Medicare Part D Coverage Gap: Trends, Recent Changes, and What’s Ahead,” August 21, 2018. Accessed at <https://www.kff.org/medicare/issue-brief/closing-the-medicare-part-d-coverage-gap-trends-recent-changes-and-whats-ahead/> on June 15, 2021.

⁵² Although the Part D coverage gap (the so-called “doughnut hole”) closed in 2019, beneficiaries still face high cost-sharing for biologics and biosimilars after the initial coverage phase. Beneficiaries still pay for 25 percent of brand-name drug costs after initial coverage ends. Bipartisan Budget Act of 2018, P.L. No. 115-123 (February 9, 2018).

⁵³ Kaiser Family Foundation, “Summary of Recent and Proposed Changes to Medicare Prescription Drug Coverage and Reimbursement,” February 15, 2018. Accessed at <https://www.kff.org/medicare/issue-brief/summary-of-recent-and-proposed-changes-to-medicare-prescription-drug-coverage-and-reimbursement/> on June 15, 2021.

⁵⁴ 42 CFR §§ 423.782(a)(2)(iii)(A) and 423.782(b)(3).

⁵⁵ CMS, “Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter,” April 2, 2018. Accessed at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf> on June 15, 2021.

to December 31, 2019.⁵⁶ We considered all biosimilars approved for the same reference product to belong to one biosimilar drug group. For each year and quarter, we summed the number of records for each biosimilar drug group and reference product. We calculated annual and quarterly utilization rates for all biosimilars and for each biosimilar drug group by dividing the number of biosimilar prescriptions by the total number of biosimilar and reference product prescriptions. We calculated Part D gross spending by summing the ingredient cost, sales tax, and dispensing fee PDE variables.⁵⁷

To analyze total beneficiary spending on biosimilars over time, we summed the patient payment amount from PDE records.⁵⁸ This amount represents the out-of-pocket copayment or coinsurance paid by a beneficiary for a prescription.

We also calculated 2019 Part D and beneficiary spending for two reference products—Humira and Enbrel—expected to have biosimilars available on the U.S. market in 2023 and 2029, respectively.

Analysis of average spending in 2019. For each biosimilar drug group and reference product, we calculated average Part D and beneficiary spending amounts for CY 2019 by dividing the Part D and beneficiary spending by the total drug weight dispensed.

We then used the average spending amounts to illustrate spending differences for typical prescriptions for biosimilars and reference products. First, to define a typical prescription, we calculated the median drug weight dispensed for each biosimilar drug group and its reference product. We then multiplied the average spending amounts for each biosimilar drug group and reference product by the amount dispensed for the typical prescription.

Analysis of changes in 2019 spending with increased biosimilar use. We calculated multiple estimates for changes in Part D and beneficiary spending had biosimilars been used at higher rates in 2019.

We took two steps to estimate how any increase in biosimilar utilization could have changed Part D and beneficiary spending.⁵⁹ We first estimated how much Part D and beneficiaries could have spent if all CY 2019 prescriptions for reference products had been for biosimilars instead, using the average biosimilar spending amounts described above. We used average spending at the biosimilar drug group level to

⁵⁶ We excluded insulin from this analysis because FDA did not regulate insulin as a biologic product until March 23, 2020.

⁵⁷ This represents the total amount paid for drugs covered by the Medicare benefit before rebates are taken into account.

⁵⁸ To better approximate most beneficiaries' cost-sharing obligations, we excluded beneficiaries who were receiving other sources of support (e.g., group health plans, governmental programs) from the analysis of beneficiary spending, as well as beneficiaries enrolled in PACE (Program of All-Inclusive Care for the Elderly) plans.

⁵⁹ We analyzed changes in spending by beneficiaries receiving the low-income subsidy (LIS) separately.

avoid making assumptions about prescribing practices (e.g., which brand or strength of a biosimilar would be prescribed). Based on this—and the actual spending and utilization for biosimilars in 2019—we then estimated how any increase in biosimilar utilization could have changed Part D and beneficiary spending.

We then used these estimates to assess 2019 Part D and beneficiary spending at various utilization rates, two of which we focused on in the report. We included conservative estimates of what Part D and beneficiary spending could have been if total biosimilar utilization had matched the 60-percent utilization rate of the most used biosimilar group (i.e., filgrastim biosimilars). We also included optimistic estimates of what Part D and beneficiary spending could have been if biosimilar utilization in 2019 had matched the 90-percent utilization rate for Part D generic drugs (i.e., approved generic versions of small-molecule, nonbiologic drugs).⁶⁰ The total difference between the actual and estimated spending amounts represented the potential reductions in Part D and beneficiary spending if biosimilar use had increased in 2019.

We used the same methodology to estimate how increased biosimilar use could have changed Part D net spending—that is, Part D spending after adjusting for rebates. To arrive at net spending calculations, we used Direct and Indirect Remuneration (DIR) data about manufacturer rebates from CMS's Health Plan Management System (HPMS).⁶¹ We did not adjust beneficiary spending to reflect rebates because rebates typically do not affect beneficiary out-of-pocket costs.

Analysis of biosimilar formulary coverage and placement. We analyzed formulary coverage and placement separately for each biosimilar drug group. To determine whether Part D plan formularies encouraged biosimilars, we used data from HPMS to calculate the percentage of formularies that included both biosimilars and their reference products; included only biosimilars; or included only the reference products for biosimilars. For formularies that covered both biosimilars and their reference products, we calculated the percentages that (1) placed biosimilars on lower, higher, or the same formulary tiers as their reference products and (2) had different requirements for step therapy and prior authorization for biosimilars than they had for those biosimilars' reference products.

See the Detailed Methodology section for more information.

⁶⁰ In an analysis of Part D prescriptions that could have been filled with an approved generic version of a small-molecule drug, CMS found that the generic drug was used 90.8 percent of the time. CMS, "Increasing Access to Generics and Biosimilars in Medicare," February 5, 2020.

⁶¹ Because HHS treats DIR data with confidentiality, we are refraining from reporting net spending or net savings totals of individual biosimilar or reference products in this report.

