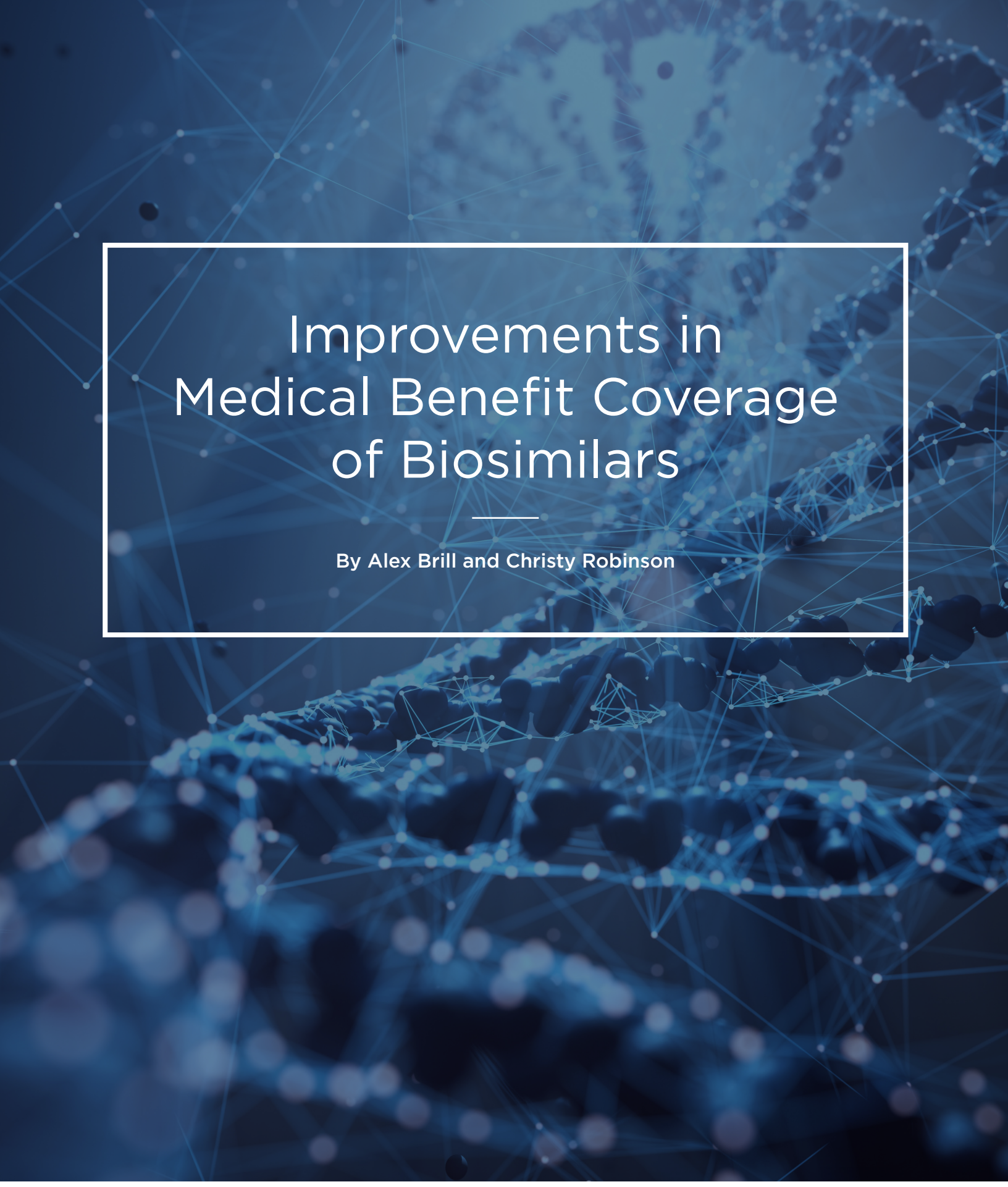

Improvements in Medical Benefit Coverage of Biosimilars

By Alex Brill and Christy Robinson

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MATRIX GLOBAL ADVISORS

Executive Summary

Prospects for biosimilars in the United States have improved in recent years. While patients and physicians play a role in the utilization of these lower-cost alternatives to reference biologic drugs, health insurance plans are an important driver of biosimilar adoption. To shed light on recent trends in payer coverage of biosimilars, this paper analyzes commercial medical benefit coverage and price trends for biosimilars and reference biologics over the period 2018–2021 in three disease areas: breast cancer and non-small cell lung cancer (NSCLC), colorectal cancer and chronic lymphocytic leukemia (CLL), and neutropenia (a side effect of chemotherapy).

This analysis shows that medical benefit coverage for biosimilars in these disease areas increased and prices declined during the period studied. Additionally, the share of preferentially covered biosimilars more than tripled.

In short, this analysis shows a positive outlook for biosimilar coverage in the commercial medical benefit. These trends in biosimilar price and commercial payer coverage are particularly promising as more biosimilars are poised to enter the market.

KEY FINDINGS

Coverage Trends
Coverage of biosimilars improved over the period studied.

Price Trends
Biosimilar and reference product prices declined over time.

