Biosimilar Use Among 38 ASCO PracticeNET Practices, 2019-2021

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ABSTRACT

PURPOSE Biosimilars offer increased patient choice and potential cost-savings, compared with originator biologics. We studied 3 years of prescribed biologics among US physician practices to determine the relationship of practice type and payment source to oncology biosimilar use.

METHODS We acquired biologic utilization data from 38 practices participating in PracticeNET. We focused on six biologics (bevacizumab, epoetin alfa, filgrastim, pegfilgrastim, rituximab, and trastuzumab) for the period from 2019 to 2021. We complemented our quantitative analysis with a survey of PracticeNET participants (prescribers and practice leaders) to reveal potential motivators and barriers to biosimilar use. We implemented logistic regression to evaluate the biosimilar use for each biologic, with covariates including time, practice type, and payment source, and accounted for clusters of practices.

RESULTS Use of biosimilars increased over the 3-year period, reaching between 51% and 80% of administered doses by the fourth quarter of 2021, depending on the biologic. Biosimilar use varied by practice, with independent physician practices having higher use of biosimilars for epoetin alfa, filgrastim, rituximab, and trastuzumab. Compared with commercial health plans, Medicaid plans had lower biosimilar use for four biologics; traditional Medicare had lower use for five biologics. The average cost per dose decreased between 24% and 41%, dependent on the biologic.

CONCLUSION Biosimilars have, through increased use, lowered the average cost per dose of the studied biologics. Biosimilar use differed by originator biologic, practice type, and payment source. There remains further opportunity for increases in biosimilar use among certain practices and payers.

ACCOMPANYING CONTENT

Appendix

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INTRODUCTION

Biologic therapies have revolutionized many areas of clinical oncology and significantly improved the treatment and supportive care of patients with cancer. Although the benefits of these novel therapies have been clearly demonstrated in controlled clinical trials, the high cost of these agents has imposed a substantial financial burden on patients and their families, as well as society, sometimes limiting drug access or prompting early stopping of known effective treatment.[1]

To increase competition, and potentially reduce the prices of originator biologics, the US Food and Drug Administration (FDA) implemented a regulatory approval process for the development of biosimilars. An approved biosimilar is defined by the FDA as a biological product that is highly similar to and has no clinically meaningful differences from an FDA-approved biologic, called a reference product.[2] The approval process for biosimilars is weighted toward use of preclinical analytic and pharmacologic testing data, reducing the need to repeat large and costly clinical trials already undertaken by the originator's manufacturer.[3] After establishing a high degree of analytic and functional similarity in preclinical studies, comparative clinical studies seek to eliminate any residual uncertainty between the biosimilar and originator biologic through pharmacokinetic and pharmacodynamic studies and the assessment of immunogenicity, as well as efficacy and safety compared with the originator product.

In 2018, ASCO established a Working Group to assess the potential role and value of biosimilars in oncology. The ASCO Working Group published a statement highlighting both the challenges and educational needs for implementing biosimilars in oncology practice.[4] While acknowledging the limited data on the impact on drug prices, the statement

CONTEXT

Key Objective

What is the relationship of time, practice type, and payment source to oncology biosimilar use in the United States from 2019 to 2021?

Knowledge Generated

Our analysis of six oncology biosimilars identified an overall increase in biosimilar use across all practices between 2019 and 2021, with independent physician practices having higher use of biosimilars compared with hospital-based health systems for epoetin alfa, filgrastim, rituximab, and trastuzumab. Compared with commercial health plans, Medicaid plans had lower biosimilar use for four biologics; traditional Medicare had lower use for five biologics.

Relevance

The findings from this study support ASCO's acknowledgment that the use of biosimilars might provide competitive, lower-cost alternatives to biologics used in cancer care; however, frequent changes in price, reimbursement, and payer policies may prevent practices from maximizing biosimilar use and place practices at financial risk of purchasing a biosimilar that may later not be adequately reimbursed.

concluded that biosimilars of important cancer treatment and supportive care biologics will play an increasingly important role in the future care of patients with cancer, potentially improving access to effective therapies.