Limitations

Changes in Part D and beneficiary spending are estimates and do not represent the exact spending changes that would have resulted from increased biosimilar use in 2019. For instance, these estimates do not account for how drug manufacturers might have responded to greater biosimilar utilization, such as by renegotiating rebates with plans or changing pricing for reference products or biosimilars in response to greater biosimilar use. These estimates also do not account for how increased use of biosimilars could have shifted beneficiaries through the Part D benefit phases or the resulting impacts on beneficiary spending.

This study did not assess whether the increased utilization rates used to estimate spending reductions are achievable. For example, this report does not include an analysis of additional barriers and challenges—such as prescriber preferences—that may prevent greater use of biosimilars. Unlike generic drugs, the biosimilars in this study cannot be substituted for their reference products by a pharmacist because FDA has not deemed them “interchangeable.”

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.

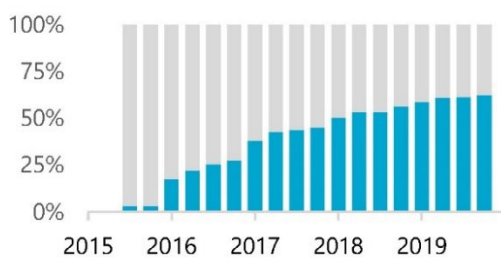
FINDINGS

Use of biosimilars in Part D increased every year, but most biosimilars were still used far less than their reference products in 2019

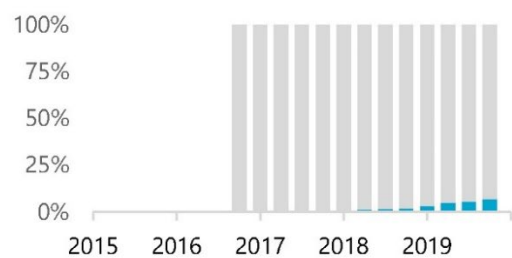
Since biosimilars were first introduced in 2015, use of these drugs in Part D has steadily grown—yet remains low compared to use of their reference products. In nearly 5 years, the total number of biosimilar prescriptions increased substantially; however, biosimilars accounted for only 17 percent of all prescriptions for biosimilars and their reference products in 2019. Among the four drug groups, only filgrastim biosimilars were used more frequently than their reference products. From 2015 to 2019, filgrastim biosimilars grew from 3 percent to 62 percent of quarterly filgrastim prescriptions, driven largely by increased use of Zarxio. In contrast, newer biosimilars in the other three drug groups were used to a much lesser extent than their reference products. Specifically, in the fourth quarter of 2019, biosimilars made up 16 percent of epoetin alfa prescriptions, 12 percent of pegfilgrastim prescriptions, and 7 percent of infliximab prescriptions. Exhibit 2 shows that most biosimilars were used much less frequently than their reference products.

Exhibit 2: For most biosimilars, use remained low compared to their reference products.

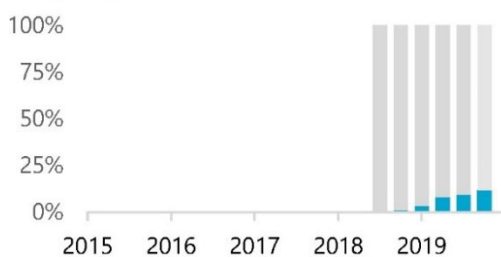
Filgrastims



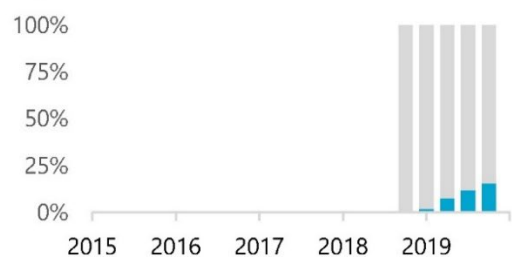
Infliximabs



Pegfilgrastims



Epoetin Alfas

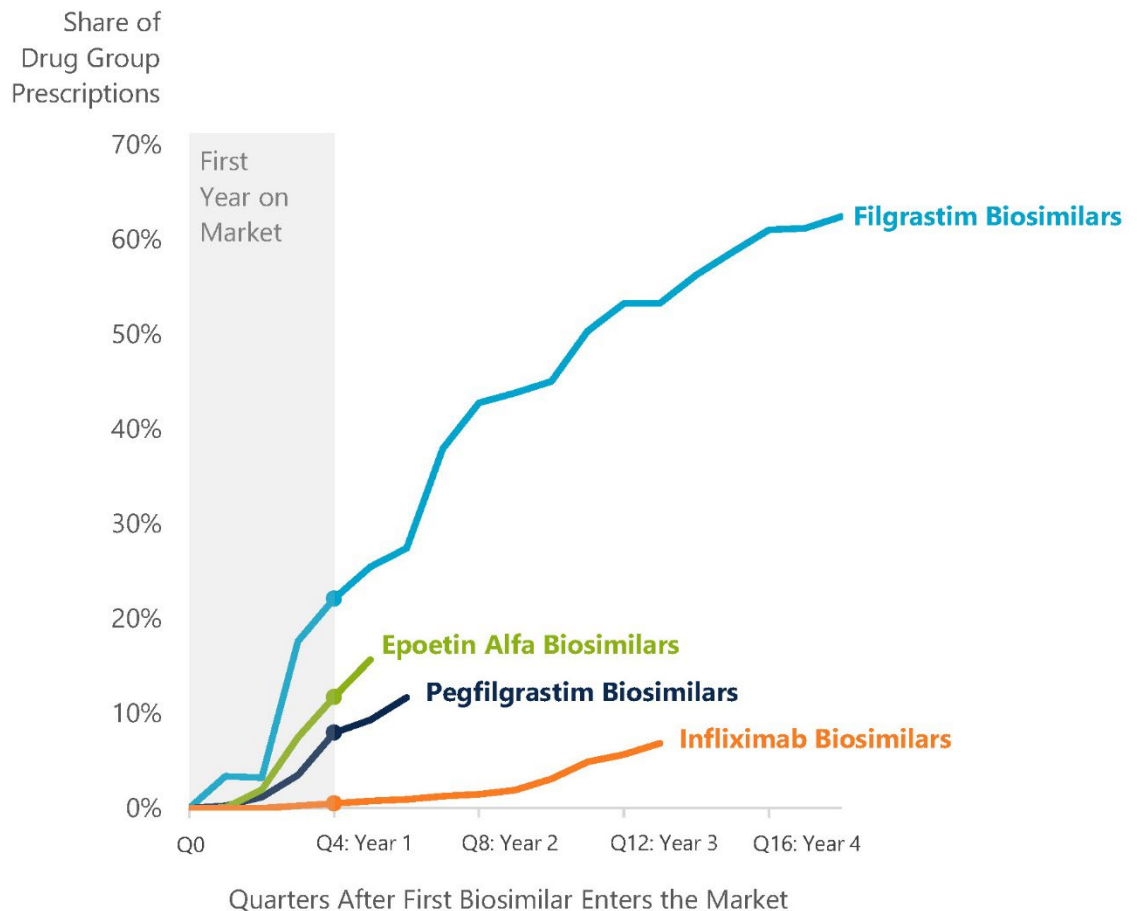


Note: We analyzed the biosimilar share of prescriptions starting in the quarter when a biosimilar alternative first became available on the U.S. market.