Relative Prices
Biosimilar prices declined faster than reference product prices in two of three disease areas.

Prices and Coverage
Larger biosimilar price declines are associated with improved biosimilar coverage.

Utilization Management
Biosimilars tend to have more favorable utilization management than reference products.

Preferential Coverage
The share of preferentially covered biosimilars more than tripled.

Introduction

Since Congress created an abbreviated approval pathway for biosimilars in 2010, hopes have been high that these lower-cost alternatives to reference biologic drugs would gain traction in the US market and produce meaningful healthcare savings. In the first decade, biosimilar competition developed sluggishly, and utilization was marked by significant barriers (*see Brill and Robinson, 2018*). But in recent years, biosimilar market prospects have improved. As of October 2022, the Food and Drug Administration (FDA) has approved a total of 39 biosimilars competing with 13 reference biologics (*FDA, 2022*). Six of these approvals were in 2022, and the likelihood of a significant uptick in new product launches is increasing (*Chen et al., 2021*; *Fontanillo et al., 2022*).

The existence of approved biosimilars does not, of course, ensure their utilization. Patients and physicians clearly play a role in biosimilar uptake, but health insurance plans are an important driver of (or impediment to) biosimilar adoption. For example, one study found that, in 2019, only 14 percent of payer decisions gave preferred coverage to biosimilars (*Chambers et al., 2020*). But the biosimilar market has been evolving rapidly, with more products launching and more patients and healthcare providers aware of biosimilars' benefits. Importantly, payers have had more time to adjust coverage decisions to incorporate biosimilars.

To shed light on recent trends in private payer coverage of biosimilars — particularly in the commercial medical benefit — this paper analyzes biosimilars and reference biologics over the period 2018–2021 in three disease areas: breast cancer and non-small cell lung cancer (NSCLC), colorectal cancer and chronic lymphocytic leukemia (CLL), and neutropenia (a side effect of chemotherapy). These disease areas were chosen because the majority of commercially available biosimilars are used in cancer treatment (*American Cancer Society, 2022*).

This analysis shows that medical benefit coverage for biosimilars increased and prices declined during the period studied. Additionally, the share of preferentially covered biosimilars more than tripled. Results also show that biosimilars in the studied disease areas have generally achieved noncoverage parity with reference biologics. (We refer here and later in the paper to noncoverage and lack of coverage because coverage can refer to unrestricted coverage or coverage governed by utilization management strategies.)

Medical benefit coverage for biosimilars increased and prices declined during the period studied.

Biosimilar Prices and Utilization

Biosimilars are medicines made from living cells that are highly similar to and have no clinically significant differences from reference biologic drugs. Congress created an abbreviated approval pathway for biosimilars more than a decade ago, but the first US biosimilar, Zarxio, which reduces the risk of infection in cancer patients receiving chemotherapy, was not approved until September 2015. Today, there are 39 FDA-approved biosimilars, and 22 are commercially available in the United States (*Amgen, 2022*).

Competing with reference biologics, which are among the most expensive and widely utilized drugs in the United States, biosimilars have enormous savings potential. But savings opportunities depend on both biosimilar utilization and price discounts relative to the brand product.

PRICES

When Congress first considered a regulatory pathway for biosimilars, it was assumed that a biosimilar would have, on average, a 40 percent price discount relative to its reference product (*CBO, 2008*). In today's market, biosimilar discounts at launch are 10–57 percent and vary by disease area (*Amgen, 2022*). Brand biologic manufacturers also tend to discount the reference product in response to biosimilar competition, resulting in additional savings.

[An] important driver of biosimilar utilization — and the subject of the analysis presented in this paper — is insurance coverage, particularly in the medical benefit.

UTILIZATION

Biosimilar utilization was initially low in part due to a lack of knowledge or awareness among stakeholders, physicians, and patients; deliberate actions by brand manufacturers to thwart competition; and biosimilar pricing relative to reference product net prices. But biosimilars have made headway over time, achieving market shares of 32–82 percent in key disease areas (*Amgen, 2022*).

Because many biologics are administered in an office or inpatient setting, physicians play a large role in product selection and thus biosimilar uptake. Another important driver of biosimilar utilization — and the subject of the analysis presented in this paper — is insurance coverage, particularly in the medical benefit. Most biologics are administered in a doctor's office or hospital setting and are billed under the medical benefit of an insurance plan (or Part B in Medicare) rather than a plan's pharmacy benefit (or Part D in Medicare). Payers' coverage decisions vis-à-vis biosimilars and reference products drive utilization of covered products. As price factors into coverage decisions, we look here at trends in both biosimilar price and coverage as well as the relationship between price and coverage.

Analysis of Medical Benefit Price and Coverage Trends

The analysis presented here considers biosimilar and reference biologic price and coverage trends in commercial medical benefits during the period 2018–2021. As noted above, the majority of commercially available biosimilars are used in cancer treatment. Given this, our analysis focuses on products in three areas: breast cancer and non-small cell lung cancer (NSCLC), colorectal cancer and chronic lymphocytic leukemia (CLL), and neutropenia.