At the present time, there are 39 FDA-approved biosimilars in the United States, of which 22 have direct application in oncology, including 12 targeted anticancer therapies and 10 supportive care agents.[5] An additional biologic, tbo-filgrastim, was approved through a traditional biologics license application before the FDA biosimilar approval pathway,[6] but is often treated as a biosimilar in medical policy[7,8]—we have classified tbo-filgrastim as a biosimilar within our analysis.

Biosimilars have a promise of increasing treatment options and reducing the cost of biologic therapy. However, over half of current biosimilars have only been approved since January 2019,[5] and many have experienced delays before clinical availability.[9] It is likely that multiple competitors in a class will need to be clinically available for a significant period of time to realize a meaningful impact on drug pricing. Likewise, increased use of biosimilars will require acceptance by clinicians and patients. Biosimilars have been introduced into guidelines from ASCO and other professional organizations as equally safe and effective agents for the treatment and supportive care of patients with cancer.[10]

To assess the acceptance and utilization of biosimilars, researchers have used real-world data to measure biosimilar use among patients with cancer. Karaca-Mandic et al[11] identified payment source (eg, Medicare Advantage) as a variable affecting differing rates of biosimilar use, while Socal et al[12] noted differences between hospital outpatient departments and physician practices. Both studies were limited, however, to biosimilar use of a single biologic, filgrastim. To determine the relationship between these two variables (payment source and practice type), and whether they have affected biosimilar use within other biologics, we analyzed data from a 3-year study among US physician practices.

METHODS

Study Population

Utilization data for six originator biologics (bevacizumab, epoetin alfa, filgrastim, pegfilgrastim, rituximab, and trastuzumab) and their associated biosimilars (Table 1)—these products were selected because of their use within the cancer population and availability of biosimilars during the study period—were obtained from 38 practices participating in ASCO's PraticeNET program. PracticeNET is a voluntary program that offers practices benchmark and trend reports on administrative, operational, and financial activities.[13] PracticeNET's primary data source is practice-submitted billing data, exported monthly from practices' billing software. Data exports include practice location; provider, patient, and charge identifiers; Healthcare Common Procedure Coding System (HCPCS) and diagnosis codes; primary source of payment; and associated units, charges, and revenue. Practices varied in size, geography, and type of setting (independent physician practice *v* hospital-based health system). Acquired data totaled 635,223 doses given from January 1, 2019, to December 31, 2021.

Classification of Data

Biologic products were identified by their associated HCPCS codes and were classified as either originator or biosimilar. In cases where originator biologics were produced in alternate forms (eg, trastuzumab and hyaluronidase) by the

TABLE 1. Study Included Originator Biologics, Biosimilars, and HCPCS Codes

Biologic	Precise Ingredient	Type	HCPCS Codes	FDA Approval[18]
Bevacizumab	Bevacizumab	Originator	J9035	February 2004
	Bevacizumab-awwb	Biosimilar	Q5107	September 2017
	Bevacizumab-bvzr	Biosimilar	Q5118	June 2019
Epoetin alfa	Epoetin alfa	Originator	J0885	June 1989
	Epoetin alfa-epbx	Biosimilar	Q5105, Q5106	May 2018
Filgrastim	Filgrastim	Originator	J1442	February 1991
	Filgrastim-aafi	Biosimilar	Q5110	July 2018
	Filgrastim-sndz	Biosimilar	Q5101	March 2015
	Tbo-filgrastim	Biosimilar	J1447	August 2012
Pegfilgrastim	Pegfilgrastim	Originator	J2505, J2506	January 2002
	Pegfilgrastim-apgf	Biosimilar	Q5122	June 2020
	Pegfilgrastim-bmez	Biosimilar	Q5120	November 2019
	Pegfilgrastim-cbqv	Biosimilar	Q5111	November 2018
	Pegfilgrastim-jmdb	Biosimilar	Q5108	June 2018
Rituximab	Rituximab	Originator	J9310, J9312	November 1997
	Rituximab and hyaluronidase	Originator	C9467, J9311	June 2017
	Rituximab-abbs	Biosimilar	Q5115	November 2018
	Rituximab-arrx	Biosimilar	Q5123	December 2020
	Rituximab-pvvr	Biosimilar	Q5119	July 2019
Trastuzumab	Trastuzumab	Originator	J9355	September 1998
	Trastuzumab and hyaluronidase	Originator	J9356	February 2019
	Trastuzumab-anns	Biosimilar	Q5117	June 2019
	Trastuzumab-dkst	Biosimilar	Q5114	December 2017
	Trastuzumab-dttb	Biosimilar	Q5112	January 2019
	Trastuzumab-pkrb	Biosimilar	Q5113	December 2018
	Trastuzumab-qyyp	Biosimilar	Q5116	March 2019

