Department of Health and Human Services
Office of Inspector General
Data Snapshot
February 2024, OEI-05-22-00141

Biosimilar Cost and Use Trends in Medicare Part B

Supplement to *Biosimilars Have Lowered Costs for Medicare Part B and Enrollees, but Opportunities for Substantial Spending Reductions Still Exist* (OEI-05-22-00140)

Biologic drugs (hereinafter referred to as 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.[1]

A biosimilar is a biologic that is highly similar to and has no clinically meaningful difference from an existing Food and Drug Administration (FDA)-approved biologic (i.e., the biosimilar's "reference product"), and biosimilars are often less expensive.[2, 3] We refer to available biosimilars and their reference product, collectively, as a **drug group**.

Biosimilar and Reference Product **Drug Groups** in this data snapshot

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

In September 2023, OIG issued *Biosimilars Have Lowered Costs for Medicare Part B and Enrollees, but Opportunities for Substantial Spending Reductions Still Exist* (OEI-05-22-00140). For that report, we analyzed quarterly biosimilar and reference product Average Sales Prices (ASP); use; and program and enrollee costs in Medicare Part B from 2015 to 2021.[4] We found that after biosimilar competition, both reference product and biosimilar prices fell, leading to lower costs for the Medicare Part B Program and enrollees. For some drug groups, the reference product price decrease was substantial enough that the reference product, rather than a biosimilar, was the lowest-cost option at the end of 2021. Furthermore, while use of biosimilars in Medicare Part B has grown significantly, 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. As a result of these findings, OIG recommended that CMS pursue one or more payment changes that could further realize savings from biosimilars for Part B and enrollees.

This data snapshot is a companion to that report. It presents additional data points from our analysis to give readers greater understanding of how biosimilar use and costs have developed in the Part B program. It includes the same 21 biosimilars that were available in 2021 and approved as alternatives to 7 different reference products in Part B. For the biosimilars and reference product in each drug group, we analyzed quarterly ASP trends, differences in Part B payments, and use rates at the Healthcare Common Procedure Code System (HCPCS) code level.[5] We also calculated estimates for the additional amount Part B and enrollees would have spent on the reference product in 2021 if the reference product's price had not declined following biosimilar competition. Finally, we estimated potential Part B and enrollee spending reductions in 2021 if more affordable biosimilars had been used at the same use rate as the filgrastim biosimilar drug group, which had the highest use rate among the seven drug groups in all four quarters of the year. To estimate this for drug groups with more than one biosimilar, we used the biosimilars' volume-weighted average cost.

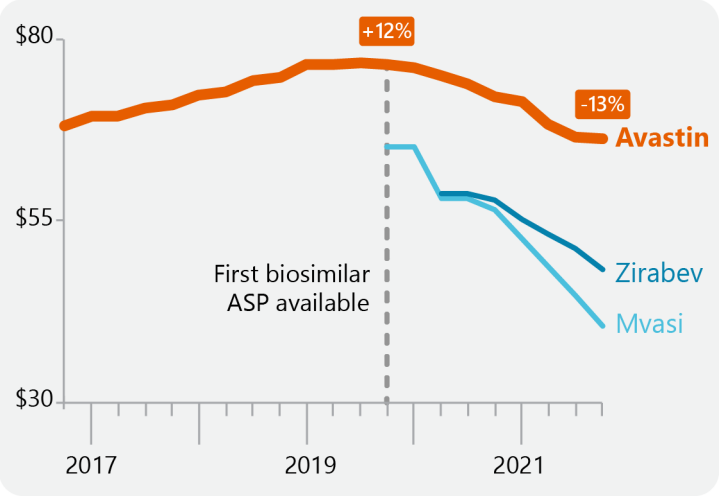
See the Methodology section for more information.

Bevacizumab

Bevacizumab is used in combination with other chemotherapy agents to treat certain cancers, such as colon and rectal cancers, non-small cell lung cancer, and some brain tumors.[6] The reference product, Avastin, was approved by FDA in 2004 and had two biosimilars available as of December 2021. The first biosimilar bevacizumab, Mvasi, was approved by FDA in September 2017 and became available in the United States in July 2019 (Q3 2019). The Part B program and enrollees spent $887 million on bevacizumab in 2021.

The reference product price, as measured by ASP, increased 12 percent in the 3 years before biosimilar competition—but then decreased 13 percent by the end of 2021.

If the ASP-based payment rate for the reference product had remained at the same level as when its first biosimilar was introduced, the Part B program and its enrollees would have spent an additional $30 million on this drug in 2021.[7] Enrollees' portion of this additional spending would have been $6 million.