Source: OIG analysis of Part D PDE data from 2015–2019.

While biosimilar filgrastim use in Part D increased substantially after a year on the market, subsequent biosimilars have been adopted more slowly. Filgrastim biosimilars grew from 3 percent to 22 percent of all filgrastim prescriptions within a year of their introduction. In contrast, after the same amount of time on the market, newer biosimilars accounted for smaller proportions of their respective drug groups' prescriptions than did filgrastim biosimilars. By the end of their respective first years on the market, biosimilars made up less than 1 percent of total infliximab prescriptions, 8 percent of pegfilgrastim prescriptions, and 12 percent of epoetin alfa prescriptions. In addition to being affected by time on the market, utilization of newer biosimilars may have been affected by other factors, such as the purpose of the drug, providers' prescribing preferences, or the number of available biosimilars. Exhibit 3 illustrates the slower adoption of these biosimilars when compared with filgrastim biosimilars.

Exhibit 3: Newer biosimilars have been adopted more slowly than filgrastim biosimilars—both at the end of their first year on the market and after.



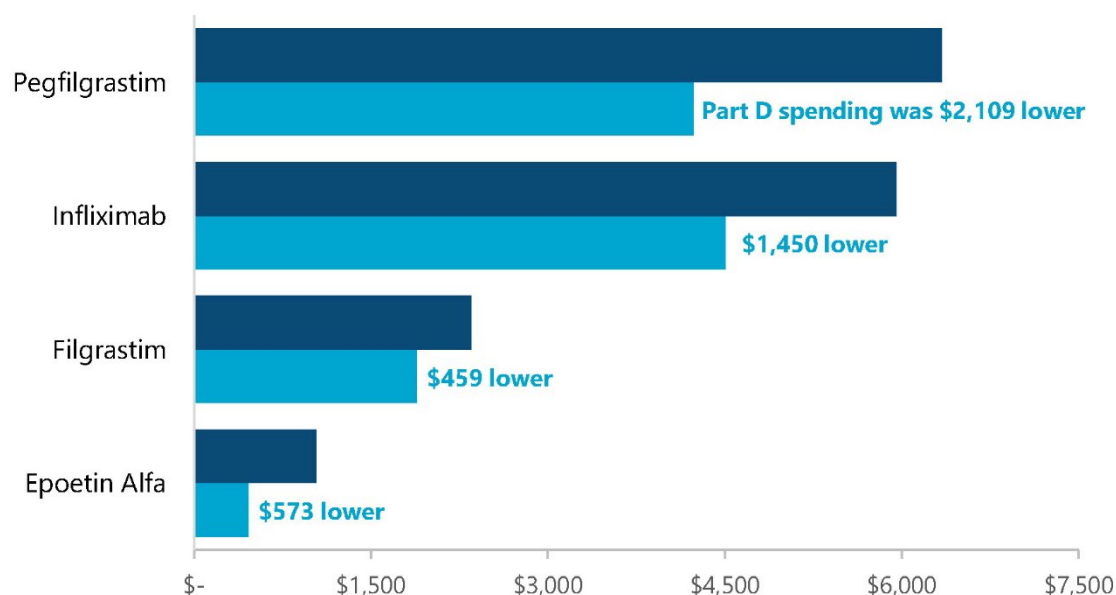
Source: OIG analysis of Part D PDE data from 2015–2019.

Part D spending. As biosimilar utilization increased, Part D spending for these drugs rose but still accounted for a small portion of overall Part D spending on biosimilars and their reference products combined. From 2015 to 2019, total spending on

biosimilars rose from \$1.7 million to \$60.8 million. In 2019, however, this amounted to only 13 percent of the overall \$466 million that Part D paid for biosimilars and their reference products combined.

Although Part D spending on biosimilars has increased, the program paid less on average for biosimilars than for their reference products, which contributed to biosimilars' small share of overall spending. Additionally, Part D spending adjusted for rebates was lower on average for biosimilars than for their reference products.⁶² See Exhibit 4 for average Part D gross spending differences for typical reference product and biosimilar prescriptions in 2019.

Exhibit 4: Part D spending for typical prescriptions was lower for biosimilars than for the biosimilars' reference products.



Source: OIG analysis of Part D PDE data from 2019.

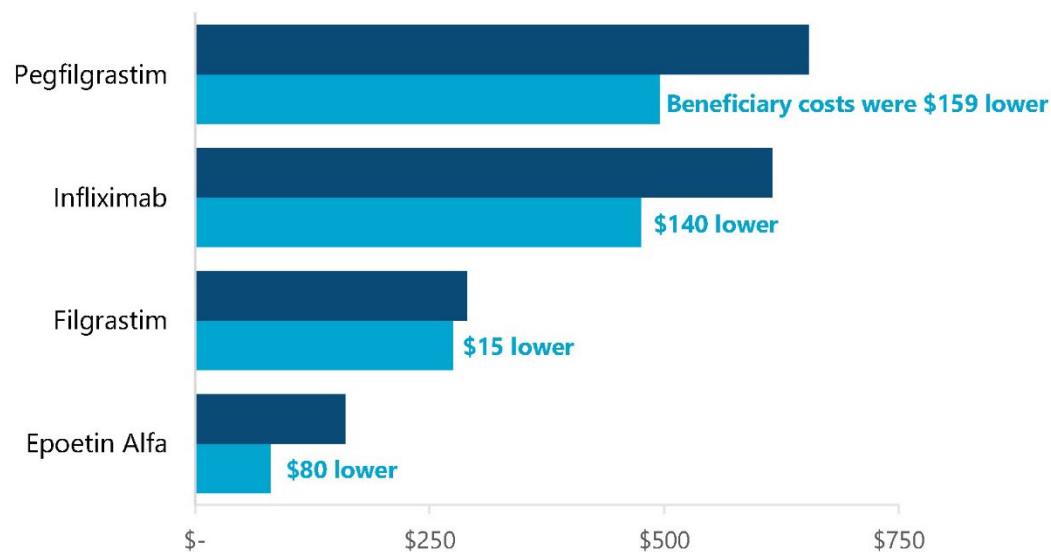
Beneficiary spending. As with the share of biosimilars in Part D spending, beneficiaries' total out-of-pocket spending on biosimilars constituted a small share of their spending on reference products and biosimilars combined. Beneficiaries' total out-of-pocket costs for biosimilars increased from \$152,000 in 2015 to \$2.8 million in 2019. This accounted for less than 20 percent of the \$14.5 million that beneficiaries spent on biosimilars and their reference products in 2019.