Abbreviations: HCPCS, Healthcare Common Procedure Coding System; US FDA, US Food and Drug Administration.

same manufacturer, we included the alternate form as an originator.

Practices were classified as either physician (ie, independent physician practice) or hospital, representing hospital-based health systems and their associated cancer centers. Physician practices primarily deliver biologic therapies in a physician office setting, whereas hospital practices primarily deliver biologic therapies in an outpatient hospital setting. Finally, we classified each charge's primary source of payment as either Medicare (Part B), Medicare Advantage (Part C), Medicaid, commercial, other, or unknown.

Assignment of Average Sales Price

The Centers for Medicare & Medicaid Services (CMS) publishes quarterly data on Medicare payment limits (MPL) of administered drugs and biologics, equal to 1.06% of the average sales prices of each product.[14] We took these MPLs and applied them to doses administered, matched on the associated HCPCS code and quarter of service. Weighted averages were then calculated for each biologic and trended over time.

Statistical Analysis

For our analyses, the unit of analysis was a dose of drug received by a patient at a single treatment visit, and the primary outcome was an indicator of whether the drug received was a biosimilar versus originator product. We implemented multivariable logistic regression models to examine the association between biosimilar use and the baseline characteristics and accounted for the cluster effects within practices. We included variables in the multivariable models on the basis of their significance in the final multivariable models if $P \leq .05$. Exploratory data analysis assisted in recognizing that trends in use were relatively linear (allowing for time to be included in models as continuous). Interactions between biologic type and practice type and that between payer classes were significant ($P < .01$ for both interactions), indicating that the associations were different across the six biologics, requiring separate models for each biologic. We thus fit models for each of the six biologics; covariates included time (continuous, measured from quarter 1 of 2019 to quarter 4 of 2021), practice type, payer class, and targeted diagnosis (ie, the clinical indication for which the biologic was prescribed). We expressed results as

adjusted odds ratios (ORs) and 95% CI. A two-sided significance level of 0.05 was used to declare statistical significance. Multiple comparisons were adjusted by Bonferroni correction of the *P* value. Analysis was done in SAS, version 9.4 (SAS Institute), and RStudio.

Survey of PracticeNET Practices

In addition to our quantitative analysis, we surveyed leaders (physicians and administrators) of our PracticeNET participants to learn what circumstances encourage or discourage use of biosimilars. A study-specific survey was developed to include seven multiple choice and four open-ended questions. Survey questions and multiple-choice answers were informed by the authors' own experiences with biosimilars and conversations within ASCO committees and workgroups. A total of 50 PracticeNET participating practices were surveyed. Answers to the survey helped us to interpret our findings and the influence of the practice and payer in a prescribers' selection of a biosimilar or originator biologic.

RESULTS

Trends and Variance in Biosimilar Use

Biosimilar use increased over time for all six biologics studied (Fig 1). In comparing the first quarter of 2019 to the fourth quarter of 2021, mean biosimilar use increased for bevacizumab from 0% to 79.4% (95% CI, 71.1 to 87.7), epoetin alfa from 8.0% (1.1 to 14.9) to 70.6% (59.2 to 81.9), filgrastim from 67.4% (53.3 to 81.6) to 80.0% (68.3 to 91.7), pegfilgrastim from 14.3% (7.4 to 21.3) to 51.2% (39.6 to 62.8), rituximab from 0% to 69.9% (61.0 to 78.7%), and trastuzumab from 0% to 75.4% (66.8 to 84.1%).