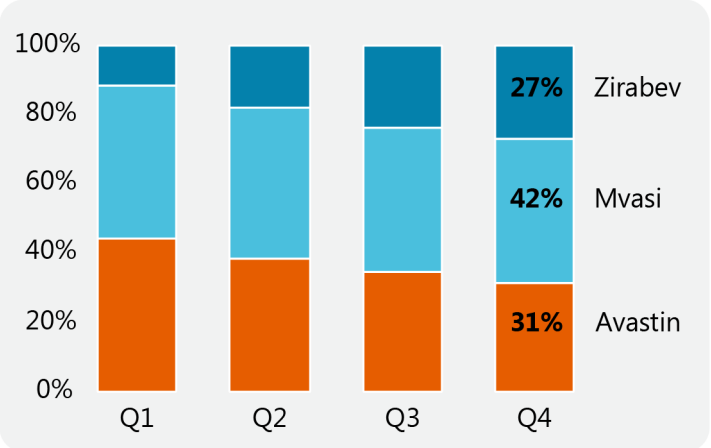


Differences in 2021 Quarterly Part B Payment Rates

Brand	Type	Q1	Q2	Q3	Q4
Avastin	Reference Product	$75.75	$72.51	$70.60	$70.41
Mvasi	Biosimilar	$56.73 (-25%)	$52.89 (-27%)	$48.78 (-31%)	$44.56 (-37%)
Zirabev	Biosimilar	$59.47 (-21%)	$57.34 (-21%)	$55.19 (-22%)	$52.37 (-26%)

2021 Quarterly Use Rates

Biosimilars accounted for 69 percent of total bevacizumab use in Q4 2021. If these more affordable biosimilars had been used at the same rate as the most widely used biosimilars, spending by Part B and its enrollees could have been reduced by $38 million in 2021. Enrollees' portion of this spending reduction would have been $8 million.



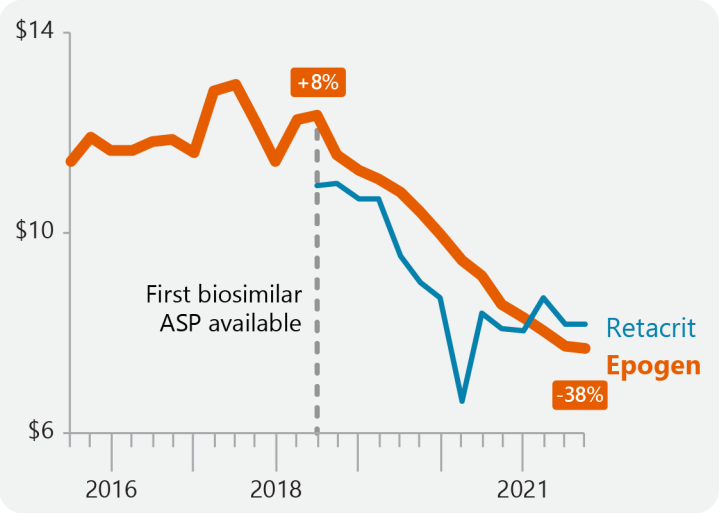
Note: ASP, quarterly Part B payment rates, and comparisons of quarterly use rates for bevacizumab are based on a 10 mg quantity.

Epoetin Alfa

Epoetin alfa treats anemia resulting from chronic kidney disease; surgery; and the use of some medications that treat HIV or cancer. The reference product, Epogen (also marketed as Procrit), was approved by FDA in 1989 and had one biosimilar available as of December 2021. The biosimilar epoetin alfa, Retacrit, was approved by FDA in May 2018 and became available in the United States in November 2018 (Q4 2018). The Part B program and enrollees spent $147 million on epoetin alfa in 2021.[8]

The reference product price, as measured by ASP, increased 8 percent in the 3 years before biosimilar competition—but then decreased 38 percent by the end of 2021.

If the ASP-based payment rate for the reference product had remained at the same level as when its biosimilar was introduced, the Part B program and its enrollees would have spent an additional $23 million on this drug in 2021.[9] Enrollees' portion of this additional spending would have been $5 million.