On average, beneficiaries paid less for most biosimilars than for their reference products. See Exhibit 5, on the next page, for an illustration of how lower average beneficiary spending for biosimilars would translate to lower out-of-pocket costs for

⁶² Because HHS treats DIR data with confidentiality, we are refraining from reporting net spending or net savings totals of individual biosimilar or reference products in this report.

typical biosimilar prescriptions in 2019. Additionally, Low-Income Subsidy (LIS) beneficiaries typically paid \$2.55 less for most biosimilars than for their reference products.

Exhibit 5: Beneficiary out-of-pocket costs for typical prescriptions were lower for biosimilars than for the biosimilars' reference products.



Note: The analysis of beneficiaries' typical prescription spending does not include spending by beneficiaries whose cost-sharing contributions were reduced by Medicare's LIS program.

Source: OIG analysis of Part D PDE data from 2019.

Increased biosimilar use could have reduced Part D and beneficiary spending considerably in 2019, suggesting the potential for far greater spending reductions when biosimilars for blockbuster drugs become available

Drug spending on biologics with available biosimilars could have been reduced considerably for the Part D program and its beneficiaries if all biosimilars had been used at higher rates. This is true both for gross spending and for net spending, which takes into account the rebates that manufacturers pay to Part D plan sponsors. The estimated net spending reductions for the Part D program from increased biosimilar use are comparable to reductions based on gross spending.⁶³ Further, rebates generally have no effect on beneficiary out-of-pocket costs and therefore do not change the estimated reductions in beneficiary spending. Although the estimated spending decreases are modest in the context of overall Part D spending, far greater

⁶³ Because HHS treats DIR data with confidentiality, we are refraining from reporting net spending or net savings totals of individual biosimilar or reference products in this report.

spending reductions may be possible as biosimilars for blockbuster drugs Humira and Enbrel come on the U.S. market—expected in 2023 and 2029, respectively.

Part D spending on biosimilars and their reference products could have been reduced between 18 percent and 31 percent if biosimilars had been used at higher rates

Part D gross spending on biosimilars and their reference products could have decreased \$84 million in 2019 if all available biosimilars had been used at the same 60-percent utilization rate as

filgrastim biosimilars. This amounts to 18 percent of the \$466 million that Part D spent on all biosimilars and their reference products in 2019. We estimated utilization for all biosimilars at 60 percent because filgrastim biosimilars had achieved this utilization rate after

nearly 5 years on the market. Furthermore, if biosimilars had been used at a 90-percent utilization rate—the utilization rate of generic, nonbiologic drugs—Part D gross spending on these drugs could have decreased by \$143 million, or 31 percent of actual 2019 gross spending.



Part D spending could have decreased by **\$84 million** if biosimilars had been used at a higher rate.

In both estimates, the largest spending reductions would have come from increased utilization of the biosimilar for epoetin alfa. Epoetin alfa products were widely used in Part D in 2019, but use of the biosimilar was low compared to use of its more expensive reference product.

Beneficiaries' out-of-pocket costs for biosimilars and their reference products could have been reduced between 12 percent and 22 percent if biosimilars had been used at higher rates

Overall beneficiary spending on biosimilars and their reference products could have decreased by nearly \$1.8 million if all biosimilars had been used at the same 60-percent utilization rate at which filgrastim biosimilars were used. This is 12 percent less than the \$14.3 million spent by these beneficiaries on all biosimilars and reference products in 2019. If all biosimilars had been used at the same rate as generic drugs (90 percent), overall beneficiary spending on these drugs could have decreased by \$3.1 million—22 percent.

For some individual beneficiaries, using a biosimilar rather than a reference product had the potential to markedly reduce the beneficiary's out-of-pocket spending for these expensive drugs. The extent to which a beneficiary could have reduced this out-of-pocket spending by using a biosimilar depends on multiple factors, such as the

type of drug prescribed, the benefit phase in which the prescription was filled, and the cost-sharing structure of the beneficiary's Part D plan. For example, beneficiaries may have greater reductions in their out-of-pocket costs when using biosimilars during the initial coverage phase, rather than during the catastrophic coverage phase, because beneficiary cost-sharing is capped at 5 percent during the latter. Exhibit 6 illustrates the differences in cost-sharing between reference product and biosimilar epoetin alfa for two beneficiaries in the same Part D plan.

Exhibit 6: Beneficiaries may have significantly different out-of-pocket costs when using **reference products and **biosimilars**—even when they are enrolled in the same Part D plan and during the same benefit phase.**



Note: We selected claims for reference product prescriptions and biosimilar prescriptions that were for the same quantity and strength of drug and that occurred in the initial coverage phase of the Part D benefit.

Source: OIG analysis of Part D PDE data from 2019.

Although out-of-pocket costs are low for LIS beneficiaries, these beneficiaries also could have realized spending reductions with increased utilization of biosimilars in 2019.⁶⁴ Spending by these beneficiaries could have decreased by 15 percent or nearly \$34,000 if all biosimilars had been used at the same utilization rate (60 percent) at which filgrastim biosimilars were used. If all biosimilars had been used at the same rate as generic drugs (90 percent), spending could have decreased 25 percent—more than \$55,000.