DATA AND METHODOLOGY

We rely on coverage data provided by Avalere Health, LLC, and derived from comprehensive medical policy data for the commercial market from Managed Markets Insight & Technology, LLC,[1] and quarterly Medicare Part B average sales price (ASP) data from the Centers for Medicare & Medicaid Services (CMS) Drug Pricing Files (*CMS, 2022*). The ASP data cover all the products represented in the coverage data.

Coverage data include enrollment-weighted medical benefit coverage shares for 16 different biosimilars and six reference biologics for each year from 2018 to 2021. (**See Table A1 in Appendix A** for included drugs and available years.) These data represent the share of weighted covered lives in a given year that drugs a) are covered without restriction, b) require utilization management for coverage, or c) are not covered. The shares sum to one for a given drug and year.

The data cover 98 percent of enrolled lives in fully funded commercial and exchange plans in the United States. For our disease areas of interest, the data reflect all of the FDA-approved and marketed biosimilars and reference biologics in each year.

To compare price and coverage trends between biosimilars and reference biologics, we calculate simple average coverage shares, construct coverage score indices for each product, and use regression analysis to examine the relationship between biosimilar price and both entry and coverage. (For a full description of the methodology, see **Appendix A**.)

[1] *While Avalere Health, LLC, provided data utilized in this analysis, it does not expressly or implicitly endorse any aspects of this report.*

RESULTS: PRICE TRENDS

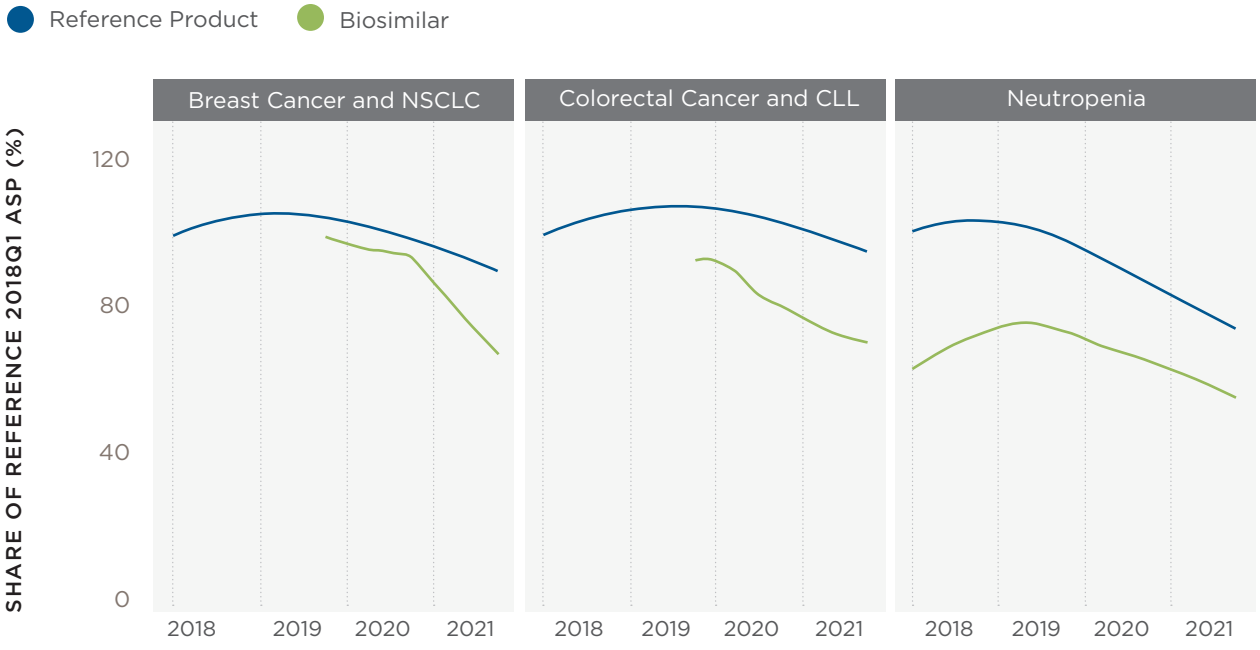
When biosimilars enter the market, they generate savings both by providing an alternative at a lower price and by driving reference product manufacturers to reduce prices.

Our results show that biosimilar ASPs and reference product ASPs declined over time in all three disease areas studied. **Figure 1** shows the average ASPs of biosimilars and reference products as a percentage of the ASPs of reference products in 2018 Q1. ASPs generally declined for biosimilars and reference products in conjunction with biosimilar entry.

In two of the disease areas, biosimilar prices declined faster than reference product prices. Compared to the initial reference drug ASPs, the prices of breast cancer/NSCLC biosimilars decreased by 22.2 percentage points between 2019 and 2021, compared with only 12.3 percentage points for reference drugs. Average prices decreased by 18.6 percentage points for colorectal cancer/CLL biosimilars from 2019 to 2021 (compared with 9.2 percentage points for reference products) and 8.4 percentage points for neutropenia biosimilars from 2018 to 2021 (compared with 24.5 percentage points for reference products). This trend can be seen by observing the widening gap between the blue and green lines in **Figure 1** in the first two disease areas.

Biosimilar ASPs and reference product ASPs declined over time.