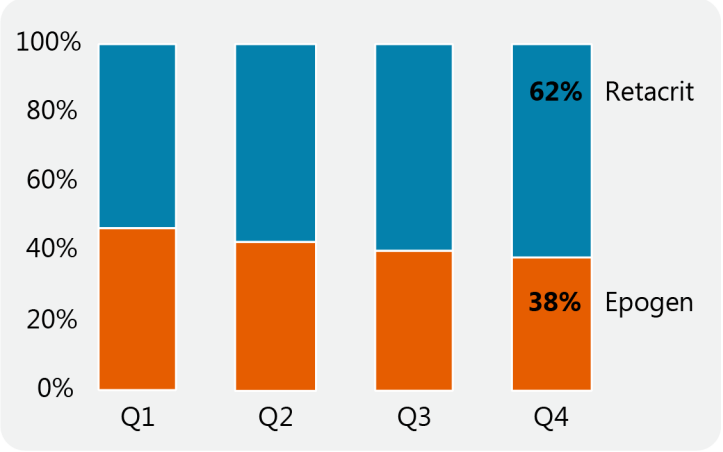


Differences in 2021 Quarterly Part B Payment Rates

Brand	Type	Q1	Q2	Q3	Q4
Epogen	Reference Product	$8.82	$8.54	$8.22	$8.15
Retacrit	Biosimilar	$8.55 (-3%)	$9.19 (+8%)	$8.63 (+5%)	$8.66 (+6%)

2021 Quarterly Use Rates

The biosimilar accounted for 62 percent of total epoetin alfa use in Q4 2021. If this biosimilar had been used at the same rate as the most widely used biosimilars when it was more affordable, spending by Part B and its enrollees could have been reduced by $300,000 in 2021. Enrollees' portion of this spending reduction would have been $60,000.



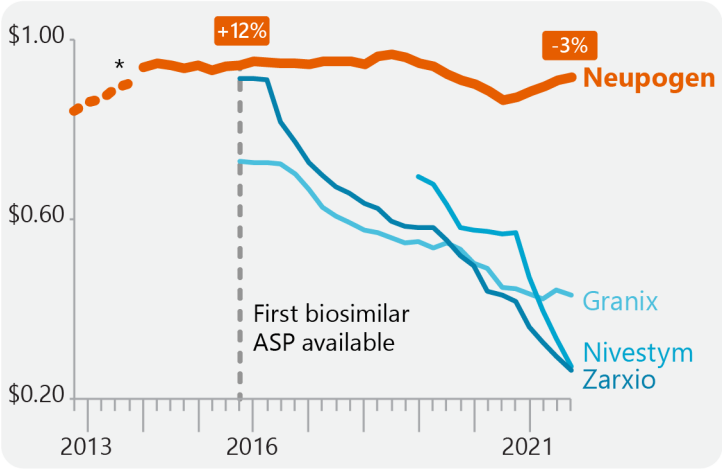
Note: ASP, quarterly Part B payment rates, and comparisons of quarterly use rates for epoetin alfa are based on a 1,000 unit quantity.

Filgrastim

Filgrastim treats neutropenia, a condition in which the body makes too few white blood cells as a result of chemotherapy. The reference product, Neupogen, was approved by FDA in 1991 and had two biosimilars and one alternative biologic available as of December 2021.[10] Zarxio, the first biosimilar for any biologic in the United States, was approved by FDA in March 2015 and became available in the United States in September 2015 (Q3 2015).[11] The Part B program and enrollees spent $45 million on filgrastim in 2021.

The reference product price, as measured by ASP, increased 12 percent in the 3 years before biosimilar competition—but then decreased 3 percent by the end of 2021.

If the ASP-based payment rate for the reference product had remained at the same level as when its first biosimilar was introduced, the Part B program and its enrollees would have spent an additional $430,000 on this drug in 2021. Enrollees' portion of this additional spending would have been $86,000.



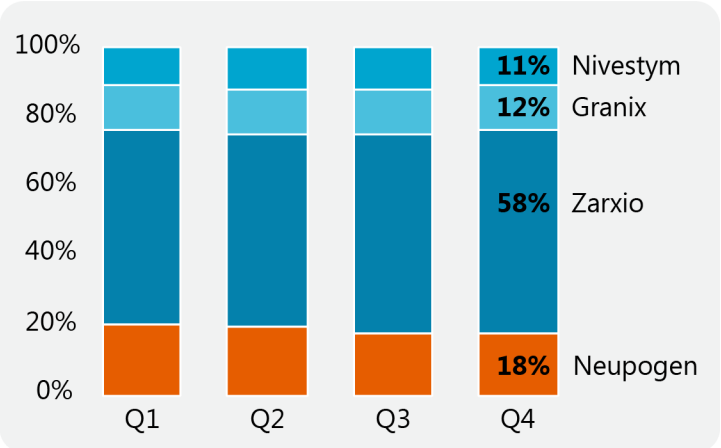
* Prior to 2014, Neupogen had two different billing amounts. For this period, we used the average of these ASPs.

