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Location, Location, Location: Spending Differences for Biologic and Biosimilar Medications by Site of Treatment

By Paul Fronstin, Ph.D., Employee Benefit Research Institute, and M. Christopher Roebuck, Ph.D., RxEconomics, LLC

AT A GLANCE

Biologics are often used to treat a range of life-threatening and debilitating conditions such as cancers, autoimmune diseases, and kidney diseases. They are made from living cells, structurally complex, and most often handled and administered to patients via IV infusion or injection by a health care professional in a hospital outpatient department (HOPD) or physician office (PO).

The original biologic, known as the innovator biologic, sometimes has substitutes, which are known as biosimilars. Biosimilars are exactly as their name implies: highly similar versions of the medicine with no clinically meaningful difference in effectiveness or safety from the innovator biologic. In recent years, a robust biosimilar marketplace has emerged, driving substantial savings for patients, employers, and insurers. As of February 2023, there are 29 biosimilars on the market competing against 11 innovator biologics.

Competition in the evolving market suggests innovator biologics and biosimilars both are competing on price to retain or gain market share. However, as HOPDs continue to mark up the price of biologics — and at rates that are higher and faster than those for biosimilars — and consolidation drives care away from POs into HOPDs, employers will continue to see costs go up, and the savings potential from biosimilars may not be fully realized.

In this *Issue Brief*, we focus on waste caused by pricing failure related to the cost of biosimilars. We conduct an analysis of site-of-treatment price differentials for innovator biologics and biosimilars. Specifically, we examine whether the potential cost savings from biosimilars is impacted by whether patients seek care from POs or higher cost HOPDs, as the trend towards HOPDs might be impacting potential savings.

Key Findings:

- Use of biosimilars among individuals with employment-based health benefits in the United States is growing as more biosimilars enter the market. Among the nine innovator biologics with available biosimilars as of October 2022, most of the biosimilars were launched in the United States in 2019 and 2020.
- With the exception of biosimilars for Neupogen, the market share for the innovator biologics was between 65 percent and 87 percent in 2020.
- HOPDs were sometimes more likely and sometimes less likely than POs to use innovator biologics over biosimilars. HOPDs were more likely than POs to use Neupogen, Herceptin, and Rituxan over their biosimilars. However, POs were more likely than HOPDs to use Remicade and Avastin. HOPDs and POs were about equally likely to use Neulasta and Epogen/Procrit.
- For all seven innovator biologics examined, allowed charges were higher in HOPDs than in POs. HOPD markups on innovator biologics are roughly doubling costs for employers and minimizing savings that could be achieved

through biosimilar competition. Allowed charges were about double in 2019, averaging 98 percent higher. In 2020, allowed charges were more than twice as high in HOPDs, averaging 121 percent.

- In 2020, the HOPD markup ranged from 75 percent to 183 percent. The HOPD markup increased between 2019 and 2020 for all innovator biologics examined.
- Allowed charges for biosimilars were higher in HOPDs than in POs. However, the markups for biosimilars were lower than the markups for innovator biologics. Biosimilar markups in HOPDs averaged 87 percent in 2019 and 101 percent in 2020. In 2022, HOPD markups ranged from 59 percent to 141 percent. The HOPD markup increased for 7 of the 9 biosimilars examined.

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By Paul Fronstin, Ph.D., Employee Benefit Research Institute, and M. Christopher Roebuck, Ph.D., RxEconomics, LLC

Introduction

Biologics are often used to treat a range of life-threatening and debilitating conditions — such as cancer, autoimmune diseases, and kidney disease — and they represent an increasingly prominent treatment option for patients in the United States. In fact, the U.S. Federal Drug Administration (FDA) has approved about 621 biologic products as of November 2021.[1] Biologics are made from living cells, are structurally complex, and are most often handled and administered to patients via IV infusion or injection by a health care professional in a hospital outpatient department (HOPD) or physician office (PO). Some of the benefits of biologics include the reduction of the number relapses, prevention of disability progression, symptom management, disease remission, and the maintenance and/or improvement of quality of life. Biologics accounted for less than 2 percent of the prescriptions written in the United States, though they accounted for 40 percent of total drug spending in 2018.[2]

Due to their complexity, they cannot be exactly reproduced or copied like generics. However, a biosimilar version can be produced, which is a highly similar version of the medicine with no clinically meaningful difference in effectiveness or safety from the innovator biologic. Since Congress enacted the Biologics Price Competition and Innovation Act (BPCIA) in 2010, creating an abbreviated approval pathway for biosimilars, a robust biosimilar marketplace has emerged driving savings for patients, employers, and insurers. As of February 2023, there are 29 biosimilars on the market competing against 11 innovator biologics.[3]

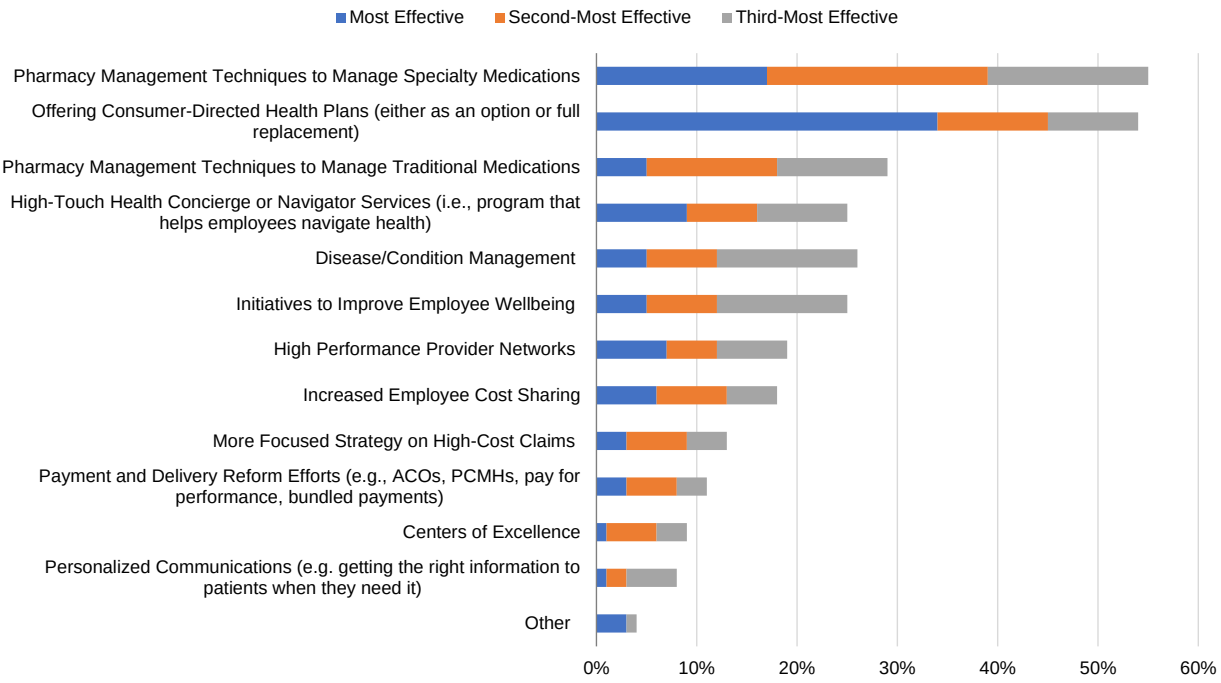
One aspect of the biologic and biosimilar marketplace that is unique relative to generic competition is the dynamics fueling competition from both innovator biologics and biosimilars as they enter the market. Though biosimilar uptake continues to climb, brand products compete to retain market share by also reducing prices.[4] In fact, the average sales price of biosimilars has decreased at an annual rate of 9–24 percent, while the average sales prices of most innovator biologics has decreased at an annual rate of 4–21 percent.[5]

In 2021, $151.7 billion was spent on outpatient prescription drugs in the United States, accounting for 13 percent of private health insurance spending.[6] Though the biosimilar market is still relatively new in the United States, it is growing rapidly, presenting a significant opportunity for employers and insurers to leverage the biosimilar competition to drive savings. Already, biosimilar competition is estimated to have produced $21 billion in overall savings in the United States over the past six years alone.[7] In the years ahead, more competition is expected with more than 100 biosimilars in development.