FIGURE 1. ASP Trends by Disease Area, 2018–2021



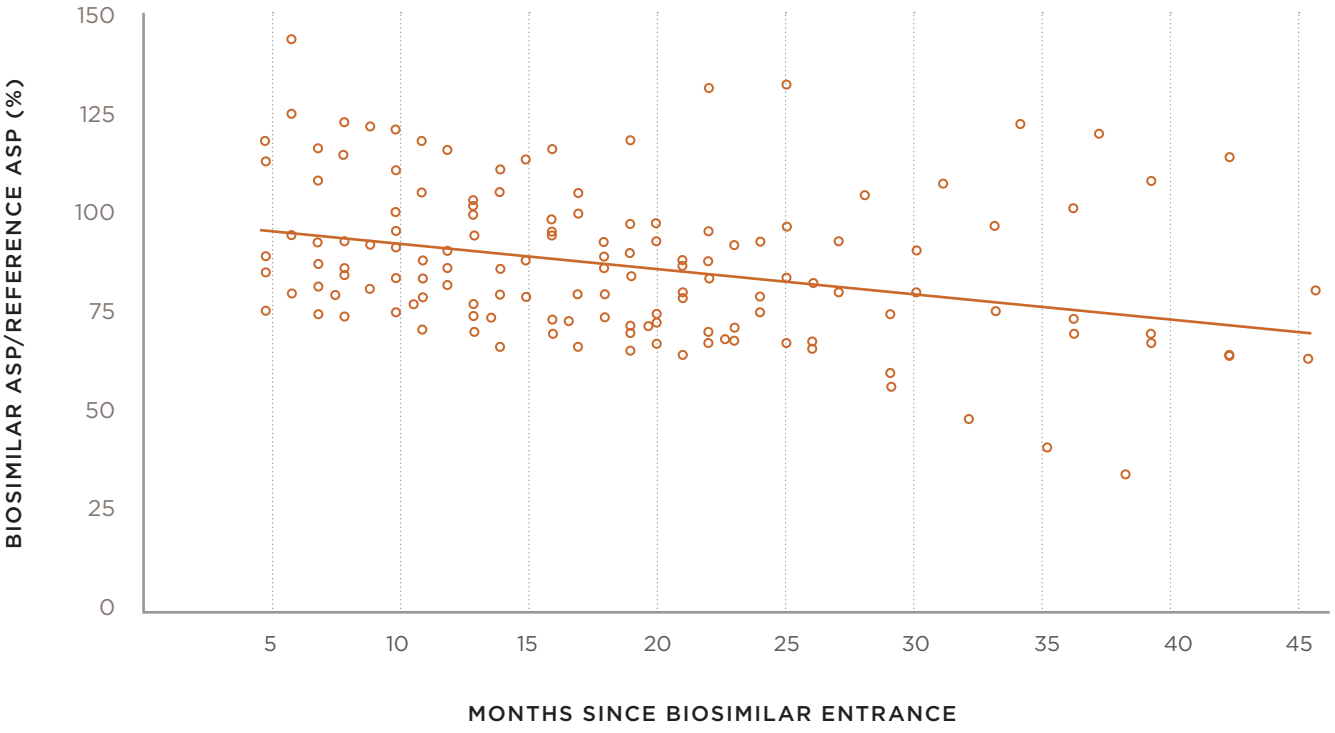
Source: *MGA analysis of CMS ASP Drug Pricing Files January 2018–October 2021.*

Compared with their first observed prices, average prices for breast cancer/NSCLC biosimilars decreased by 23.1 percentage points from 2019 to 2021. Average prices decreased by 17.8 percentage points for colorectal cancer/CLL biosimilars from 2019 to 2021 and 27.7 percentage points for neutropenia biosimilars from 2018 to 2021.

Figure 2 shows that biosimilar market duration is significantly correlated with a lower ratio of biosimilar to reference product ASPs. The longer a biosimilar is on the market, the less costly it is relative to its reference product. (Regression results for this figure are available in **Table B1 in Appendix B.**)

The longer a biosimilar is on the market, the less costly it is relative to its reference product.