⁶⁴ LIS beneficiaries generally paid very little for prescription drugs in 2019—between \$0 and \$8.50 for a brand-name drug or reference product and between \$0 and \$3.40 for a generic or biosimilar. CMS, “Announcement of Calendar Year (CY) 2019 Medicare Advantage Capitation Rates and Medicare Advantage and Part D Payment Policies and Final Call Letter,” April 2, 2018. Accessed at <https://www.cms.gov/Medicare/Health-Plans/MedicareAdvtgSpecRateStats/Downloads/Announcement2019.pdf> on June 15, 2021.

Substantial reductions in both Part D and beneficiary spending may be possible when biosimilars for blockbuster drugs become available

The potential for even greater spending reductions is possible as more biosimilars come on the market. Nine biosimilars for two blockbuster drugs—Humira and Enbrel—have been approved but are not yet available to U.S. consumers. Unlike with the drugs we analyzed for this study, which are also covered under Medicare’s Part B, Humira and Enbrel are covered solely by Part D. As a result, all savings on biosimilars for these drugs will accrue to Part D and its beneficiaries. Further, many Part D beneficiaries likely will continue to take drugs such as Humira and Enbrel because they treat diseases like rheumatoid arthritis that are prevalent among the Medicare population. Finally, these drugs are typically administered more frequently—as often as weekly or every other week—than the drugs included in this study.

Together, Humira and Enbrel accounted in 2019 for more than \$5.7 billion in Part D spending—more than 14 times the \$405 million that Part D spent that year for reference products with available biosimilars. In 2019, beneficiary spending for Humira and Enbrel totaled more than \$70 million. When biosimilars for Humira and Enbrel become available—expected in 2023 and 2029, respectively—they present an opportunity to dramatically decrease spending if there is significant use of the biosimilars. Furthermore, at least seven biosimilars for Humira—including one designated as interchangeable—may be available and could bring even greater spending reductions. For instance, one recent study indicates that with each additional biosimilar alternative that enters the market, the average price decreases for the entire group of biosimilars and their corresponding reference product.⁶⁵ With numerous biosimilars available as alternatives to Humira, they may have a greater impact on the market than if a single biosimilar alternative were available. Additionally, Humira may see increased competition from the biosimilar alternative that has been designated as interchangeable, which means that pharmacists can substitute it for the reference product without consulting with the prescriber.⁶⁶

Not all Part D plan formularies covered available biosimilars in 2019, and those that did rarely encouraged their use

The Part D program and its beneficiaries would have seen spending reductions with more widespread biosimilar use, but biosimilar use may have been limited by Part D formularies’ lack of biosimilar coverage. As of 2019, not all plan formularies that covered reference products also covered their biosimilar alternatives. Those that covered both reference products and biosimilars usually treated them equally—

⁶⁵ Richard G. Frank et al., “Biosimilar Competition: Early Learning,” National Bureau of Economic Research Working Paper Series, March 2021. Accessed at <http://www.nber.org/papers/w28460> on July 26, 2021.

⁶⁶ Biosimilar substitution by pharmacists is subject to State pharmacy laws, which vary by State.

in other words, they did not use formulary design or utilization management tools to encourage the use of biosimilars instead of reference products.

When biosimilars for Humira and Enbrel become available, plans may have strong incentives to exclude them from formularies or otherwise discourage their use. Humira and Enbrel account for billions—rather than millions—of dollars in Part D spending. To maintain their market share, manufacturers may provide substantial rebates to Part D plan sponsors in exchange for exclusive coverage or preferred placement of these drugs—either of which would discourage the use of biosimilars.⁶⁷ These rebates typically would not lower out-of-pocket costs for beneficiaries using the reference products.

In 2019, plan formularies did not always include biosimilars—particularly those that had been more recently introduced

Biosimilars—especially those that were newer on the market—were not always included on plan formularies in 2019.⁶⁸ The plan formularies that covered only reference products in effect discouraged biosimilar utilization by preventing beneficiaries from using their Part D coverage for biosimilars instead of reference products. Specifically, in 2019, 38 percent of plan formularies that covered an epoetin alfa reference product did not cover the biosimilar and 32 percent of formularies that covered the pegfilgrastim reference product did not cover a biosimilar. These coverage decisions occurred despite the biosimilars costing Part D less on average than their reference products, even when accounting for rebates. Although nearly all plan formularies covered at least one filgrastim biosimilar, 40 percent did not cover Zarxio—the most widely used filgrastim biosimilar and the primary competitor to the reference product.⁶⁹

Few plan formularies covered biosimilars without also covering their corresponding reference products, and thereby actively encouraged the use of biosimilars. Filgrastim biosimilars were the only biosimilars that a considerable number of plan formularies—

⁶⁷ MedPAC, “Chapter 14: The Medicare prescription drug program (Part D): Status Report,” *Report to the Congress: Medicare Payment Policy*, March 2020, p. 431. Accessed at http://medpac.gov/docs/default-source/reports/mar21_medpac_report_to_the_congress_sec.pdf on October 5, 2021.

⁶⁸ In 2019, Part D plans did not include infliximab products on their formularies because of a change that CMS made to its list of drugs that may be included on formularies. (CMS had removed some drugs primarily covered under Part B, like infliximab products, from this list.) Although infliximab reference products and biosimilars were not explicitly included on Part D formularies, they were still covered and paid for by Part D. Any beneficiary who needed an infliximab product had to submit a formulary exception request—with provider documentation—to the beneficiary’s Part D plan. CMS, “Parts C & D Enrollee Grievances, Organization/Coverage Determinations, and Appeals Guidance,” § 40.5. Accessed at <https://www.cms.gov/Medicare/Appeals-and-Grievances/MMCAG/Downloads/Parts-C-and-D-Enrollee-Grievances-Organization-Coverage-Determinations-and-Appeals-Guidance.pdf> on October 4, 2021.

⁶⁹ Zarxio is considered the primary competitor to Neupogen—the reference product for filgrastim biosimilars—because it was approved for all five of the filgrastim indications and has gained a larger market share in Part D than other filgrastim biosimilars.

18 percent—covered *instead* of the reference product. In contrast, no plan formularies covered only the epoetin alfa biosimilar rather than the reference products. Similarly, only one plan formulary covered only a pegfilgrastim biosimilar without also covering the reference product.