As biologics are medications administered by a physician on an outpatient basis, the claims for these medications are adjudicated as a medical benefit instead of as a pharmacy benefit. Employers are increasingly aiming to manage the costs of biologics covered under the medical benefit. In fact, over 50 percent of employers rated pharmacy management techniques to manage specialty medications as either the most, second-most, or third-most effective tactic for controlling health care costs (Figure 1). Offering consumer-driven health plans was the only other option that over 50 percent of employers rated as one of the top three most effective tactics for controlling costs.

Concurrent to the increasing use of innovator biologics and biosimilars, there have been changes to the health care delivery system that may impact the delivery of these medications. Care has been shifting from physician offices (POs) to hospital outpatient departments (HOPDs). This shift occurs when a hospital system acquires an independent physician practice. One example of the shift from PO to HOPD is related to chemotherapy infusions. In 2004, approximately 94 percent of chemotherapy infusions were administered in POs, but by 2014, that percentage had dropped to 57 percent with a corresponding shift toward HOPDs (Winn, Keating, Trogdon, Basch, and Dusetzina 2018).

Figure 1
Employer Opinion on Most Effective Tactics to Control Health Care Costs



Source: National Business Group on Health, 2018 Health Care Strategy and Plan Design Survey.

Compounding the shift in care from POs to HOPDs is the fact that not only do HOPDs charge higher prices than POs for the same medicines, but HOPD prices are growing faster than PO prices. A recent study found that between 2007 and 2014, prices for HOPD care increased 25 percent, while PO prices grew 6 percent (Cooper et al. 2019). Ultimately, employers and workers bear the brunt of cost differences when HOPDs perform services that can be provided in less costly POs.

This *Issue Brief* is the fourth in a series examining site-of-treatment price differentials for health care services. First, we determined that hospital outpatient departments (HOPDs) charged 81 percent more for oncology medications than physician offices (POs), controlling for drug mix and treatment intensity (Fronstin, Roebuck, and Stuart 2020). We concluded that, had PO prices prevailed in the HOPD setting, payers could have saved $9,766 per oncology patient in 2016. Next, we analyzed 25 outpatient services consisting of lab, imaging, and selected specialty medications (Fronstin and Roebuck 2021a). For each of the 25 health care services examined, HOPDs charged more per unit of service than POs; costs were higher by between 15 percent and 531 percent, with a median difference of 91 percent. In aggregate, we estimated that employer health plan sponsors and plan enrollees could have saved more than $11 billion on these services in 2018 if HOPDs had charged PO prices. This represented about 1 percent of total health care spending on workers and their families. Finally, we expanded and updated our prior analyses to include 72 physician-administered outpatient drugs (PAODs) (Fronstin and Roebuck 2021b). Together, these medications account for 49 percent of all claims and 73 percent of all spending on PAODs paid via the medical benefit. In the aggregate, employers and workers would collectively save $10.3 billion annually if price differentials between HOPDs and POs were eliminated for the 72 PAODs examined. If we extended the savings to all PAODs, aggregate savings would be $14.1 billion each year.

In this *Issue Brief*, we examine trends in the use of innovator biologics and biosimilars. We also focus on waste caused by pricing failure related to the cost of biosimilars. We conduct an analysis of site-of-treatment price differentials for innovator biologics and biosimilars. Specifically, we examine whether the potential cost savings from biosimilars is impacted by whether patients seek care from POs or higher-cost HOPDs, as the trend toward HOPDs might be impacting potential savings. HOPD markups on innovator biologics are roughly doubling costs for employers and minimizing savings that could be achieved through biosimilar competition.

Data and Methods

Study Sample

For this study, we analyzed the Merative™ MarketScan® Commercial Database, which includes member enrollment information and paid claims on nearly 25 million people with private health insurance. For each year from 2013 through 2020 (i.e., the study period), we subset all available data to the cohort of full-time active employees and their dependents, less than 65 years of age, who were continuously enrolled within each calendar year in a non-capitated health plan. Sample sizes varied by year from 13.5 million to 24.5 million. For descriptive purposes, we calculated variable means (by year) for the following characteristics: gender, age, geographic region (Northeast, Midwest, South, West), relationship to policyholder (self, spouse, child/dependent), and health plan type (preferred provider organization/point-of-service plan/comprehensive, exclusive provider organization/health maintenance organization, consumer-directed health plan, high-deductible health plan). Sample means for 2020 are shown in Figure 2.

Figure 2
Sample Characteristics, 2020

Gender	
Male	49%
Female	51%
Age, Years	34.2
Under 18	23%
18–24	12%
25–34	14%
35–44	16%
45–54	18%
55–64	17%
Person Covered	
Policyholder	47%
Spouse	18%
Child/other dependent	35%
Type of Health Plan	
HMO/EPO	15%
PPO/POS	57%
HRA	13%
HSA-eligible health plan	14%

Source: Employee Benefit Research Institute estimates based on administrative enrollment and claims data.

Note: HMO=health maintenance organization; EPO=exclusive provider organization; PPO=preferred provider organization; POS=point of service; HRA=health reimbursement arrangement; HSA=health savings account.

20% sample of full Marketscan with continuous eligibility in each year. Non-capitated plans only.

Study Drugs

As of February 2023, a total of 40 biosimilars had been approved for 11 innovator biologics (Figure 3). Eleven of these biosimilars have not yet launched, however. Rather than investigate the historical and current market status of each drug, we relied on the medical and pharmacy claims data for the study sample. Specifically, we extracted all claims for the 51 candidate study drugs using their associated Healthcare Common Procedure Coding System (HCPCS) codes.[8] Hence, we focus on seven innovator biologics with biosimilars that had been launched as of 2020. They include the following innovator biologics: Neupogen, Remicade, Neulasta, Epogen/Procrit, Herceptin, Avastin, and Rituxan.