FIGURE 2. Ratio of Biosimilar to Reference Product ASPs Over Time



Source: *MGA analysis of CMS ASP Drug Pricing Files January 2018–October 2021.*

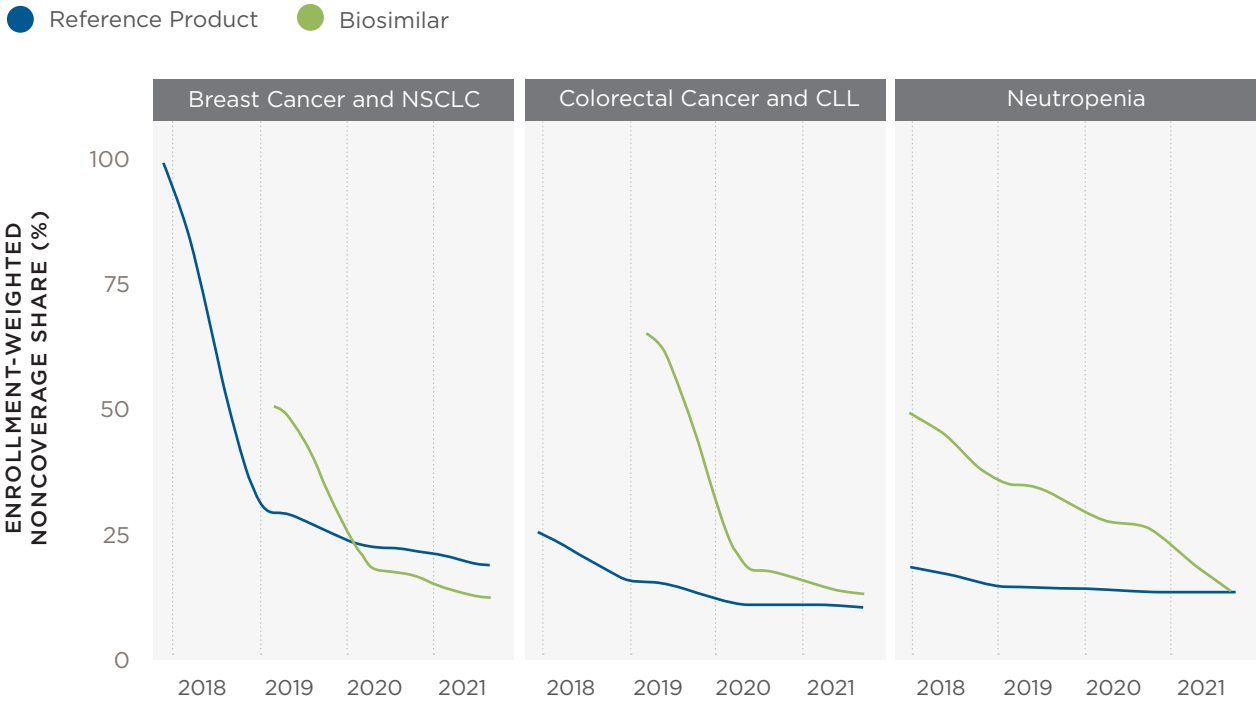
RESULTS: COVERAGE TRENDS

Our results show that coverage of biosimilars improved over time. Across all three disease areas, lack of biosimilar coverage decreased by 36.5 percentage points, from 44.3 percent to 7.8 percent, and lack of reference product coverage decreased by 33.1 percentage points, from 43 percent to 9.9 percent, over the period 2018–2021.[2] The share of noncovered biosimilars decreased from 46 percent to 7.5 percent for breast cancer/NSCLC, from 60.7 percent to 8.2 percent for colorectal cancer/CLL, and from 44.3 percent to 8.1 percent for neutropenia. (**See Figure 3.**)

Our results show that coverage of biosimilars improved over time.

Noncoverage of biosimilars was initially higher than noncoverage of reference biologics. However, in 2021, biosimilars achieved noncoverage parity with reference biologics for colorectal cancer/CLL and neutropenia products while noncoverage of breast cancer/NSCLC biosimilars was 6.3 percentage points lower than noncoverage of the reference product.[3]

FIGURE 3. Lack of Medical Benefit Coverage by Drug Type and Disease Area, 2018–2021



Source: *MGA analysis of data provided by Avalere Health, LLC, and derived from comprehensive medical policy data for the commercial market from Managed Markets Insight & Technology, LLC.*

[2] *We focus initially on noncoverage shares, or lack of coverage, because total coverage includes unrestricted coverage and coverage governed by utilization management strategies.*

[3] *When we adjust trend lines for biosimilars that are not available in each sample year, the results are similar. Average noncoverage of biosimilars available in the data during the entire period (2018–2021) decreases from 44.3 percent to 7.8 percent (0.3 percentage points higher in 2021 than our primary result). Only considering biosimilars available in the data from 2019 to 2021 results in average noncoverage decreasing from 44.1 percent in 2019 to 7.9 percent (0.4 percentage points higher than our primary result in 2021). After these small increases, biosimilar noncoverage is still lower, on average, than reference noncoverage by 2021.*

The decreases in biosimilar and reference product noncoverage from 2018 through 2021 have resulted primarily in an increase in coverage with utilization management. Utilization management refers to step therapy and/or prior authorization strategies. Step therapy requires the patient to try one or more preferred treatment alternatives before the listed product is covered. The patient must "step" through, and fail, a prior treatment, often the cheaper option, before they can access another, often more expensive, product. Prior authorization requires the patient's physician to obtain approval from the payer for an intended treatment option. If the payer decides not to cover the intended treatment of the prescriber, often the prescriber will choose an alternative drug for the patient.