Differences in 2021 Quarterly Part B Payment Rates

Brand	Type	Q1	Q2	Q3	Q4
Neupogen	Reference Product	$0.94	$0.95	$0.96	$0.97
Granix	Alternative Biologic	$0.46 (-51%)	$0.45 (-53%)	$0.47 (-51%)	$0.46 (-53%)
Nivestym	Biosimilar	$0.52 (-44%)	$0.45 (-53%)	$0.39 (-60%)	$0.33 (-67%)
Zarxio	Biosimilar	$0.41 (-56%)	$0.38 (-60%)	$0.35 (-64%)	$0.32 (-67%)

2021 Quarterly Use Rates

Biosimilars and the alternative biologic accounted for 82 percent of total filgrastim use in Q4 2021.[12] These filgrastim alternatives had the highest use rate among the seven drug groups in each quarter in 2021.



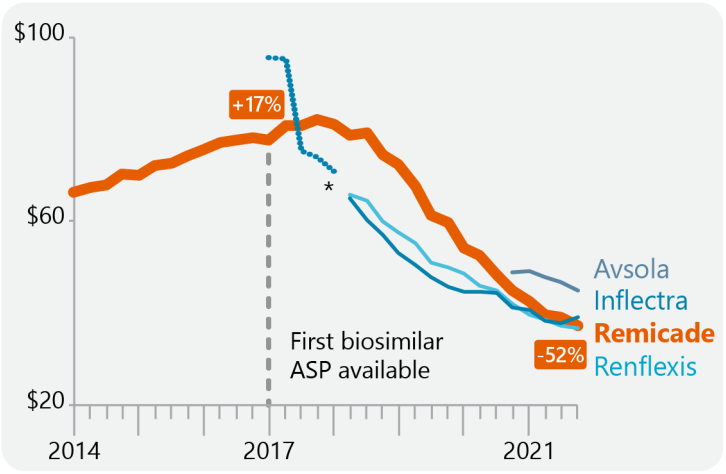
Note: ASP, quarterly Part B payment rates, and comparisons of quarterly use rates for filgrastim are based on a 1 mcg quantity.

Infliximab

Infliximab treats autoimmune diseases including Crohn's disease, ulcerative colitis, and rheumatoid arthritis. The reference product, Remicade, was approved by FDA in 1998 and had three biosimilars available as of December 2021. The first biosimilar infliximab, Inflectra, was approved by FDA in April 2016 and became available in the United States in November 2016 (Q4 2016). The Part B program and enrollees spent $656 million on infliximab in 2021.

The reference product price, as measured by ASP, increased 17 percent in the 3 years before biosimilar competition—but then decreased 52 percent by the end of 2021.

If the ASP-based payment rate for the reference product had remained at the same level as when its first biosimilar was introduced, the Part B program and its enrollees would have spent an additional $411 million on this drug in 2021. Enrollees' portion of this additional spending would have been $82 million.



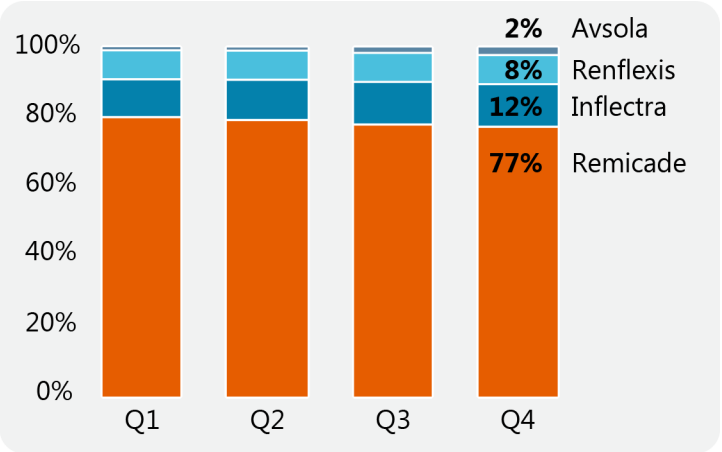
* Prior to 2018, Inflectra and Renflexis shared a payment rate.

Differences in 2021 Quarterly Part B Payment Rates

Brand	Type	Q1	Q2	Q3	Q4
Remicade	Reference Product	$44.90	$41.95	$41.32	$39.53
Avsola	Biosimilar	$51.50 (+15%)	$50.06 (+19%)	$49.15 (+19%)	$47.12 (+19%)
Inflectra	Biosimilar	$43.06 (-4%)	$40.61 (-3%)	$40.05 (-3%)	$41.19 (+4%)
Renflexis	Biosimilar	$42.09 (-6%)	$40.88 (-3%)	$39.56 (-4%)	$38.79 (-2%)

2021 Quarterly Use Rates

Biosimilars accounted for 23 percent of total infliximab use in Q4 2021. If these biosimilars had been used at the same rate as the most widely used biosimilars when they were more affordable, spending by Part B and its enrollees could have been reduced by $6 million. Enrollees' portion of this spending reduction would have been $1 million.