Figure 3

Innovator Biologic and Biosimilar Market Landscape in United States

Class	Supportive Care			Oncology			Insulin	Ophthalmology	Immunomodulators		
Molecule	Filgrastim	Epoetin	Pegfilgrastin	Rituximab	Bevacizumab	Trastuzumab	Insulin Glargine	Ranibizumab	Infliximab	Etanercept	Adalimumab
Innovator	**Neupogen**	**Epogen / Procrit**	**Neulasta**	**Rituxan**	**Avastin**	**Herceptin**	**Lantus**	**Lucentis**	**Remicade**	**Enbrel**	**Humira**
Biosimilars (date launched)	**Granix**	**Retacrit** (Nov. 2018)	**Fulphila** (July 2018)	**Truxima** (Nov. 2019)	**Mvasi** (July 2019)	**Kanjinti** (July 2019)	**Semglee** (Nov. 2021)	**Byooviz** (July 2022)	**Inflectra** (Nov. 2016)		**Amjevita** (Jan. 2023)
	Zarxio (Sep. 2015)		**Udenyca** (Jan. 2019)	**Ruxience** (Jan. 2020)	**Zirabev** (Jan. 2020)	**Ogivri** (Nov. 2019)		**Cimerli** (Oct. 2022)	**Renflexis** (July 2018)		
	Nivestym (Oct 2018)		**Ziextenzo** (Nov. 2019)	**Riabni** (Jan. 2021)	**Alymsys** (Oct. 2022)	**Trazimera** (Feb. 2020)			**Avsola** (July 2020)		
	Releuko (Nov. 2022)		**Nyvepria** (Dec. 2020)			**Herzuma** (March 2020)					
			Stimufend (Feb. 2023)			**Ontruzant** (Apr. 2020)					
Approved Biosimilars (not yet launched)			**Fylnetra**		**Vegzelma**		**Rezvoglar**		**Ixifi**	**Erelzi**	**Cyltezo**
										Eticovo	**Hyrimoz**
											Hadlima
											Abrilada
											Hulio
											Yusimry

Source: Adapted in part from https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/biosimilars-page/sgs-biosimilars-usmarketlandscape-020623---copy.pdf.
Innovator biologics and biosimilars examined in this paper.

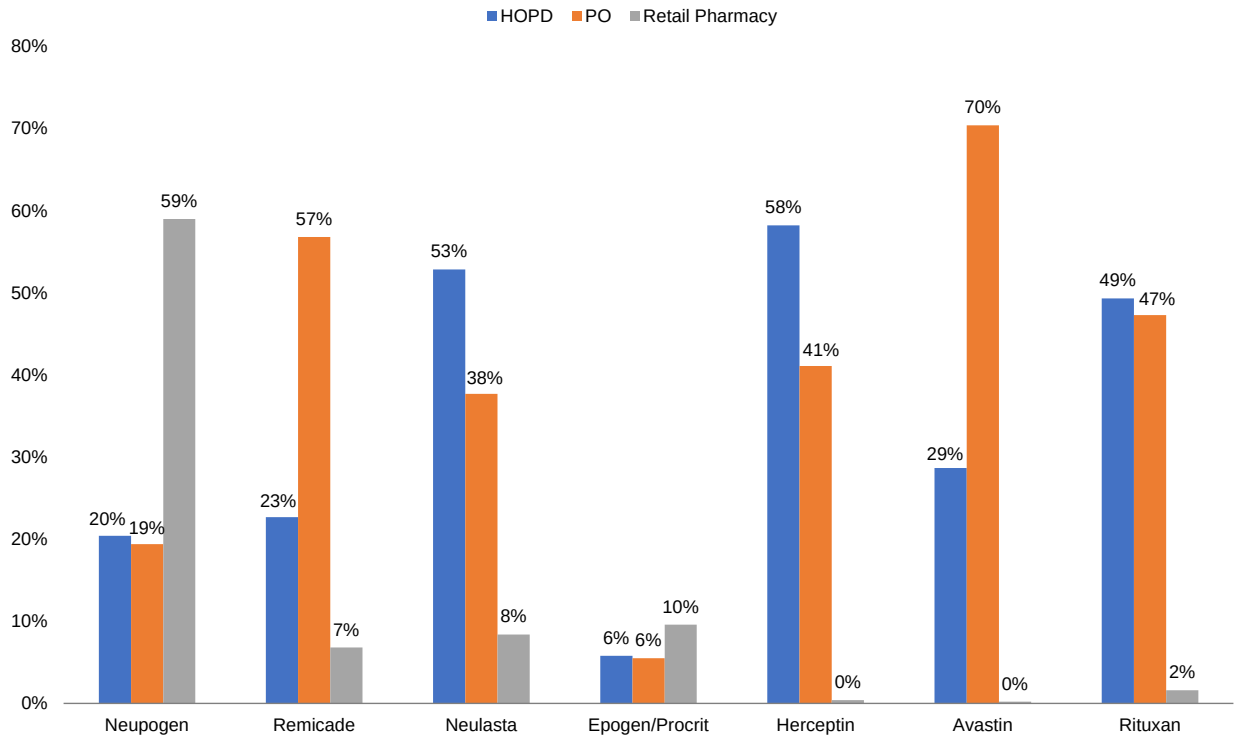
Market Share

For each of the seven drug sets, we determined the proportion of utilization that was captured by the innovator biologics compared with each of its biosimilars. Both medical and pharmacy claims were included in the analysis. Dispensed prescriptions were converted into doses for equivalence to medical infusions/injections. The innovator biologics market share was calculated for each year during the study period.

Similarly, for each of the seven drug sets, the share of use by site of service was also derived. Specifically, we calculated the proportion of medication administered in hospital outpatient departments (HOPD), physician offices (PO), other medical settings, and community-based pharmacies. HOPD market share was calculated for each year during the study period.

There is variation in the site of service for the seven innovator biologics examined. The percentage of innovator biologics delivered in HOPDs varies from 6 percent to 58 percent (Figure 4). For nearly all of the innovator biologics examined, HOPD and PO account for nearly all of the sites of service. But there were a few exceptions. Neupogen was the only innovator biologic with a sizable share (59 percent) delivered by a retail pharmacy. This is not a surprise, as the injection can be self-administered by a patient. The other exception is Epogen/Procrit, where only 6 percent was provided by an HOPD, 6 percent was provided at a PO, and 10 percent at a retail pharmacy. The remaining 78 percent were delivered in a stand-alone infusion center, which is not shown separately in Figure 4.

Figure 4
Distribution of Innovator Biologics, by Site of Treatment, 2020



Source: Employee Benefit Research Institute estimates based on administrative enrollment and claims data.