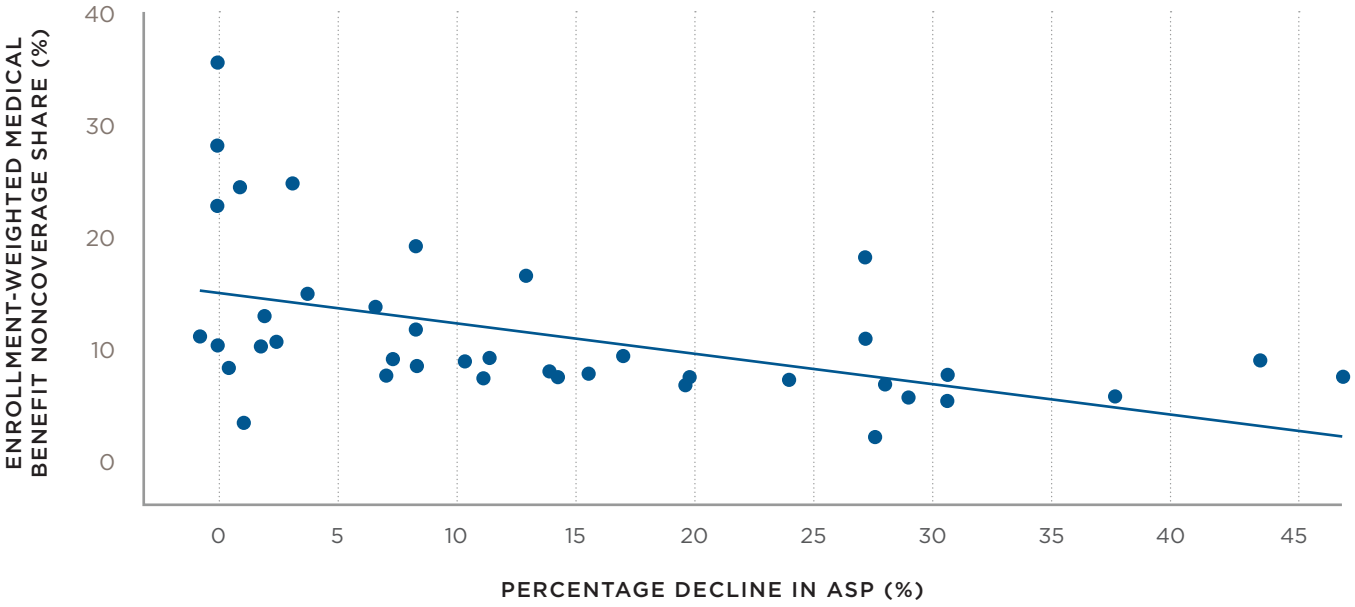
By 2021, the most common utilization management strategy for reference products (39.8 percent) was prior authorization and step therapy combined, while the most common strategy for biosimilars (50.5 percent) was prior authorization by itself.

RESULTS: RELATIONSHIP BETWEEN BIOSIMILAR PRICE AND COVERAGE

Beyond trends in prices and coverage, we examine the relationship between changes in the price of biosimilars and the lack of biosimilar coverage. **Figure 4** shows that a decline in biosimilar price is significantly correlated with a decline in medical benefit noncoverage. (Regression results are shown in **Table B2 in Appendix B.**)

A decline in biosimilar price is significantly correlated with a decline in medical benefit noncoverage.

FIGURE 4. Relationship Between Biosimilar ASP and Noncoverage



Source: *MGA analysis of CMS ASP Drug Pricing Files January 2018–October 2021 and data provided by Avalere Health, LLC, and derived from comprehensive medical policy data for the commercial market from Managed Markets Insight & Technology, LLC.*

RESULTS: PREFERENTIAL COVERAGE

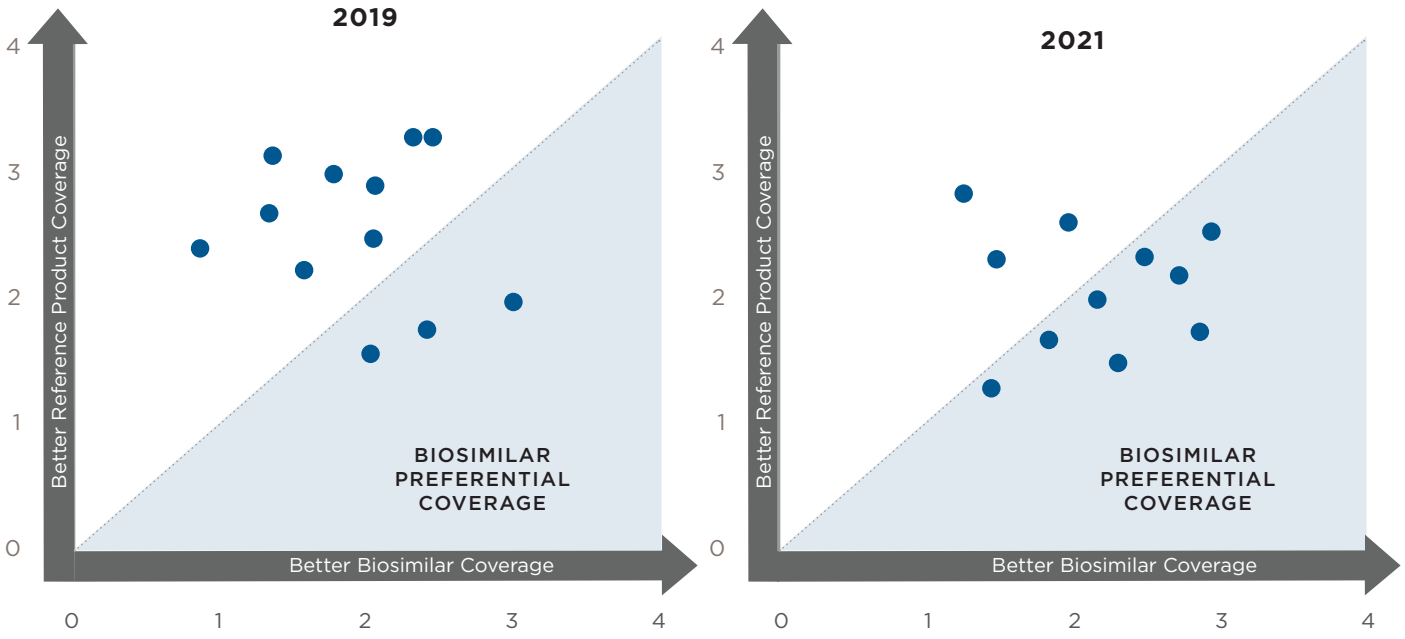
To better understand how well-covered biosimilars are relative to reference drugs, we construct coverage scores for each product. We multiply the enrollment-weighted shares of each drug by an index: zero is assigned to noncoverage, one to prior authorization and step therapy, two to step therapy only, three to prior authorization only, and four to unrestricted coverage. Of the utilization management strategies, we consider prior authorization to signify better coverage for patients as step therapy requires them to first fail on another product. On this scale, higher average scores indicate better overall coverage for a product.