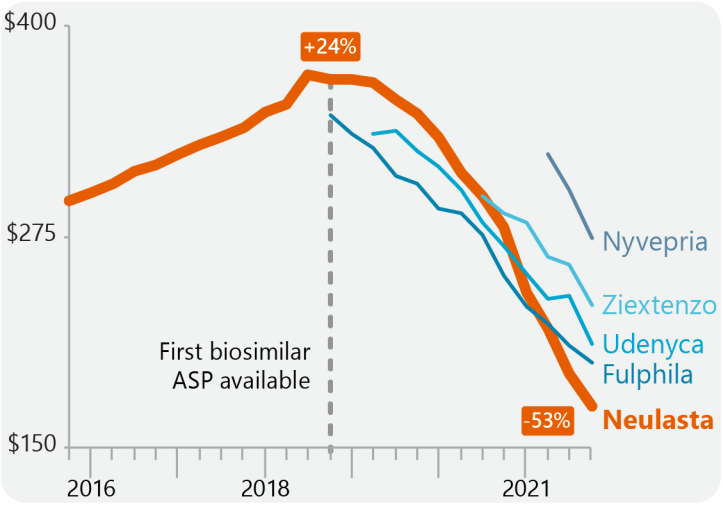
Note: ASP, quarterly Part B payment rates, and comparisons of quarterly use rates for infliximab are based on a 10 mg quantity.

Pegfilgrastim

Pegfilgrastim treats neutropenia, a condition in which the body makes too few white blood cells as a result of chemotherapy. The reference product, Neulasta, was approved by FDA in 2002 and had four biosimilars available as of December 2021. The first biosimilar pegfilgrastim, Fulphila, was approved by FDA in June 2018 and became available in the United States in July 2018 (Q3 2018). The Part B program and enrollees spent $873 million on pegfilgrastim in 2021.

The reference product price, as measured by ASP, increased 24 percent in the 3 years before biosimilar competition—but then decreased 53 percent by the end of 2021.

If the ASP-based payment rate for the reference product had remained stable at the same level as when its first biosimilar was introduced, the Part B program and its enrollees would have spent an additional $264 million on this drug in 2021. Enrollees' portion of this additional spending would have been $53 million.

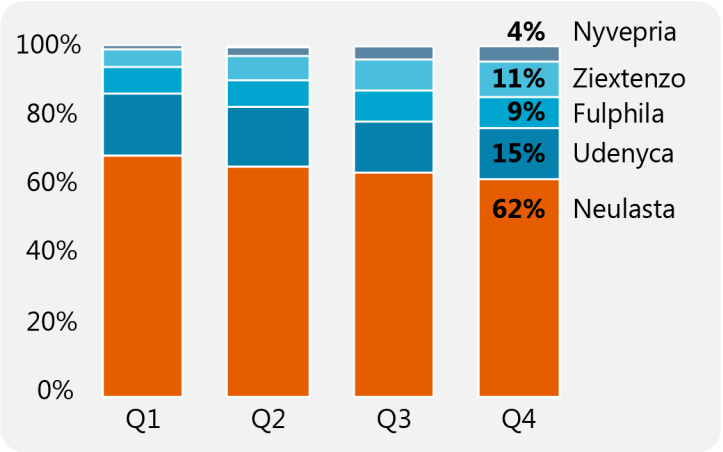


Differences in 2021 Quarterly Part B Payment Rates

Brand	Type	Q1	Q2	Q3	Q4
Neulasta	Reference Product	$256.62	$234.01	$205.78	$185.14
Fulphila	Biosimilar	$248.16 (-3%)	$236.46 (+1%)	$222.26 (+8%)	$211.19 (+14%)
Nyvepria	Biosimilar		$336.90 (+44%)	$314.21 (+53%)	$284.69 (+54%)
Udenyca	Biosimilar	$267.79 (+4%)	$251.30 (+7%)	$251.74 (+22%)	$222.38 (+20%)
Ziextenzo	Biosimilar	$297.96 (+16%)	$276.82 (+18%)	$270.56 (+31%)	$245.43 (+33%)

2021 Quarterly Use Rates

Biosimilars accounted for 38 percent of total pegfilgrastim use in Q4 2021. Because the reference product almost always had a lower price than its biosimilars in 2021, increased biosimilar use would not have reduced Part B and enrollee spending.