HOPD Markup

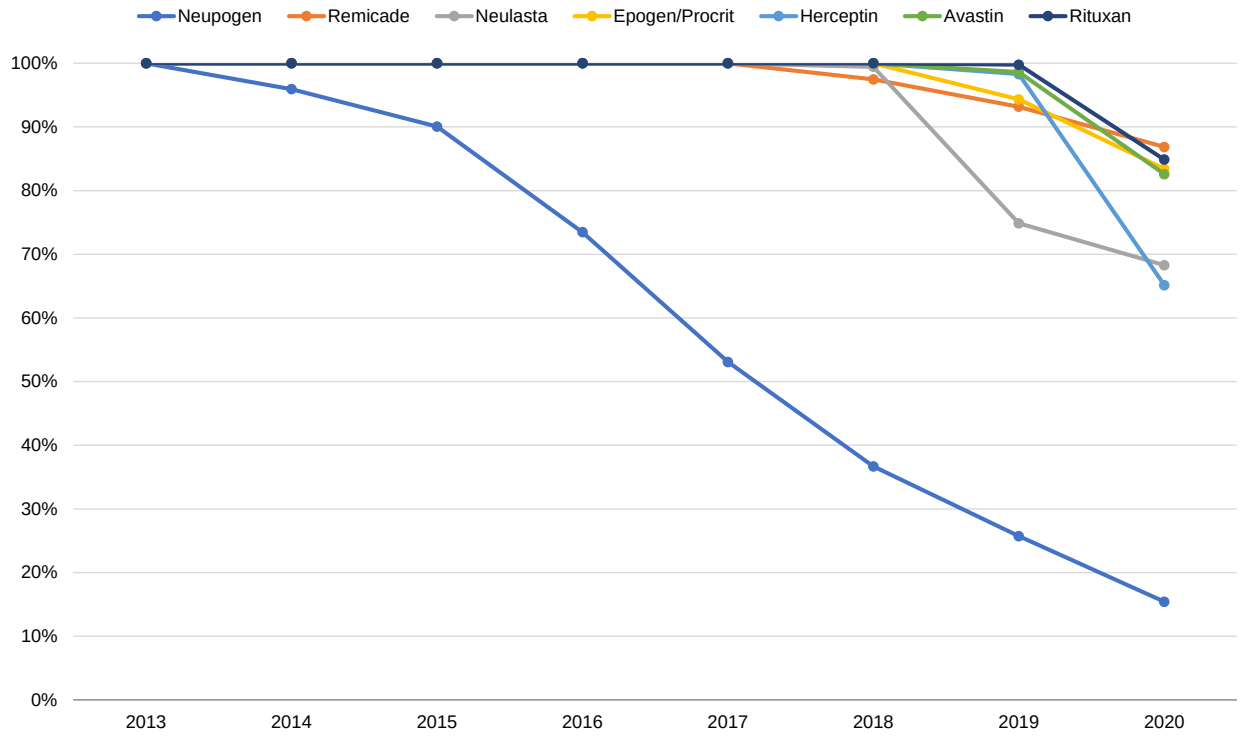
In the final part of the analysis, we examined the prices charged by HOPDs relative to POs. This entailed making use of the "units" field on medical claims, which includes values that either pertain to the amount of medication administered according to a specific national drug code (NDC) or the number of HCPCS-based units. Moreover, this claim field often also contains zeros or is missing. Thus, to make the data usable in subsequent calculations, we deleted claims that contained these and other implausible units' values based on manufacturer-reported dosage ranges.

Using the cleansed claims data, we calculated the average unit price by specific innovator biologic or biosimilar drug, site of service, and year by dividing the total allowed amount by the total number of units. The HOPD over PO markup was derived as (1 - HOPD/PO).

Findings

Use of biosimilars among individuals with employment-based health benefits in the United States is growing as more continue to enter the market. Among the seven innovator biologics, most of the biosimilars were released in the United States in 2019 and 2020, so the innovator biologics were able to maintain a relatively large market share until recently (Figure 5). The exception is Neupogen. The first biosimilar for Neupogen launched in 2014. This explains why Neupogen accounted for only 15 percent of the market share in 2020, and the biosimilars accounted for 85 of the market, demonstrating that market share may be likely to increase over time and as more biosimilar competitors enter the market for each brand biologic. Otherwise, the market share for the innovator biologics was between 65 percent and 87 percent in 2020, and the biosimilar share was between 13 percent and 35 percent. As discussed above, biosimilars are expected to continue to account for an increasingly larger market share in the future given the large pipeline, with more than 100 biosimilars in development. In addition, several new biosimilars that have been approved in the United States have recently launched or are planned to launch in 2023.

Figure 5
Innovator Biologics Market Share, 2013–2020

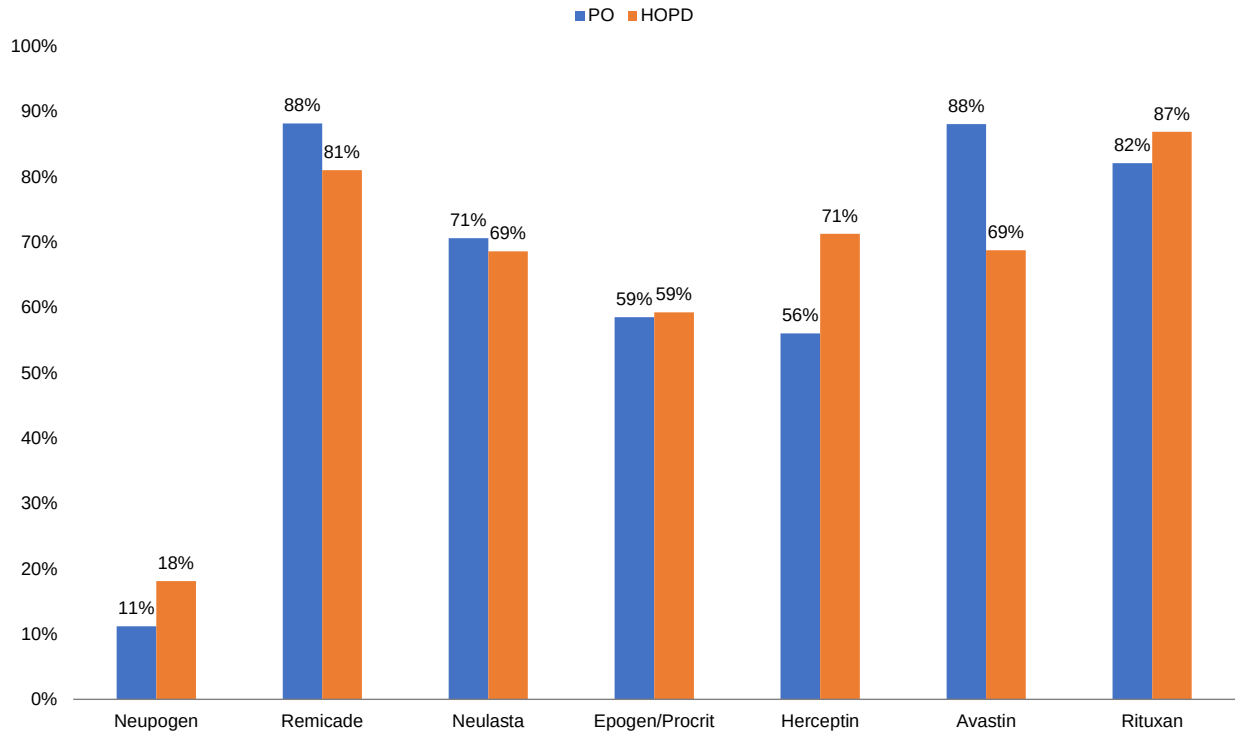


Source: Employee Benefit Research Institute estimates based on administrative enrollment and claims data.

We thought that since HOPDs are a more costly site of treatment as compared with POs, we might find that HOPDs were more likely than POs to use innovator biologics over biosimilars. The findings were mixed (Figure 6). HOPDs were more likely than POs to use Neupogen, Herceptin, and Rituxan. By 2020, the market share for Neupogen was relatively low because the biosimilars started to launch in 2014. Yet, HOPDs were nearly two-thirds more likely than POs to use Neupogen as opposed to a biosimilar, which lessens the potential savings from the availability of the biosimilar. POs

were more likely than HOPDs to use Remicade and Avastin. HOPDs and POs were about equally likely to use Neulasta and Epogen/Procrit.