Biosimilar use varied across the 38 studied practices. For doses administered in 2021, IQRs in biosimilar use among studied practices were calculated for each biologic (Appendix Fig A1, online only), including bevacizumab (IQR, 71.5%-94.3%), epoetin alfa (IQR, 47.8%-99.5%), filgrastim (IQR, 79.9%-100%), pegfilgrastim (IQR, 20.0%-80.2%), rituximab (IQR, 52.2%-85.0%), and trastuzumab (IQR, 60.8%-93.2%).

Key Factors in Biosimilar Use

Compared with hospital practices, physician practices were associated with a higher likelihood of biosimilar use in four of the studied biologics (Table 2)—epoetin alfa (OR, 1.37; 95% CI, 1.33 to 1.41), filgrastim (OR, 1.83; 95% CI, 1.76 to 1.9), rituximab (OR, 1.15; 95% CI, 1.11 to 1.2), and trastuzumab (OR, 1.40; 95% CI, 1.36 to 1.45)—and lower likelihood of biosimilar use for bevacizumab (OR, 0.86; 95% CI, 0.83 to 0.89) and pegfilgrastim (OR, 0.60; 95% CI, 0.58 to 0.61).

When compared with commercial plans, Medicaid plans were associated with a lower likelihood of biosimilar use, except for epoetin alfa (OR, 1.32; 95% CI, 1.19 to 1.45) and pegfilgrastim (OR, 1.59; 95% CI, 1.53 to 1.66). Traditional Medicare (Part B) was associated with lower likelihood of biosimilar use in five of the studied biologics; only pegfilgrastim with Medicare was associated with a higher likelihood of biosimilar use (OR, 1.04; 95% CI, 1.01 to 1.07), although this was modest difference. Medicare Advantage plans, which commonly use step therapy policies to enforce

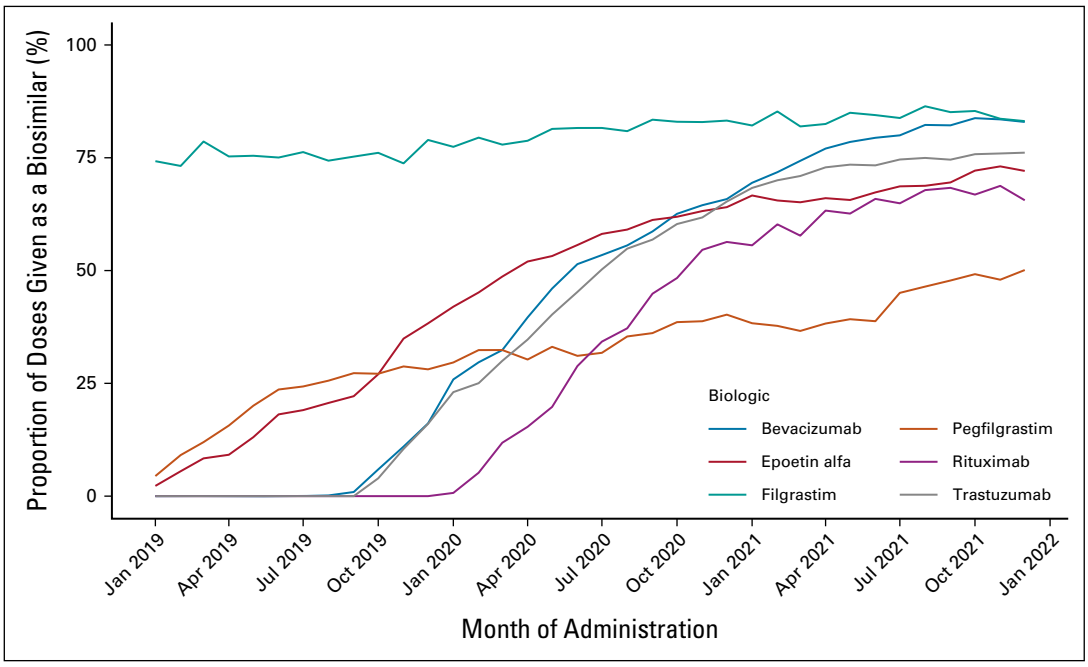

FIG 1. Biosimilar use from 2019 to 2021 per biologic in 38 practices.