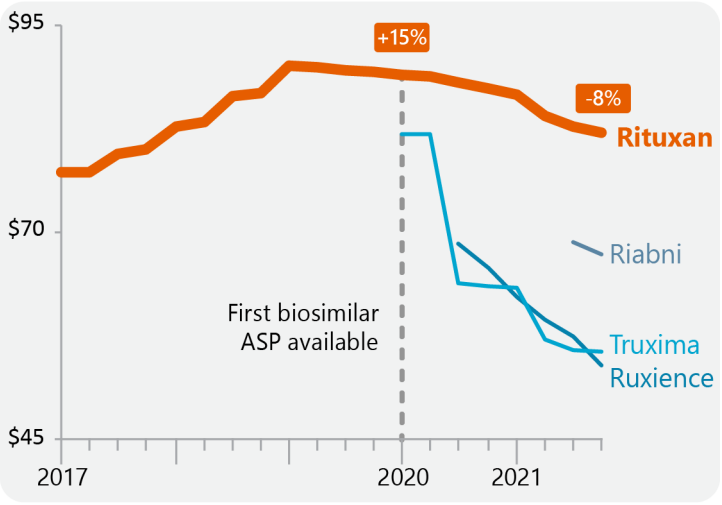
Note: ASP, quarterly Part B payment rates, and comparisons of quarterly use rates for pegfilgrastim are based on a .5 mg quantity.

Rituximab

Rituximab treats cancers such as non-Hodgkin's lymphoma and leukemia, as well as the symptoms of rheumatoid arthritis. The reference product, Rituxan, was approved by FDA in 1997 and had three biosimilars available as of December 2021. The first biosimilar rituximab, Truxima, was approved by FDA in November 2018 and became available in the United States in November 2019 (Q4 2019). The Part B program and enrollees spent $1.3 billion on rituximab in 2021.

The reference product price, as measured by ASP, increased 15 percent in the 3 years before biosimilar competition—but then decreased 8 percent by the end of 2021.

If the ASP-based payment rate for the reference product had remained at the same level as when its first biosimilar was introduced, the Part B program and its enrollees would have spent an additional $36 million on this drug in 2021. Enrollees' portion of this additional spending would have been $7 million.

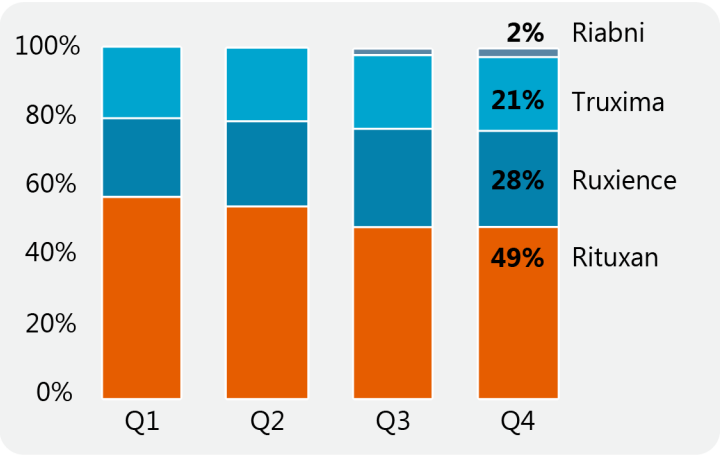


Differences in 2021 Quarterly Part B Payment Rates

Brand	Type	Q1	Q2	Q3	Q4
Rituxan	Reference Product	$91.84	$89.14	$87.78	$86.94
Riabni	Biosimilar			$73.83 (-16%)	$72.23 (-17%)
Ruxience	Biosimilar	$67.32 (-27%)	$64.51 (-28%)	$62.48 (-29%)	$58.80 (-32%)
Truxima	Biosimilar	$68.50 (-25%)	$62.06 (-30%)	$60.84 (-31%)	$60.58 (-30%)

2021 Quarterly Use Rates

Biosimilars accounted for 51 percent of total rituximab use in Q4 2021. If these more affordable biosimilars had been used at the same rate as the most widely used biosimilars, spending by Part B and its enrollees could have been reduced by $114 million in 2021. Enrollees' portion of this spending reduction would have been $23 million.