Figure 6
Innovator Biologics Market Share, HOPD vs. PO, 2020



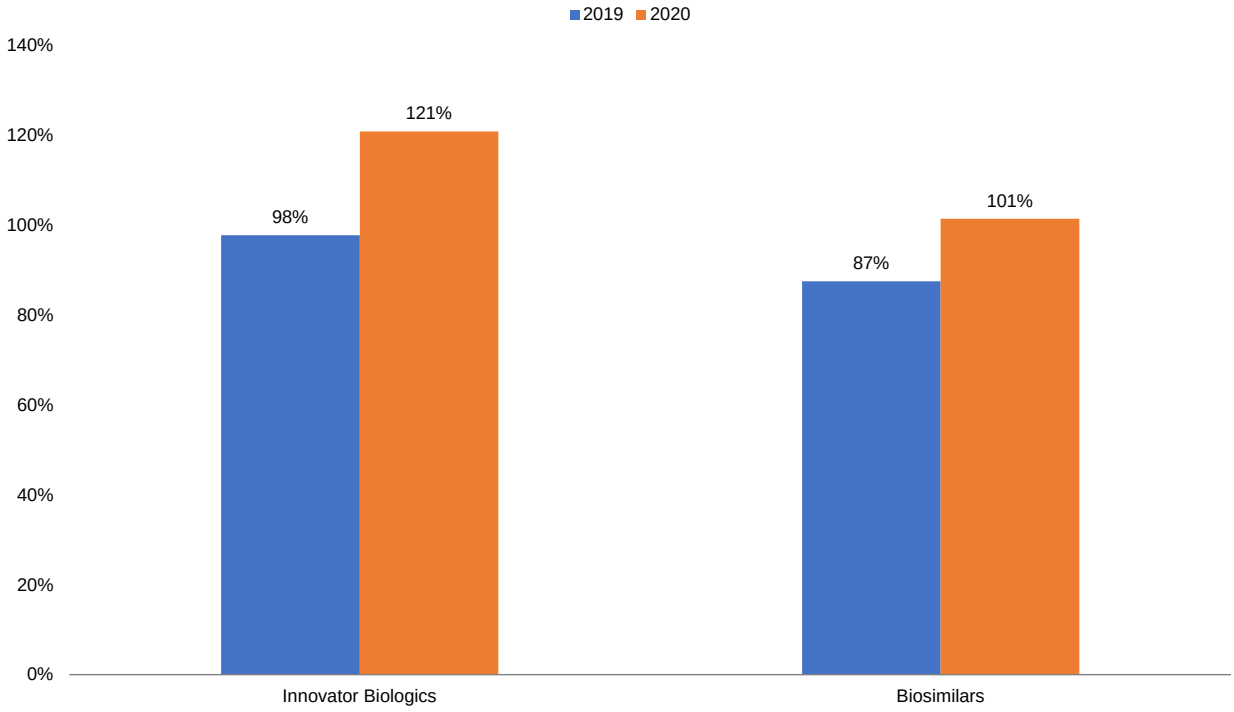
Source: Employee Benefit Research Institute estimates based on administrative enrollment and claims data.

For all seven innovator biologics examined, allowed charges were higher in HOPDs than in POs. Allowed charges were about double in 2019, averaging 98 percent higher (Figure 7). In 2020, allowed charges were more than twice as high in HOPDs, averaging 121 percent. Allowed charges for biosimilars were also higher in HOPDs than in POs. The markups for biosimilars were lower than the markups for innovator biologics but continued to be about double, similar to the markup for the innovator biologics. Biosimilar markups in HOPDs averaged 87 percent in 2019 and 101 percent in 2020. For both innovator biologics and biosimilars, HOPD markups appear to be growing.

With respect to trends in HOPD markups, Neupogen has had an available biosimilar the longest and is essentially the only innovator biologic with trend information. While there is some variation over time, HOPD markups of both Neupogen and the available biosimilars are more than double and are trending upward (Figure 8).

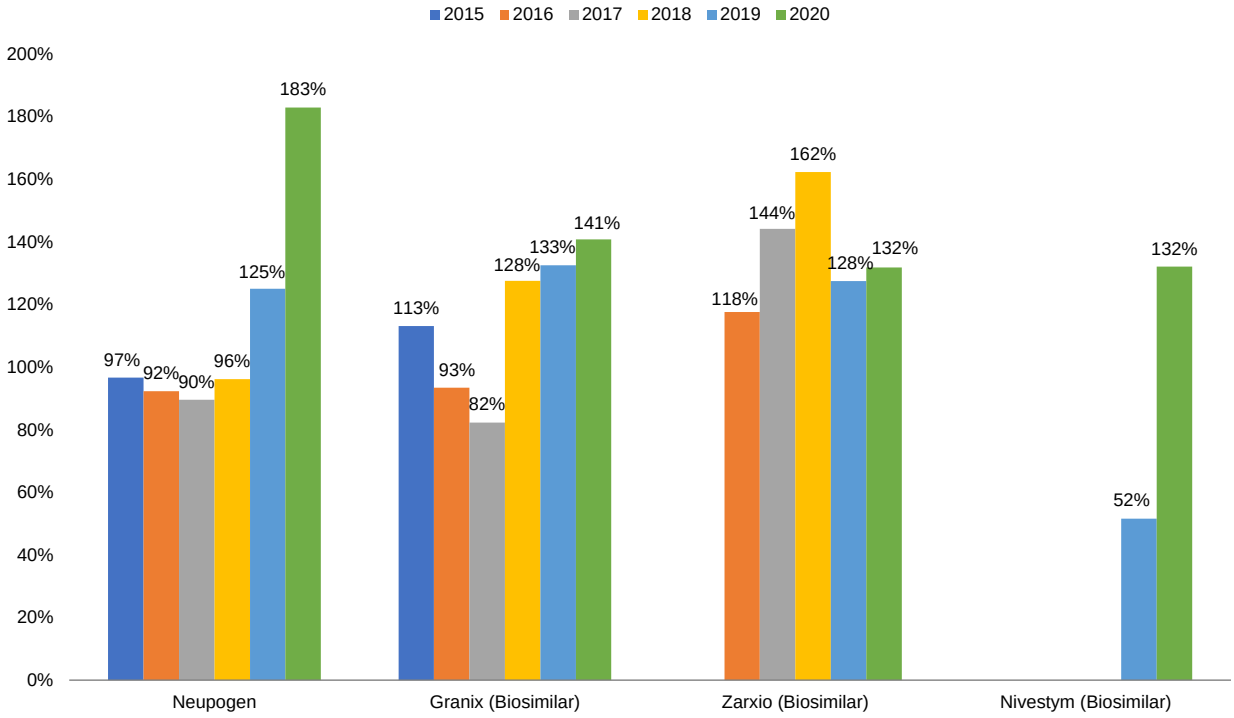
Innovator biologics and biosimilar markups for Remicade, Neulasta, Epogen/Procrit, Herceptin, Avastin, and Rituxan are shown in Figures 9 through 14. In 2020, the HOPD markup ranged from 75 percent for Herceptin to 177 percent for Epogen/Procrit. The HOPD markup increased between 2019 and 2020 for all innovator biologics examined. For the biosimilar medications, HOPD markups ranged from 59 percent to 141 percent in 2020. The HOPD markup increased for 7 of the 9 biosimilars examined between 2019 and 2020.