Most plan formularies that included biosimilars did not use tools to encourage biosimilar use

Plan formularies rarely used formulary tools—such as preferential tier placement or utilization management—to encourage the use of biosimilars instead of their reference products.

Tier placement. Tier placement plays a key role in whether prescribers decide to prescribe biosimilars. For example, in addition to affecting beneficiary cost-sharing, tier placement on a plan formulary can influence prescribers' preferences. Specifically, a recent survey (conducted from December 2019 through January 2020) found that when both the biosimilar and its reference product are available on the formulary, prescribers will choose the reference product unless the biosimilar is in a preferred position on the formulary.⁷⁰

Most plan formularies that covered both biosimilars and reference products did not encourage biosimilar use by placing these drugs in preferred positions on the formulary relative to the positions of their reference products. Instead, most placed biosimilars on the same formulary tier as their reference products. Specifically, more than 97 percent of these plan formularies placed all covered biosimilar and reference product filgrastims or pegfilgrastims on the same formulary tier. Less than 3 percent of these formularies placed either a filgrastim biosimilar or a pegfilgrastim biosimilar on a lower tier than its reference product. Additionally, more than 60 percent of these plan formularies placed all epoetin alfa biosimilars and reference products on the same formulary tiers. Only 12 percent of these formularies placed all epoetin alfa biosimilars on lower tiers than their reference product.

When plan formularies place a biosimilar and its reference product on the same tier, beneficiaries have fewer financial incentives to use the biosimilar. As drugs on lower (i.e., preferential) formulary tiers typically have lower out-of-pocket costs, placing a biosimilar and its reference product on the same tier limits the potential cost savings for beneficiaries using the biosimilar.⁷¹ Notably, when a biosimilar and its reference product are on the same tier, with a fixed copayment, using the biosimilar may not reduce beneficiary cost-sharing at all.

Utilization management tools. Similarly, most plan formularies used the same utilization management tools for biosimilars and their reference products—meaning

⁷⁰ Allison R. Kolbe et al., "Physician Understanding and Willingness to Prescribe Biosimilars: Findings from a US National Survey," *BioDrugs*, Vol. 35, Issue 3, pp. 363-372, 370.

⁷¹ CMS, *Medicare Prescription Drug Benefit Manual*, ch. 6, § 30.2.7.

they neither actively encouraged nor discouraged biosimilar use. For newer biosimilars, most 2019 plan formularies that covered both biosimilars and their reference products used the same prior authorization or step therapy requirements for these drugs. More than 95 percent of these plan formularies had the same prior authorization or step therapy requirements for pegfilgrastim or epoetin alfa biosimilars and their reference products. For filgrastims, more than 85 percent of plan formularies had the same utilization management requirements for biosimilars and for their reference product.

There were some exceptions—a small number of plan formularies used utilization management tools to encourage use of the most used biosimilars, particularly the filgrastim biosimilar Zarxio. Specifically, 13 percent of plan formularies did not require prior authorization for at least one filgrastim biosimilar but did for the reference product. Also, 8 percent of plan formularies used step therapy in a way that would encourage the use of these biosimilars—usually requiring that beneficiaries try the biosimilar Zarxio before other filgrastims.

CONCLUSION AND RECOMMENDATIONS

Biosimilars have the potential to reduce costs for the Part D program and its beneficiaries, both now and in the future. Although use of these drugs has steadily increased, most are still used far less often than their reference products. We estimated that even a conservative increase in the use of currently available biosimilars could have greatly reduced spending for the Part D program and its beneficiaries in 2019. With biosimilars for the blockbuster drugs Humira and Enbrel on the horizon, the scale of the potential savings from increased utilization of biosimilars stands to grow substantially.

Part D plans' limited coverage and promotion of biosimilars have prevented the program and its beneficiaries from maximizing potential savings. By not including biosimilars on formularies, many Part D plans effectively discouraged the use of these drugs. Even the most used and successful biosimilar—Zarxio—likely would have been used more frequently with wider formulary coverage. Most Part D plans also did not actively encourage use of biosimilars by placing them on lower formulary tiers or by requiring beneficiaries to try a biosimilar before the reference product.

Without further changes to the Part D program, the impact of these limitations will be magnified as biosimilars for blockbuster drugs become available. Unlike the drugs we examined in our study, Humira and Enbrel account for billions of dollars in Part D spending. As a result, plans may have even more incentives to limit formulary coverage or to employ utilization management tools to potentially discourage the use of biosimilars for these biologics. This is because drug manufacturers pay substantial rebates to Part D plans, potentially encouraging Part D plans to cover the manufacturers' reference products instead of the corresponding biosimilars, or to give the reference products preferential treatment. Left unexamined, this issue represents a serious vulnerability for future savings for Part D and especially for its beneficiaries, who—unlike Part D plans—typically do not realize any direct financial benefit from manufacturer rebates.

CMS could do more to ensure that beneficiaries have access to currently available lower-cost biosimilars under Part D and to prepare the program for the launch of future biosimilars. CMS has already taken some steps to increase utilization of lower-cost biosimilar drugs by allowing Part D plans to establish a second, "preferred" specialty tier with lower cost-sharing for beneficiaries. Part D plans have the flexibility to use this tier for either biosimilars or their reference products. To further promote the use of biosimilars now and help ensure that the program is poised to capitalize on potential future savings, CMS can encourage Part D plans to use formularies designed to increase the use of biosimilars and CMS can monitor Part D plans' treatment of biosimilars to identify future areas of concern.

We recommend that CMS:

Encourage Part D plans to increase access to and use of biosimilars

CMS should encourage Part D plans to increase access to and the use of biosimilars instead of their reference products within its authority. To do this, CMS could use a demonstration project to evaluate incentives for encouraging biosimilar use. For example, CMS could conduct a demonstration project to determine whether capped copayments increase the use of lower-cost biosimilars. CMS could also explore other methods to encourage biosimilar use, such as continuing its efforts to use the Star Ratings system, which helps beneficiaries compare the quality of prescription drug plans when they shop for Part D coverage. Although CMS—after receiving public feedback—did not pursue a previously proposed biosimilar utilization measure, it could explore additional options.⁷² For example, CMS could consider developing a biosimilar access measure based on whether plans cover at least one biosimilar as an alternative to each reference product in instances when the biosimilar is less expensive or when there are two or more biosimilars on the market.