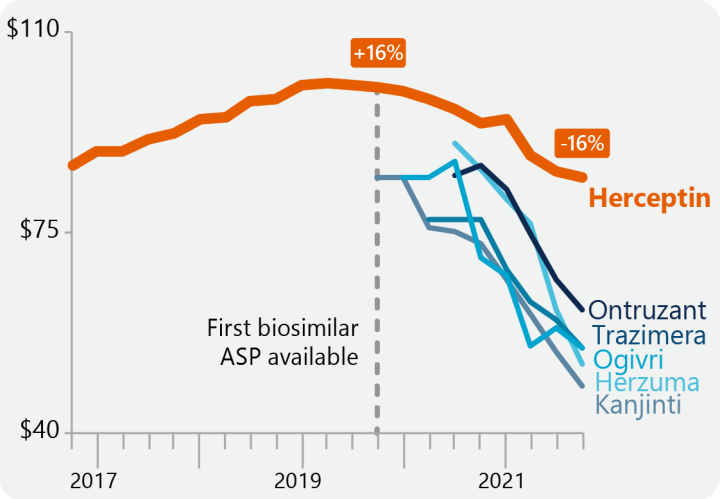
Note: ASP, quarterly Part B payment rates, and comparisons of quarterly use rates for rituximab are based on a 10 mg quantity.

Trastuzumab

Trastuzumab is used in the treatment of certain breast, stomach, and gastroesophageal cancers. The reference product, Herceptin, was approved by FDA in 1998 and had five biosimilars available as of December 2021. The first available biosimilar trastuzumab, Kanjinti, was approved by FDA in June 2019 and became available in the United States in July 2019 (Q3 2019).[13] The Part B program and enrollees spent $514 million on trastuzumab in 2021.

The reference product price, as measured by ASP, increased 16 percent in the 3 years before biosimilar competition—but then decreased 16 percent by the end of 2021.

If the ASP-based payment rate for the reference product had remained at the same level as when its first biosimilar was introduced, the Part B program and its enrollees would have spent an additional $18 million on this drug in 2021. Enrollees' portion of this additional spending would have been $4 million.

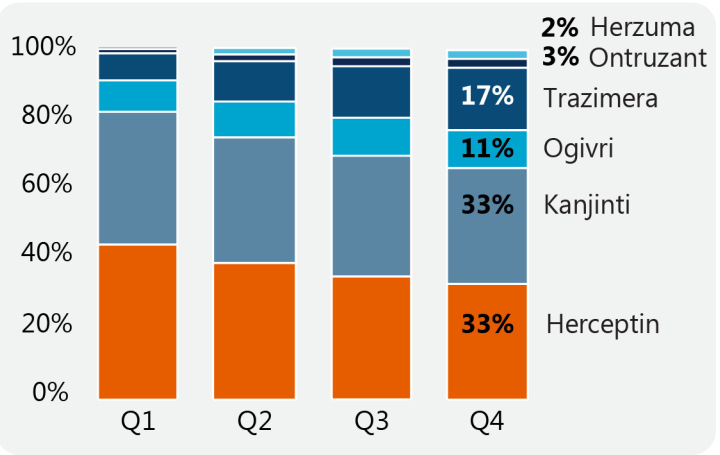


Differences in 2021 Quarterly Part B Payment Rates

Brand	Type	Q1	Q2	Q3	Q4
Herceptin	Reference Product	$100.49	$93.68	$90.98	$89.81
Herzuma	Biosimilar	$86.43 (-14%)	$81.99 (-12%)	$66.76 (-27%)	$57.30 (-36%)
Kanjinti	Biosimilar	$72.50 (-28%)	$66.29 (-29%)	$59.34 (-35%)	$53.18 (-41%)
Ogivri	Biosimilar	$73.21 (-27%)	$60.66 (-35%)	$63.40 (-30%)	$59.91 (-33%)
Ontruzant	Biosimilar	$88.17 (-12%)	$80.16 (-14%)	$72.08 (-21%)	$66.55 (-26%)
Trazimera	Biosimilar	$74.17 (-26%)	$68.11 (-27%)	$64.79 (-29%)	$59.93 (-33%)

2021 Quarterly Use Rates

Biosimilars accounted for 67 percent of total trastuzumab use in Q4 2021. If these more affordable biosimilars had been used at the same rate as the most widely used biosimilars, spending by Part B and its enrollees could have been reduced by $21 million in 2021. Enrollees' portion of this spending reduction would have been $4 million.



Note: ASP, quarterly Part B payment rates, and comparisons of quarterly use rates for trastuzumab are based on a 10 mg quantity.

Methodology

We analyzed trends in biosimilar and reference product prices; use rates; and program and enrollee costs in the fee-for-service Medicare Part B program. 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.