Figure 7
HOPD/PO Markup, Innovator Biologics and Biosimilars, 2019–2020



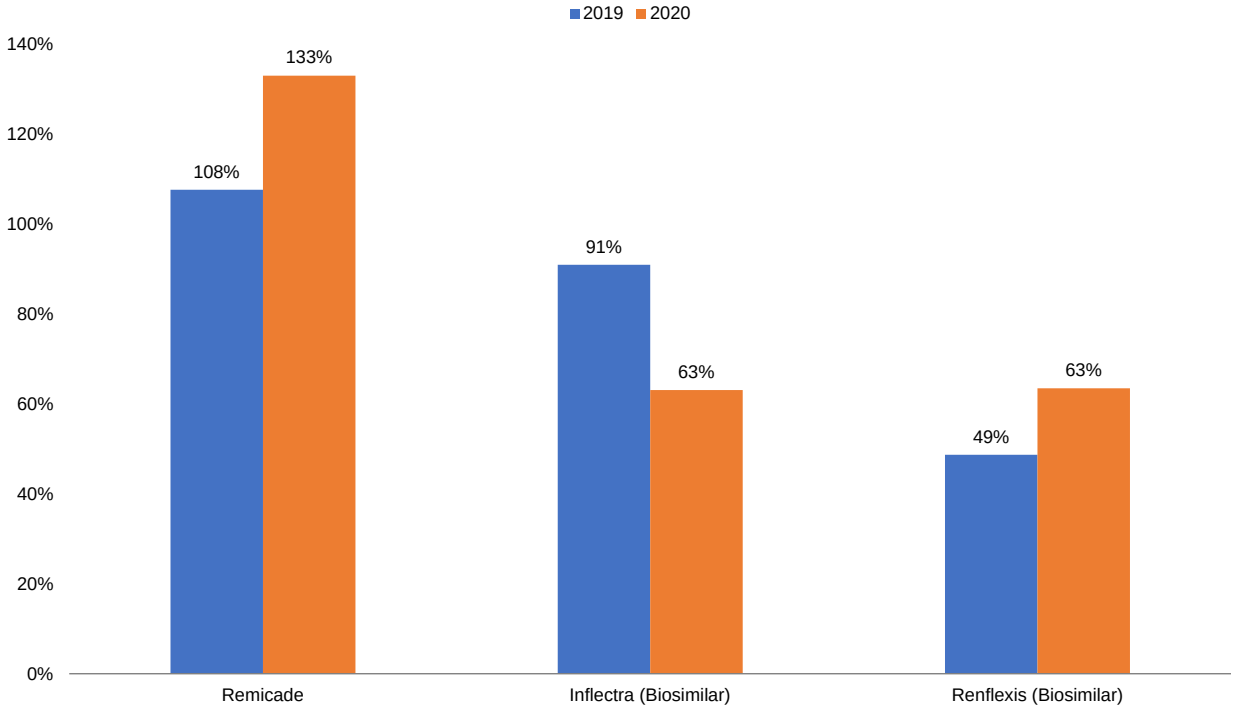
Source: Employee Benefit Research Institute estimates based on administrative enrollment and claims data.

Figure 8
HOPD/PO Markup, Neupogen and Biosimilars, 2015–2020



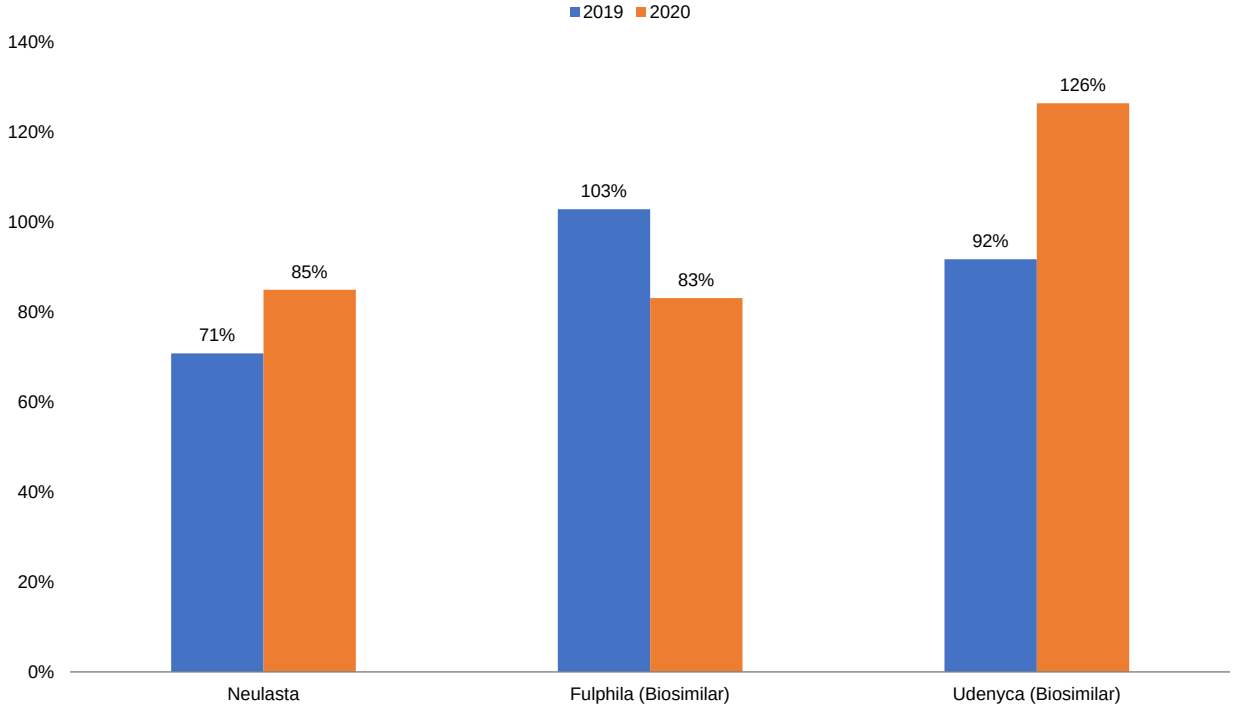
Source: Employee Benefit Research Institute estimates based on administrative enrollment and claims data.