Monitor Part D plans' submitted formularies to determine whether they discourage beneficiaries from using biosimilars

CMS should monitor biosimilar coverage, cost-sharing, and utilization management requirements in Part D plan formularies on a regular basis to understand biosimilar coverage trends. Ideally, CMS would begin conducting such monitoring prior to any upcoming expected launches of biosimilars into the market—such as biosimilars for Humira and Enbrel, which would be the first biosimilars to be covered only under Part D. Such monitoring could be integrated into CMS's annual review of Part D formulary performance and content or could be conducted separately, to the extent that CMS's authority allows. To identify concerning trends in biosimilar coverage, CMS could monitor whether Part D plan formularies (1) exclude biosimilars, (2) place biosimilars on less preferential tiers than their reference products, or (3) employ stricter utilization management policies—such as prior authorization and step therapy—for biosimilars than for their reference products. The results of monitoring trends in biosimilar coverage could inform CMS's efforts to encourage biosimilar access and use within its authority.

⁷² In its 2021 Rate Announcement, CMS stated that it would consider the public feedback it received “for any potential future development of generic utilization measures.” CMS, “Announcement of Calendar Year (CY) 2021 Medicare Advantage (MA) Capitation Rates and Part C and Part D Payment Policies,” April 6, 2020. Accessed at <https://www.cms.gov/files/document/2021-announcement.pdf> on February 28, 2022.

AGENCY COMMENTS AND OIG RESPONSE

CMS concurred with our first recommendation and neither concurred nor nonconcurred with our second recommendation.

In response to our first recommendation, CMS stated that it plans to examine how demonstration projects could be used to incentivize the use of biosimilars. CMS also indicated that it will continue to explore other options within its authority to increase access to and use of biosimilar drugs. CMS's commitment to supporting the increased use of biosimilars has the potential to protect the Part D program and beneficiaries from significant drug costs.

In response to our second recommendation, CMS stated that it has limited authority to review Part D plan formularies. Specifically, CMS said that its formulary review process is limited to ensuring that formularies provide access to medically necessary treatments and that formularies do not discriminate against particular types of beneficiaries. In response to CMS's comments, we clarified that the monitoring we recommend is intended to inform CMS's efforts to encourage the use of biosimilars within its authority. It is critical for HHS, Congress, and the public to have information about biosimilar coverage on Part D plans' formularies, particularly as biosimilars for Humira and Enbrel become available in the coming years.

DETAILED METHODOLOGY

Data Sources

Product information for biosimilars and reference products. We used FDA's Biosimilar Product Information, FDA's Purple Book, and First Databank to identify all biosimilars and reference products and their National Drug Codes (NDCs). FDA's Biosimilar Product Information lists all FDA-approved biosimilars. The Purple Book lists all biological products, including biosimilars. First Databank links drugs' proprietary names with their NDCs.

Prescription drug data. To analyze biosimilar utilization, Part D spending, and beneficiary spending, we used Medicare Part D PDE records. PDE records include the quantity of the drug dispensed, variables necessary to calculate Part D gross spending, and beneficiary spending. We considered each PDE record to be one prescription. We used detailed DIR data from CMS's Health Plan Management System (HPMS) to calculate rebates in order to calculate net Part D spending.

Formulary coverage and design data. To analyze biosimilar formulary coverage, we used Approved Formulary Submission data from HPMS. These data include information about the drugs covered on Part D plan formularies, such as tier placement and utilization management requirements.

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, 2019 and their reference products. We used First Databank to identify all NDCs associated with these biosimilars and reference products. In total, we identified 81 NDCs for 4 reference products and 8 biosimilars covered by Part D plans.

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 biosimilars with different proprietary names and strengths. We analyzed average spending for each biosimilar drug group to avoid making assumptions about prescribing practices that are beyond the scope of this study (e.g., which biosimilar brand or strength would be prescribed).

Analysis of utilization and spending over time. We calculated Part D biosimilar utilization and spending over time by using PDE records for biosimilars and reference products from January 1, 2015 to December 31, 2019. For each year and quarter, we summed the number of prescriptions for each biosimilar drug group and reference product.

We calculated annual and quarterly utilization rates for all biosimilars and for each biosimilar drug group by dividing the number of biosimilar prescriptions by the total number of biosimilar and reference product prescriptions.

We calculated annual Part D and beneficiary spending for each biosimilar drug group and reference product. For Part D gross spending, we summed three PDE variables: ingredient cost, sales tax, and dispensing fee. This represents the total amount paid to a pharmacy at the point of sale for drugs covered by the Medicare benefit before rebates are taken into account. For beneficiary spending, we used the patient payment amount from PDE records. This amount represents the copayment or coinsurance paid by a beneficiary for a prescription.⁷³

Lastly, we calculated 2019 Part D and beneficiary spending for the two reference products covered by Part D expected to face biosimilar competition in the coming years—Humira and Enbrel. Biosimilars for these drugs have been approved by FDA but are not yet available on the U.S. market.

Converting quantity to drug weight. To analyze biosimilars of different strengths as one biosimilar drug group, we converted the quantity dispensed to drug weight dispensed. To calculate the drug weight dispensed for each prescription, we multiplied the strength of the prescription (e.g., 480 mg/0.8 ml) by the quantity dispensed of the prescription (e.g., 1.6 ml). We summed the drug weight dispensed for each biosimilar drug group to calculate the total drug weight dispensed.

Average Part D and beneficiary spending by drug weight dispensed. We calculated average Part D and beneficiary spending amounts at the reference product and biosimilar drug group level by dividing Part D and beneficiary spending by the total drug weight dispensed.⁷⁴

Part D and beneficiary spending for typical prescriptions. We used average Part D and beneficiary spending to illustrate differences in spending for typical biosimilar and reference product prescriptions. To calculate the amount dispensed for a typical prescription, we used the median drug weight dispensed for each biosimilar drug group and reference product. We then multiplied the average spending amounts for

⁷³ We excluded beneficiaries receiving other sources of support, such as State Pharmaceutical Assistance Plans, group health plans, or governmental programs, from the analyses of beneficiary spending and spending reductions. We also excluded beneficiaries enrolled with PACE (Program of All-Inclusive Care for the Elderly) organizations because these beneficiaries do not pay for their prescription drugs. For beneficiaries receiving the low-income subsidy (LIS), we analyzed only pre-catastrophic prescriptions because such beneficiaries often pay nothing in the catastrophic phase.