We refer to available biosimilars and their reference product, collectively, as a drug group. For this data snapshot, we calculated and visually presented the following data points for each drug group:

- **Quarterly price trends** for the reference product and each individual biosimilar. We used ASP to reflect the prices charged by manufacturers, beginning 3 years before biosimilar competition until the end of 2021. For each drug group, we used the date on which CMS published the first ASP-based payment rate for the first biosimilar as the start of biosimilar price competition.[14] To calculate ASP, we subtracted the add-on amount from the Part B payment amounts published by CMS.
- Estimates for the **additional amount Part B would have spent** on the reference product in 2021 if the reference product's price had not declined following biosimilar competition. We first multiplied the reference product's ASP-based payment rate from the first quarter a biosimilar became available by the quantity of the reference product used in 2021. We then subtracted total actual payments for the reference product in 2021 from this amount. To estimate enrollees' additional spending, we calculated 20 percent of the total additional spending.
- **Quarterly differences in Part B payments** between the reference product and each individual biosimilar in 2021.
- **Quarterly use rates** for the reference product and each individual biosimilar in 2021.[15]
- **Spending reduction with greater biosimilar use in 2021.** For each drug group, we estimated reductions in Part B and enrollee spending if biosimilars had been used at the same use rate as the filgrastim biosimilars and alternative biologic (the most widely used biosimilar group) in quarters in which the biosimilars were more affordable. We considered a drug group's biosimilars to be more affordable for a given quarter when their volume-weighted average cost was lower than the reference product's cost. We calculated spending reductions by multiplying the difference between the biosimilars' volume-weighted average cost and reference product cost by the increase in biosimilar use needed to achieve the filgrastim biosimilar use rate. We then summed the quarterly spending reductions to calculate total 2021 spending reductions. To estimate enrollees' reduced spending, we calculated 20 percent of the total reduced spending.

A detailed methodology, including information about data sources and study limitations, can be found in the main report: *Biosimilars Have Lowered Costs for Medicare Part B and Enrollees, but Opportunities for Substantial Spending Reductions Still Exist* (OEI-05-22-00140).

Acknowledgments and Contact

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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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To obtain additional information concerning this report, contact the Office of Public Affairs at Public.Affairs@oig.hhs.gov. OIG reports and other information can be found on the OIG website at oig.hhs.gov.

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Endnotes

[1] OIG analysis of the Centers for Medicare & Medicaid Services' (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.

[2] 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 BPCIA, FDA may approve a biosimilar once its manufacturer demonstrates that the biosimilar is "highly similar" to the already approved biologic reference product and that there are no "clinically meaningful differences" between the reference product and biosimilar. P.L. 111–148, Title VII, §§ 7001-7003, and 42 U.S.C. § 262(i).

[3] Biosimilars can also be deemed "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. None of the biosimilars in this analysis had been deemed interchangeable as of January 2024. 42 U.S.C. § 262(k)(4).

[4] ASP reflects the prices manufacturers charge for drugs. Manufacturers submit quarterly pricing and sales volume information to CMS, which CMS uses to calculate the ASP for Part B drugs. Providers administering Part B drugs receive payment that is based on a drug's ASP plus an add-on amount.

[5] When it was necessary, we adjusted ASP, Part B payment rates, and use to reflect a standardized quantity for the drug group.

[6] The bevacizumab reference product Avastin is also commonly used off-label to treat eye diseases.

[7] There is a lag between the sales quarter for which manufacturers submit pricing and sales volume information and the effective date of the ASP-based payment rate.

[8] 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*, Ch. 8 § 10, August 6, 2021. Accessed at https://www.cms.gov/Regulations-and-Guidance/Guidance/Manuals/Downloads/clm104c08.pdf on March 7, 2023.

[9] Although the epoetin alfa biosimilar had a launch date of Q4 2018, CMS first published an ASP-based payment rate in Q3 2018.

[10] Granix was approved as a new biologic, rather than a biosimilar, before the BPCIA created the biosimilar approval pathway. We have included it as an alternative biologic in our analyses of biosimilars in Medicare because it was first approved as a filgrastim biosimilar in Europe and acts as a competitor to Neupogen in the United States.

[11] Lisa A. Raedler, "Zarxio (Filgrastim-sndz): First Biosimilar Approved in the United States," *Journal of Hematology Oncology Pharmacy*, March 2016, vol. 6. 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.

[12] We used the filgrastim biosimilar and alternative biologic use rate as the benchmark for our estimates of spending reductions if other biosimilars were more widely used. Therefore, we did not calculate reduced Part B and enrollee spending with increased biosimilar filgrastim use.

[13] While Kanjinti was the first trastuzumab biosimilar available in the United States, Ogivri was the first FDA-approved trastuzumab biosimilar (December 2017). Ogivri became available in the United States in December 2019, nearly five months after Kanjinti.

[14] Biosimilar and reference product ASPs from that quarter reflect the prices manufacturers charged when a biosimilar competitor first became available.

[15] Numbers do not always add to 100 percent due to rounding.