Figure 9
HOPD/PO Markup, Remicade and Biosimilars, 2019–2020



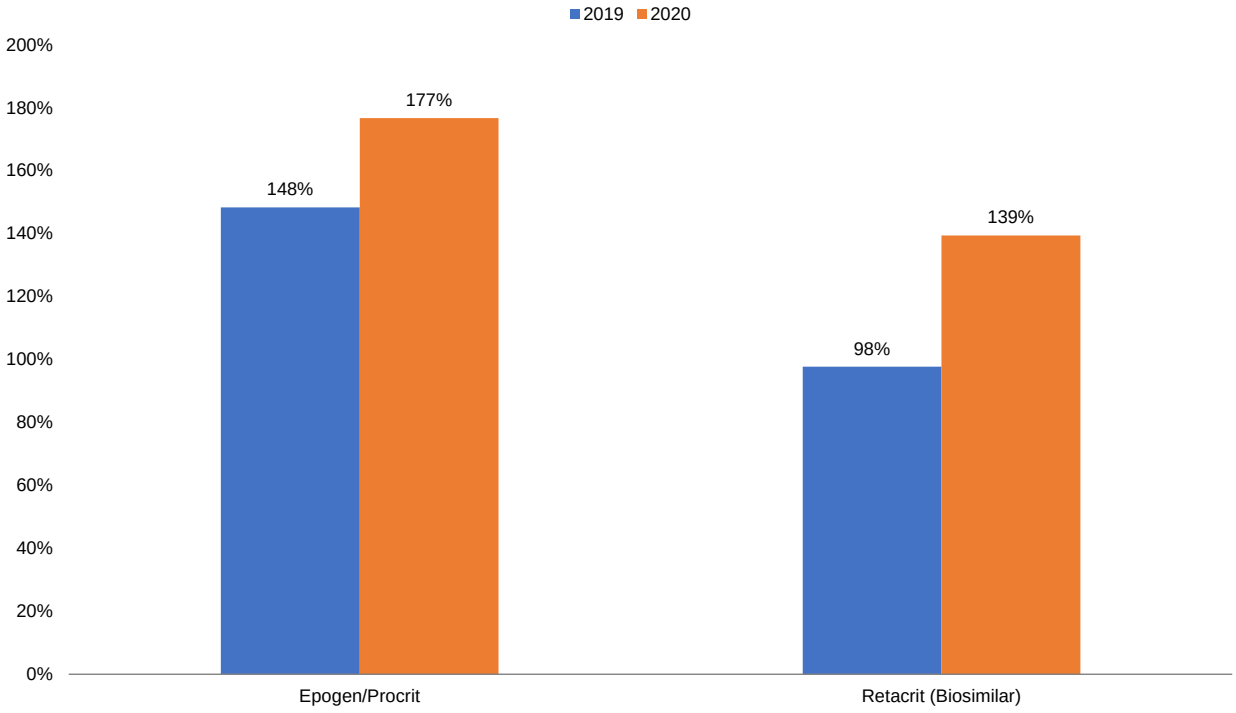
Source: Employee Benefit Research Institute estimates based on administrative enrollment and claims data.

Figure 10
HOPD/PO Markup, Neulasta and Biosimilars, 2019–2020



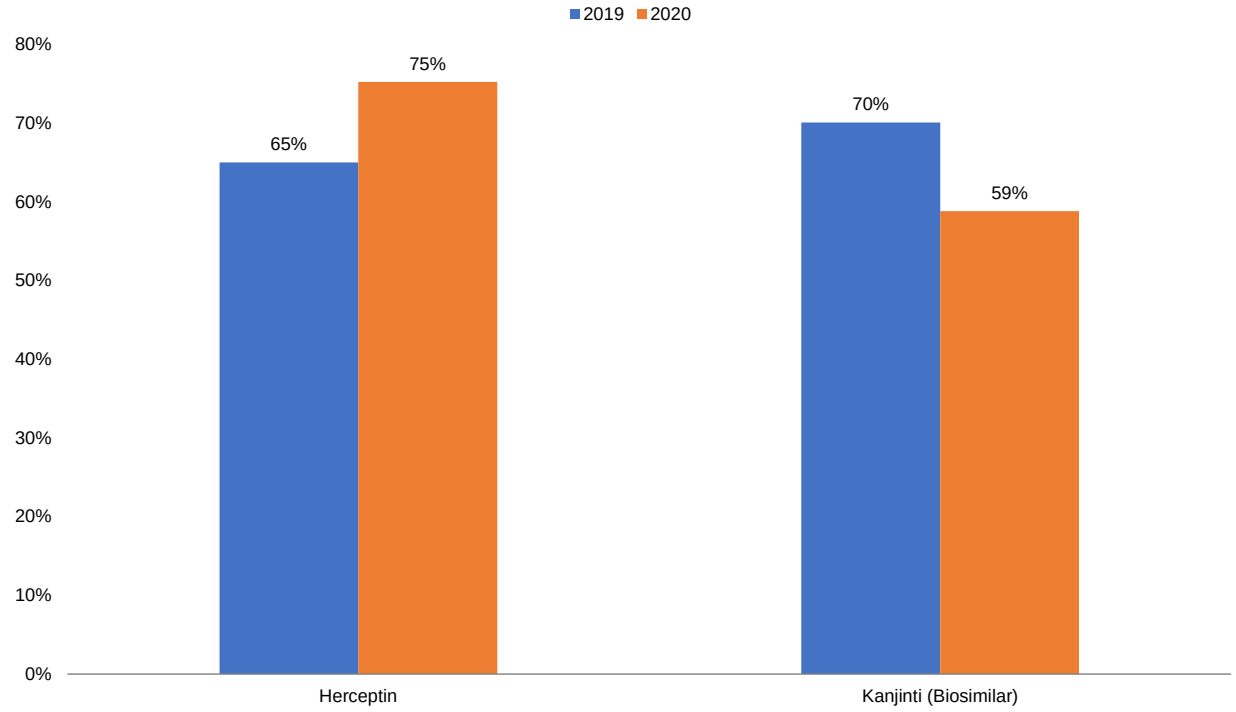
Source: Employee Benefit Research Institute estimates based on administrative enrollment and claims data.

Figure 11
HOPD/PO Markup, Epogen/Procrit and Biosimilars, 2019–2020



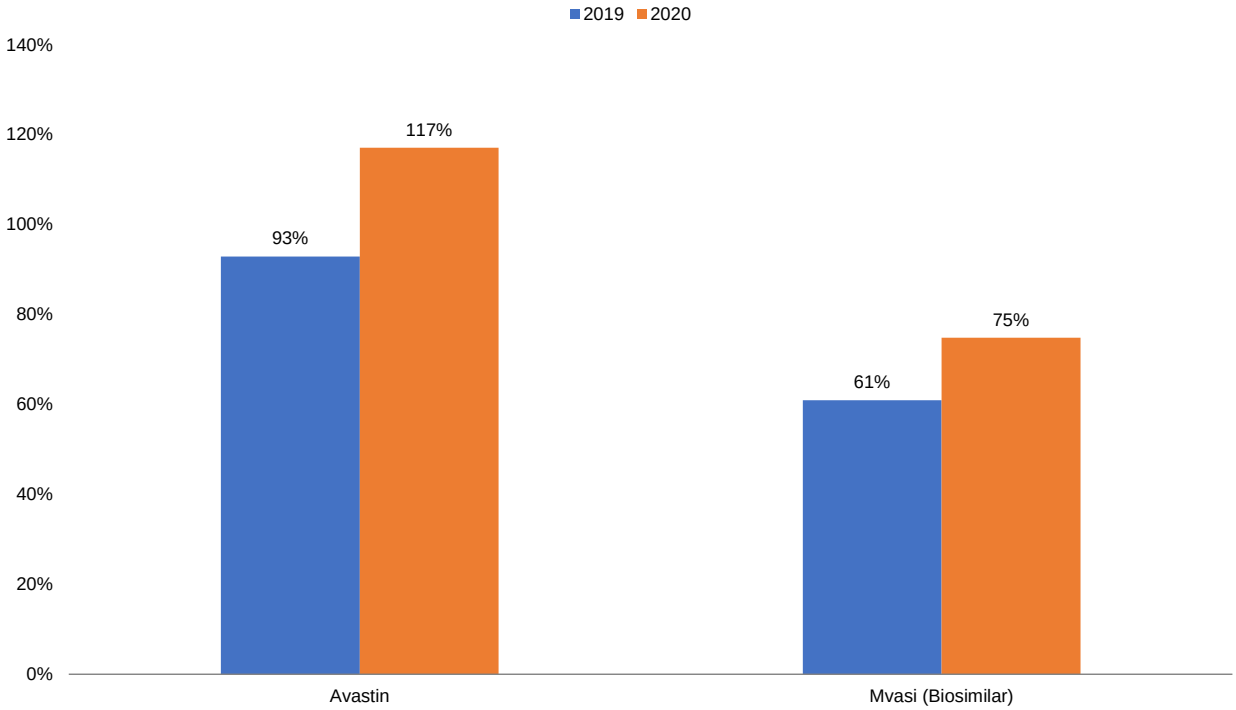
Source: Employee Benefit Research Institute estimates based on administrative enrollment and claims data.