TABLE 2. Multivariable Logistic Regression Model of Use of Biosimilars

	Bevacizumab		Epoetin Alfa		Filgrastim	
Variable	OR	95% CI	OR	95% CI	OR	95% CI
Time (year and quarter, continuous)	1.70	1.69 to 1.71	1.33	1.32 to 1.33	1.07	1.07 to 1.08
Practice type: hospital	1		1		1	
Physician	0.86	0.83 to 0.89	1.37	1.33 to 1.41	1.83	1.76 to 1.90
Payer class: commercial	1		1		1	
Medicaid	0.57	0.54 to 0.61	1.32	1.19 to 1.45	0.61	0.57 to 0.66
Medicare	0.73	0.71 to 0.76	0.40	0.39 to 0.42	0.38	0.36 to 0.40
Medicare Advantage	1.18	1.13 to 1.24	0.87	0.83 to 0.92	0.34	0.33 to 0.36

	Pegfilgrastim		Rituximab		Trastuzumab	
Variable	OR	95% CI	OR	95% CI	OR	95% CI
Time (year and quarter, continuous)	1.15	1.15 to 1.16	1.73	1.72 to 1.75	1.66	1.65 to 1.67
Practice type: hospital	1		1		1	
Physician	0.60	0.58 to 0.61	1.15	1.11 to 1.20	1.40	1.36 to 1.45
Payer class: commercial	1		1		1	
Medicaid	1.59	1.53 to 1.66	0.87	0.79 to 0.96	0.58	0.54 to 0.62
Medicare	1.04	1.01 to 1.07	0.92	0.88 to 0.96	0.85	0.81 to 0.88
Medicare Advantage	1.10	1.06 to 1.14	0.72	0.68 to 0.76	1.14	1.08 to 1.20

NOTE. Positive OR indicated increasing trend of biosimilar use over time.
Abbreviation: OR, odds ratio.

preferred brands, had a higher likelihood of biosimilar usage for bevacizumab (OR, 1.18; 95% CI, 1.13 to 1.24), pegfilgrastim (OR, 1.10; 95% CI, 1.06 to 1.14), and trastuzumab (OR, 1.14; 95% CI, 1.08 to 1.2), when compared with commercial plans. Epoetin alfa (OR, 0.87; 95% CI, 0.83 to 0.92) and rituximab (OR, 0.72; 95% CI, 0.68 to 0.76) showed lower likelihood of biosimilar use for Medicare Advantage plans, while filgrastim (OR, 0.34; 95% CI, 0.33 to 0.36) demonstrated a dramatically lower likelihood of biosimilar use for Medicare Advantage plans.

Pricing Trends

All six studied biologics decreased in their MPL over the past 3 years. Between January 2019 and December 2021, the average MPL per dose of all administered originator and biosimilar products decreased for bevacizumab from $4,568.86 US dollars (USD) to $2,918.26 USD (−36%), epoetin alfa from $424.12 USD to $323.93 USD (−24%), filgrastim from $308.23 USD to $183.08 USD (−41%), pegfilgrastim from $4,684.08 USD to $2,952.07 USD (−37%), rituximab from $5,572.37 USD to $3,809.66 USD (−32%), and trastuzumab from $4,702.67 USD to $2,851.45 USD (−39%). These decreases in price were driven by the introduction of lower-cost biosimilars, as well as decreasing trends in prices of originator and available biosimilars. In most cases, a biosimilar remained the least costly alternative throughout the 3 years; exceptions include epoetin alfa and pegfilgrastim, where the originator biologic competed more aggressively on price.

Survey Results

From our survey of 50 PracticeNET practices, a total of 17 (34%) complete responses were received. Fourteen respondents reported roles in determining their organizations use of biosimilars, including establishing organizational policies (10), selection of biosimilars for inclusion in formularies (eight), negotiation or approval of drug/biologic purchasing agreements (six), review of treatment plans for inclusion of biosimilars (six), and negotiation or approval of payer participation and reimbursement agreements (five). Three respondents were prescribers who did not report another role as listed above. Two of the 17 respondents were from academic-affiliated health systems, six from other health systems, and nine from independent physician practices; this distribution is representative of all PracticeNET practices.