Biosimilars were only preferentially covered in 20–25 percent of cases in 2018 and 2019 relative to their reference product. By 2020, 68 percent of biosimilars were preferentially covered. And in 2021, 78 percent of biosimilars were preferentially covered.

Biosimilars were only preferentially covered in 20–25 percent of cases in 2018 and 2019. . . . In 2021, 78 percent of biosimilars were preferentially covered.

Figure 5 shows how coverage scores changed from 2019 to 2021 for each biosimilar-reference drug pair, with higher average scores indicating better overall coverage for a product.[4] In 2019, more reference drugs were preferentially covered, but by 2021, many pairs had shifted to more preferential coverage for biosimilars.

FIGURE 5. Biosimilar and Reference Product Coverage Scores, 2019 and 2021



Source: MGA analysis of data provided by Avalere Health, LLC, and derived from comprehensive medical policy data for the commercial market from Managed Markets Insight & Technology, LLC.

[4] *Figure 5 starts with 2019 instead of 2018 because there were only four biosimilar-reference drug pairs in 2018.*

Conclusion

In recent years, prospects for the US biosimilar market have improved, and the barriers that once hindered biosimilar adoption may be changing. In this analysis, we show a positive outlook for biosimilar coverage in the commercial medical benefit. From 2018 to 2021, lack of biosimilar coverage declined while prices decreased. Furthermore, larger biosimilar price declines are associated with larger declines in biosimilar noncoverage. Biosimilars have generally achieved noncoverage parity with reference biologics, and the share of preferentially covered biosimilars increased from 20–25 percent of biosimilars in 2018 and 2019 to 78 percent in 2021.

These positive trends in biosimilar price and commercial payer coverage are particularly promising as more biosimilars are poised to enter the market. The next wave of biosimilars to launch will include some that are covered under the pharmacy benefit, and stakeholders can expect trends like those seen in the medical benefit for competitively priced products.

Appendix A: Data and Methodology

DATA

TABLE A1. Biosimilars in Coverage Data by Disease Area, Reference Product, and Year

DRUGS	2018	2019	2020	2021	Approval Date	Marketing Date
Colorectal Cancer and NSCLC Systemic Therapy						
Avastin	N	Y	Y	Y	Feb. 2004	Feb. 2004
Mvasi	N	Y	Y	Y	Sep. 2017	Jun. 2018
Zirabev	N	N	Y	Y	Jun. 2019	Dec. 2019
Breast Cancer: HR+ (HER2+)						
Herceptin	N	Y	Y	Y	Sep. 1998	Feb. 2017
Herceptin Hylecta	N	Y	Y	Y	Feb. 2019	Feb. 2019
Herzuma	N	Y	Y	Y	Dec. 2018	Mar. 2020
Kanjinti	N	Y	Y	Y	Jun. 2019	Jul. 2019
Ogivri	N	Y	Y	Y	Dec. 2017	Nov. 2019
Ontruzant	N	Y	Y	Y	Jan. 2019	Apr. 2020
Trazimera	N	Y	Y	Y	Mar. 2019	Feb. 2020
Neutropenia						
Neulasta	Y	Y	Y	Y	Jan. 2002	Apr. 2002
Fulphila	Y	Y	Y	Y	Jun. 2018	Jul. 2018
Nyvepria	N	N	Y	Y	Jun. 2020	Dec. 2020
Udenyca	Y	Y	Y	Y	Nov. 2018	Nov. 2018
Ziextenzo	N	Y	Y	Y	Nov. 2019	Nov. 2019
Neupogen	Y	Y	Y	Y	Dec. 1994	Dec. 1994
Nivestym	Y	Y	Y	Y	Jul. 2018	Oct. 2018
Zarxio	Y	Y	Y	Y	Mar. 2015	Mar. 2015
Rituxan	N	Y	Y	Y	Nov. 1997	Nov. 1997
Riabni	N	N	N	Y	Dec. 2020	Jan. 2021
Ruxience	N	Y	Y	Y	Jul. 2019	Jan. 2020
Truxima	N	Y	Y	Y	Nov. 2018	May 2020