Figure 12
HOPD/PO Markup, Herceptin and Biosimilars, 2019–2020



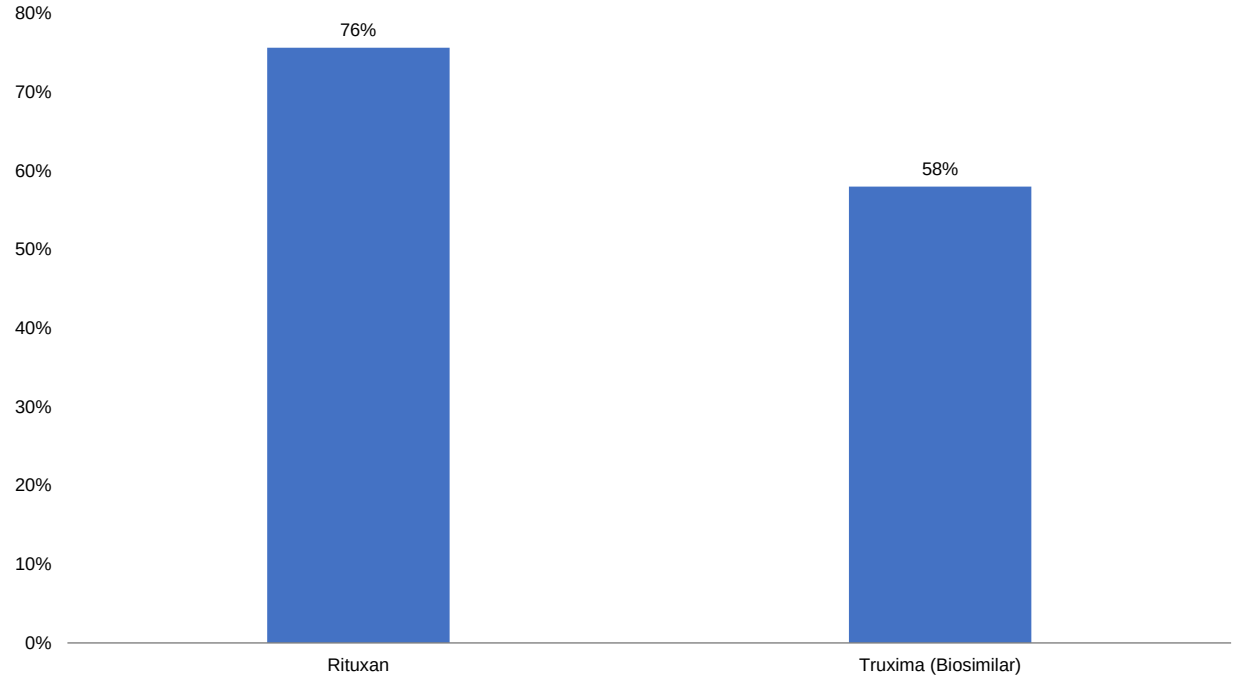
Source: Employee Benefit Research Institute estimates based on administrative enrollment and claims data.

Figure 13
HOPD/PO Markup, Avastin and Biosimilars, 2019–2020



Source: Employee Benefit Research Institute estimates based on administrative enrollment and claims data.

Figure 14
HOPD/PO Markup, Rituxan and Biosimilars, 2020



Source: Employee Benefit Research Institute estimates based on administrative enrollment and claims data.

Conclusions

While HOPDs tend to charge higher prices for all medicines relative to the PO, higher HOPD markups on biologic medicines are roughly doubling costs for employers and minimizing savings that could be achieved through biosimilar competition.

Biosimilars can offer patients a more affordable treatment option than innovator biologics. Though uptake of biosimilars is growing, use of biosimilars among individuals with employment-based health benefits in the United States is varied. Among the seven innovator biologics with available biosimilars examined in this paper, most of the biosimilars were released in the United States in 2019 and 2020, reflecting the status of the implementation of the biosimilars pathway. With the exception of biosimilars for Neupogen, the market share for the innovator biologics was between 65 percent and 87 percent in 2020, and the market share of biosimilars was between 13 percent and 35 percent. The biosimilars for Neupogen accounted for 85 percent of the market in 2020. With a robust flow of biosimilars in development, the biosimilar market is still in its infancy.

The pipeline of biosimilars is quite large, with greater competition expected in the years ahead. As of March 2022, there were more than 100 biosimilars in development. However, due to HOPD markups on biosimilar prices, the savings will not fully be realized. Furthermore, to the degree that HOPDs use innovator biologics in lieu of biosimilars, payer interest in managing medicines covered under the medical benefit will continue to be stifled, and savings potential due to biosimilars may never be fully realized. Future research should continue to examine the uptake of biosimilars relative to innovator biologics, the potential cost savings, and the role of site of treatment.

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Endnotes

[1] See https://www.fda.gov/media/154548/download.

[2] See https://www.fda.gov/news-events/press-announcements/remarks-fda-commissioner-scott-gottlieb-md-prepared-delivery-brookings-institution-release-fdas.

[3] See https://www.amerisourcebergen.com/-/media/assets/amerisourcebergen/biosimilars-page/sgs-biosimilars-usmarketlandscape-020623---copy.pdf.

[4] See https://www.medpac.gov/wp-content/uploads/2022/07/July2022_MedPAC_DataBook_Sec10_v2_SEC.pdf.

[5] See https://www.amgenbiosimilars.com/commitment/2022-Biosimilar-Trends-Report.

[6] See https://www.cms.gov/Research-Statistics-Data-and-Systems/Statistics-Trends-and-Reports/NationalHealthExpendData.

[7] https://www.amgenbiosimilars.com/commitment/-/media/Themes/Amgen/amgenbiosimilars-com/Amgenbiosimilars-com/pdf/USA-CBU-81397-2022-Amgen-Biosimilars-Trend-Report-Oct-2022.pdf

[8] HCPCS is a collection of standardized codes that represent medical procedures, supplies, products, and services. The codes are used to facilitate the processing of health insurance claims by Medicare and other insurers. See https://www.cms.gov/medicare/coding/medhcpcsgeninfo for more information.

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