Respondents to our survey of PracticeNET practices reported familiarity with biosimilar availability (94%) and safety (88%), but less so the requirements for biosimilar approval (59%) and safety monitoring (35%) processes for biosimilars used by the FDA. Respondents reported that their organizations supported use of biosimilars through pharmacy-driven substitution of ordered biologics in new treatment plans (82%), purchasing agreements favoring biosimilar utilization (41%), and payer agreements incentivizing biosimilar utilization (29%); no organizations reported discouraging use of biosimilars. Payer policies factored heavily in the decision to use biosimilars (71%). Part B Step Therapy, a federal policy allowing Medicare Advantage plans to require use of their preferred drug or biologic before approving use of a competing product,[15] was reported as a barrier to prescribing an organization's own preferred biosimilar (86%). Ninety-three percent of respondents reported that their organization had to stock multiple alternatives of the same biologic to comply with conflicting payer policies.

DISCUSSION

Use of ASCO PracticeNET data, complemented with survey responses from participating practices, has given insights into the use and impact of biosimilars for anticancer and supportive care therapies. The use of PracticeNET data for this study allowed us to examine biosimilar use across time and among different provider organizations, biologics, and payment sources. The increasing comfort level among prescribers with use of targeted therapy and supportive care

biosimilars, along with organizational policies encouraging use of biosimilars, was evident in the growth of biosimilar use over the 3-year period.

Overall, biosimilar usage has grown significantly over the past 3 years in each of the six studied biologics. We can expect this trend to continue. Biosimilar use to influence drug costs will be an integral contributor in future value-based payment arrangements, including CMS's next generation of innovation with the Enhancing Oncology Model.[16] Controlling the dynamics of biosimilar drug use will be of paramount importance to be successful in arrangements that have financial risks to practices.

Our analysis of biosimilar use by product and practice type confirmed the results of Socal et al,[12] which also found higher uptake of biosimilar filgrastim among physician practices. Similarly, we found higher uptake among physician practices for biosimilar epoetin alfa, rituximab, and trastuzumab. It is noteworthy, however, that hospital-based practices had higher biosimilar uptake for both bevacizumab and pegfilgrastim. The reason for this conflicting finding between the studied biologics was not answered in our analysis. Therefore, another factor not yet studied may influence biosimilar use.

Comparative biosimilar use among payer classes was also different per biologic. In general, traditional Medicare lagged behind Commercial plans in biosimilar use for five biologics; in the case of pegfilgrastim, traditional Medicare had slightly higher use. The differences per biologic could be due to plans prioritizing specific biologics for negotiated rebates and creation of step therapy policies.

Step therapy policies and payers' desire for limited formularies, whether for the originator product or a specific biosimilar, could become a barrier to practices to maximize the benefits from their own well-defined formularies. Pharmacies of nearly all surveyed practices had to stock multiple alternatives of the same biologic. This could adversely affect the effectiveness of a practice's biologic purchasing contracts.

The emergence of biosimilars has coincided with a decrease in the price per administered dose, accomplishing the FDA's goal of increased choice and reduced patient costs. However, frequent changes in price, reimbursement, and payer policies may prevent practices from maximizing biosimilar use and place practices at financial risk of purchasing a biosimilar that may later not be adequately reimbursed. Understanding the dynamics of the total cost of care, drug choices, and their impact on patient outcomes and quality of life needs to be better understood. Under the current drug purchasing programs involving biosimilars, there is a crude relationship between the price of drugs and the ultimate out-of-pocket costs that can fall upon the patients. Policymakers will need to continue to explore policies and advocacy to remedy these concerns.

From the patient's perspective, the communication between the patient and provider on biosimilar efficacy and safety compared with the originator product, the substitution of products on the basis of payer influences, and the patient's understanding of these factors are still not well known. As patients with cancer pursue treatment, improving access to biosimilar drug information and education as well as transparency regarding treatment regimens will be essential to maintain the trust within a patient-physician relationship.