⁷⁴ LIS beneficiaries were analyzed separately. We calculated average spending for LIS beneficiaries by dividing total spending by the total number of prescriptions because LIS beneficiaries typically pay only a fixed copayment for biosimilars. To illustrate differences in LIS spending for typical biosimilar and reference product prescriptions, we compared the median LIS beneficiary payment for each biosimilar drug group and its reference product.

the biosimilar drug group and reference product by the drug weight dispensed for the typical prescription.

Part D and beneficiary spending reduction estimates with increased biosimilar utilization. We took two steps to estimate how any increase in biosimilar utilization could have changed Part D and beneficiary spending. We first estimated how much Part D and beneficiaries could have spent if all CY 2019 reference product prescriptions had been for biosimilars, using the average biosimilar spending amounts. We then used these figures—and actual biosimilar utilization and spending in 2019—to estimate how any increase in biosimilar utilization could have changed Part D and beneficiary spending.

We reported estimates of 2019 Part D and beneficiary spending at two specific utilization rates—if biosimilars had accounted for 60 percent and 90 percent of prescriptions. The first estimate assumed total biosimilar utilization matched the 60 percent utilization rate of the most used biosimilar group (i.e., filgrastim biosimilars). The second estimate assumed biosimilar utilization matched the 90 percent utilization rate for Part D generic drugs.⁷⁵ The total difference between the actual and estimated spending amounts represented the potential reductions in Part D and beneficiary spending had biosimilar use increased in CY 2019.

We used the same methodology to estimate how increased biosimilar utilization could have changed Part D net spending (i.e., when adjusting Part D spending for rebates). We calculated net spending by subtracting total rebates for each biosimilar drug group and reference product from its total Part D gross spending.⁷⁶ We did not adjust beneficiary spending for rebates because they do not typically affect beneficiary out-of-pocket costs.

Analysis of biosimilar formulary coverage and placement for CY 2019. We analyzed CMS's 2019 HPMS Approved Formulary Data to determine whether Part D plan formularies encouraged the use of biosimilars. We excluded Part D plan formularies without any enrolled beneficiaries from our analysis.

We analyzed formulary coverage and placement separately for each biosimilar drug group. We calculated the percentage of Part D plan formularies that included both biosimilars and their reference products, only biosimilars, and only biosimilars' reference products. For formularies that covered both biosimilars and their reference products, we calculated the percentage that (1) placed biosimilars on lower, higher, or the same formulary tiers as their reference products and (2) had different step therapy or prior authorization requirements for biosimilars and their reference products. We also checked Part D plans' cost-sharing requirements for the small number of formularies that placed biosimilars on lower formulary tiers than their reference

⁷⁵ CMS, "Increasing Access to Generics and Biosimilars in Medicare," February 5, 2020.

⁷⁶ Because HHS treats DIR data with confidentiality, we are refraining from reporting net spending or net savings totals of individual biosimilar or reference products in this report.

products. We did this to confirm that these plans, in fact, had lower cost-sharing for biosimilars on lower tiers than their reference products on higher tiers.



Administrator
Washington, DC 20201

DATE: February 23, 2022

TO: Suzanne Murrin
Deputy Inspector General for Evaluation and Inspections
Office of Inspector General

FROM: Chiquita Brooks-LaSure *Chiq B LaS*
Administrator
Centers for Medicare & Medicaid Services

SUBJECT: Office of Inspector General (OIG) Draft Report: *Medicare Part D and Beneficiaries Would Realize Significant Spending Reductions with Increased Biosimilar Use*, OEI-05-20-00480

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 large 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 biosimilar and generic drugs, reduce the federal government's spending on drugs, and achieve greater equity in drug access and affordability for beneficiaries.

Under the Medicare Part D system, Medicare contracts with private plan sponsors to provide a prescription drug benefit and entrusts plan sponsors with authority to negotiate drug prices with pharmaceutical companies. A provision in the law that established the Medicare Part D program specifically prohibits the Health and Human Services Secretary from interfering with the negotiations between drug manufacturers and pharmacies and plan sponsors, requiring a particular formulary, or instituting a price structure for the reimbursement of covered Part D drugs. However, CMS exercises its authority to review Part D plan formularies to ensure that drug plans provide access to medically necessary treatments and do not discriminate against any particular types of beneficiaries.

It is important to note that factors outside of coverage and payment policy may affect provider and beneficiary preferences for a reference product versus the biosimilars, as well as inclusion on plan formularies. For example, prescribers or beneficiaries may prefer the more familiar reference product when a biosimilar first enters the market. In addition, after the biosimilar has been on the market for some time, the price of a biosimilar may fall below the cost 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. As an example, the earliest biosimilar, Zarxio, which came onto the market in 2015 is now represented on over 80 percent of Medicare Part D plan formularies and has a significantly greater market share than its reference product.

CMS is committed to continuing to work within its authority to address both cost and access concerns. OIG's recommendations and CMS' responses are below.

OIG Recommendation

CMS should encourage Part D plans to increase access to and use of biosimilars.

CMS Response

CMS concurs with OIG's recommendation. Within our authority, CMS is committed to taking action, as appropriate, to increase access to and use of biosimilars. As discussed above, CMS' authority to review Part D plan formularies centers on ensuring that drug plans provide access to medically necessary treatments and do not discriminate against any particular types of beneficiaries. In addition, while a multitude of policy and operational considerations influence whether CMS implements a demonstration project, CMS intends to examine how demonstration projects could be used to test methods to lower beneficiary and program spending on drugs and incentivize the use of biosimilar and generic drugs.¹ CMS will continue to explore options to address this issue.

OIG Recommendation

CMS should monitor Part D plans' submitted formularies to determine whether they discourage beneficiaries from using biosimilars.

CMS Response

As discussed above, CMS has the authority to review Part D plan formularies to ensure that drug plans provide access to medically necessary treatments and do not discriminate against any particular types of beneficiaries. CMS uses that authority to review plan formularies for appropriate inclusion of all drug classes, including biosimilars.

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

¹ <https://innovation.cms.gov/strategic-direction-whitepaper>

ACKNOWLEDGMENTS AND CONTACT

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