Source: *Coverage data provided by Avalere Health, LLC, and derived from comprehensive medical policy data for the commercial market from Managed Markets Insight & Technology, LLC.*

METHODOLOGY

To compare coverage between biosimilars and reference biologics in the medical benefit, we calculate the simple average of drugs' enrollment-weighted shares, each grouped by disease area and graphed over the time series. We also discuss alternative trend lines that remove biosimilars unavailable in each sample year from the average. Newly launched biosimilars often have lower coverage and utilization in their first year, potentially biasing our average coverage/noncoverage enrollment-weighted shares downward/upward.

We also consider the relationship between biosimilar price and coverage and estimate the following regression:

$$Noncoverage_y = \beta_0 + \beta_1 P_y + \epsilon_y$$

where $Noncoverage_y$ is the enrollment-weighted noncovered share for a biosimilar in year y. On the right-hand side, P_y is the percentage decline in a biosimilar's ASP in year y (average over four quarters), and ϵ_y is a stochastic error term.

To compare prices between biosimilars and reference biologics in the medical benefit, we calculate the drugs' ASPs as a share of 2018 Q1 reference ASPs, using quarterly data from 2018–2021, and take the simple average by disease area. We select reference and biosimilar ASPs by matching dosage strengths at the Healthcare Common Procedure Coding System (HCPCS) level. HCPCS dosages used in this analysis are shown in **Table A2**.

We also examine the relationship between biosimilar entry and price by estimating the following regression:

$$Price_q = \beta_0 + \beta_1 M_q + \epsilon_q$$

where $Price_q$ is the ratio between a biosimilar's ASP and the reference biologic's ASP in quarter q. M_q is the number of months the biosimilar has been on the market as of the last month in each quarter, and ϵ_q is a stochastic error term.

TABLE A2. Selected HCPCS Dosages by Product

DRUGS	Dosage
Avastin	10 mg
Mvasi	10 mg
Zirabev	10 mg
Herceptin	10 mg
Herzuma	10 mg
Kanjinti	10 mg
Ogivri	10 mg
Ontruzant	10 mg
Trazimera	10 mg
Herceptin Hylecta	10 mg
Herzuma	10 mg
Kanjinti	10 mg
Ogivri	10 mg
Ontruzant	10 mg
Trazimera	10 mg
Neulasta	6 mg (converted to 0.5 mg)
Fulphila	0.5 mg
Nyvepria	0.5 mg
Udenyca	0.5 mg
Ziextenzo	0.5 mg
Neupogen	1 mcg
Nivestym	1 mcg
Zarxio	1 mcg
Rituxan	100 mg (converted to 10 mg)
Riabni	10 mg
Ruxience	10 mg
Truxima	10 mg

Source: *CMS ASP Drug Pricing Files January 2018—October 2021.*

Appendix B: Results

TABLE B1. Relationship Between Biosimilar Entry and Ratio of Biosimilar to Reference Product ASPs, by Disease Area

VARIABLES	Biosimilar ASP/ Reference ASP, All	Biosimilar ASP/ Reference ASP, Breast Cancer and NSCLC	Biosimilar ASP/ Reference ASP, Colorectal Cancer and CLL	Biosimilar ASP/ Reference ASP, Neutropenia
Months Since Biosimilar Entrance	-0.0064*** (0.0006)	-0.0117*** (0.0017)	-0.0034*** (0.0010)	-0.0075*** (0.0009)
Constant	0.9857*** (0.0193)	1.0697*** (0.0308)	0.8287*** (0.0197)	1.0768*** (0.0444)
Observations	197	88	32	77
R-squared	0.3801	0.3523	0.2840	0.4627

Notes: *Months since biosimilar entrance is the period between biosimilar market entry and the last month of each quarter. Standard errors in parentheses. *** p<0.01*

Source: *MGA analysis of data provided by Avalere Health, LLC, and derived from comprehensive medical policy data for the commercial market from Managed Markets Insight & Technology, LLC.*

TABLE B2. Relationship Between Biosimilar ASP and Noncoverage

VARIABLES	Enrollment-Weighted Noncoverage Share
Percentage Decline in ASP	-0.2675*** (0.0655)
Constant	0.1545*** (0.0119)
Observations	54
R-squared	0.2428

Notes: *Percentage decline in ASP is the average of quarterly price data for each year. Standard errors in parentheses. *** p<0.01*

Source: *MGA analysis of data provided by Avalere Health, LLC, and derived from comprehensive medical policy data for the commercial market from Managed Markets Insight & Technology, LLC.*

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ABOUT MGA

MGA is an economic policy consulting firm in Washington, DC. Founded by Alex Brill in 2007, MGA specializes in healthcare, tax, and fiscal policy. Drawing on years of policy experience, the MGA team uses analytics to help identify, quantify, and solve economic policy problems. On behalf of clients, MGA conducts original data analysis, constructs economic models, conducts research, writes white papers and expert reports, and offers strategic advice.

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