The findings from this study support ASCO's acknowledgment that the use of biosimilars might provide competitive, lower-cost alternatives to biologics used in cancer care.[17] Strengths of the study include use of contemporary data from 38 practices participating in ASCO's PracticeNET program. This sample allowed us to estimate the biosimilar use and make comparisons between practice types and payer classes with precision.

Our analysis has several limitations. Our comparisons reveal biosimilar usage only within this early adoption period and may not reflect differences in biosimilar usage moving forward. Only filgrastim had significant biosimilar usage before 2019 and likely reveals the most confident results in comparing practice type and payer class; subsequent results for other biologics may differ as biosimilar usage starts to plateau. We were also limited to data from 38 practices participating in PracticeNET, which may not be generalizable to the entire US oncology market. The limited number of practices prevented further subdivision into geographic regions, practice size, or other factors that may have influenced biosimilar use. Our findings also apply only to the United States and may differ in other countries with their own unique methods of organizing health care and payment. Finally, our survey and statistical analyses were limited to the effects of organizational policies and payer policies on the use of biosimilars. It is possible that there are other factors influencing biosimilar use that may be uncovered through larger survey and real-world data studies.

In the effort to accelerate safe and widespread adoption of biosimilars, we recommend continuing research efforts to use real-world, postmarket evidence to demonstrate the safety, effectiveness, and value of each unique biosimilar product. Use of a wide variety of data sources could help provide a comprehensive view of the extent and diversity of biosimilar use. It would also be beneficial to study biosimilar among individual patients to determine whether patients have been switched from one product to another over the duration of their treatment.

On the basis of our findings, we encourage researchers to adopt a change in measurement for further studies on biosimilar use. A simplified measure of biosimilar use, which we ourselves have used, is not always synonymous with value-based care. In the case of epoetin alfa and

pegfilgrastim, the originator brand has been the least costly alternative in at least one quarter in the past 3 years. Measurement and trending of the average cost per dose of each biologic would be a more meaningful measure of plan policies and physician prescribing patterns, with the goal of lowering the cost of biologic therapy for patients, while maintaining prices necessary for continued production and innovation of biologic products.

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AUTHORS' DISCLOSURES OF POTENTIAL CONFLICTS OF INTEREST

Biosimilar Use Among 38 ASCO PracticeNET Practices, 2019-2021

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APPENDIX

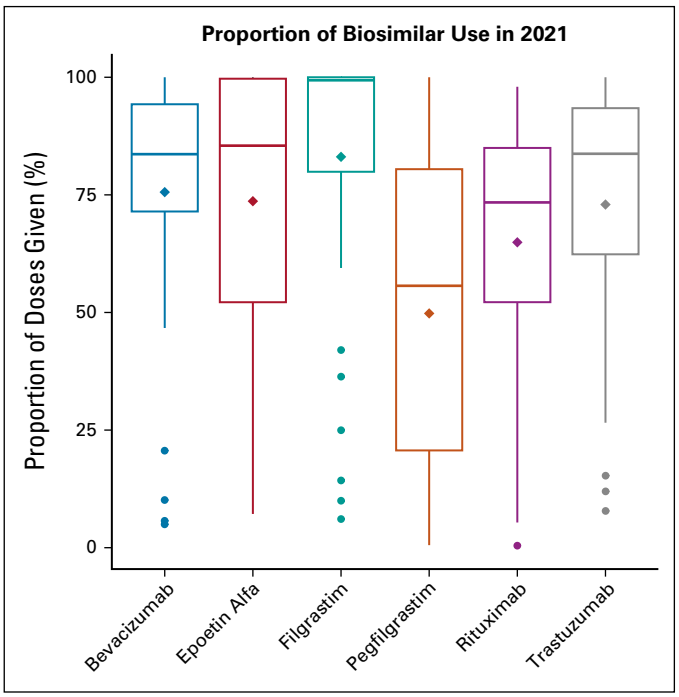

FIG A1. Boxplots of proportion of biosimilar use for each biologic in 2021. Data were aggregated across 38 practices from PracticeNET. Within each box, horizontal lines denote median values; diamonds denote mean values; boxes extend from the 25th to the 75th percentile of each biologic's distribution of values.