WHITE PAPER

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Boost or Bust?

Evaluating the Impact of the IRA's Enhanced Reimbursement on Uptake of Biosimilars

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BACKGROUND

In his history-making announcement to exit the 2024 presidential race, President Biden referenced the Inflation Reduction Act (IRA) as one of his administration's key victories. Certainly, this major healthcare legislation will form a significant part of his legacy. On the eve of its second anniversary, Certara examines the evidence of the legislation's impact on uptake of biosimilars.

One of the IRA's key objectives is expanding benefits and lowering costs for Medicare beneficiaries. In October 2022, the first Medicare provision went into effect—a temporary, five-year, boost in Medicare Part B reimbursement for biosimilar drugs (also known as follow-on biologics or subsequent entry biologics). The reimbursement enhancement is meant to overcome financial disincentives to biosimilar adoption. The IRA encourages uptake by reimbursing 108% of the originator product's Average Selling Price (ASP). This represents an increase over the standard reimbursement (106% of the product's ASP).

A couple of nuances:

- Only biosimilars whose ASP is less than the reference drug ASP qualify for enhanced reimbursement. In markets with aggressive discounting, a biosimilar may lose eligibility one quarter and regain it the next
- The 5-year term begins when ASP is established. As such, subsequent entry biologics launching in 2027 qualify for enhanced reimbursement until 2032

To assess the impact of this provision thus far, Certara surveyed 79 facilities administering intravenous (IV) oncology therapies to quantify respondents':

- Awareness of the policy
- Perception of its impact on biosimilar utilization at their institution

The survey asked specifically about 17 oncology and supportive care biosimilars and five reference products. The categories were selected based on eligibility for enhanced reimbursement under the IRA. We also researched ASP, market share, and IRA reimbursement eligibility for the products over 14 quarters to contextualize the findings.[1]

SURVEY METHODOLOGY AND SAMPLE

Oncology Account Administrators

Online survey with oncology account staff

Staff responsible for reimbursement tasks at oncology accounts (n=79)

January-February 2024

- Mix of hospitals and community infusion sites
- Have reimbursement responsibilities (benefits investigations, billing/coding, PAs, manufacturer support program enrollment etc.)
- Not a physician
- Proportionate mix of geographic areas

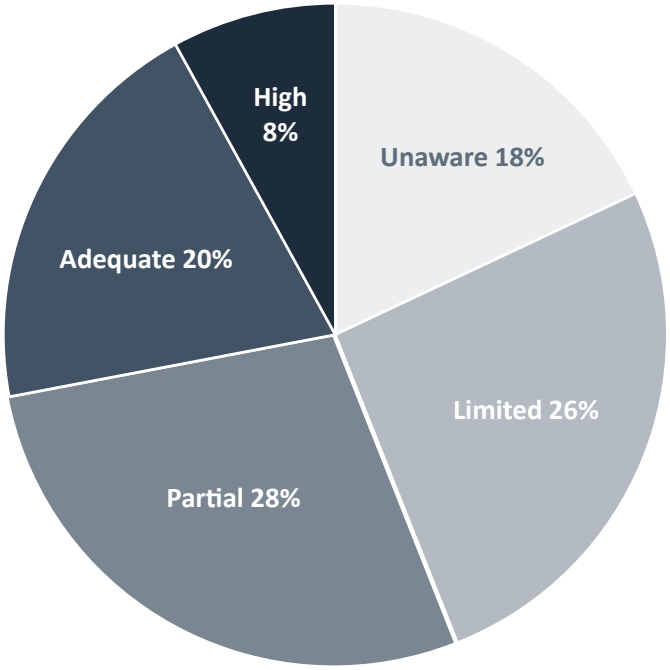
The survey asked specifically about 17 oncology and supportive care biosimilars for five reference products:

Product	Name	Reference Drug	US Launch Date	Manufacturer
MVASI	bevacizumab-awwb	Avastin	Jul 2019	Genetech
ALYMSYS	bevacizumab-maly	Avastin	Jul 2019	Amneal
ZIRABEV	bevacizumab-bvzr	Avastin	Jan 2020	Pfizer
VEGZELMA	bevacizumab-adcd	Avastin	Feb 2020	Celltrion
AVZIVI	bevacizumab-tnjn	Avastin	Mar 2020	Bio-Thera
KANJINTI	transtuzumab-anns	Herceptin	Jul 2019	Amgen
OGIVRI	trastuzumab-dkst	Herceptin	Nov 2019	Mylan
TRAZIMERA	transtuzumab-qyyp	Herceptin	Feb 2020	Pfizer
HERZUMA	transtuzumab-pkrb	Herceptin	Mar 2020	Teva
ONTRUZANT	transtuzumab-dttb	Herceptin	Apr 2020	Merck
ZARXIO	filgrastim-sndz	Neupogen	Sep 2015	Sandoz
NIVESTYM	filgrastim-aafi	Neupogen	Oct 2018	Pfizer
RELEUKO	filgrastim-ayow	Neupogen	Nov 2022	Amneal
RETACRIT	epoetin alfa-epbx	Epogen/Procrit	Nov 2018	Pfizer
TRUXIMA	rituximab-abbs	Rituxan	Nov 2019	Teva
RUXIENCE	rituximab-pvvr	Rituxan	Jan 2020	Pfizer
RIABNI	rituximab-arrx	Rituxan	Jan 2021	Amgen

RESEARCH FINDINGS

Stakeholders are relatively well informed of the IRA's enhanced biosimilar reimbursement

Respondent Awareness of IRA Biosimilar Add-On Payments (n=61)



Respondents in the survey rated their awareness level of the IRA's biosimilar add-on payments as well as the awareness level of their facility's leadership. Results demonstrate a moderate level of awareness; less than 20% of staff are completely unaware of the reimbursement provision. Respondents believe that facility leadership is even more informed. Ninety-five percent (95%) of respondents indicated their administration is at least partially aware of the provision.

Awareness and facility size are correlated. Respondents from larger facilities (based on the volume of oncology infusions administered) tend to rate themselves and their facility's leadership as more informed than those from smaller facilities.

ONCOLOGY BIOSIMILARS ARE WIDELY USED AND ACCEPTED

Our survey examined biosimilars of five oncology and supportive care reference products: Herceptin, Rituxan, Neupogen, Procrit/Epogen, and Avastin. Of the 17 biosimilars included in the survey, the overall average number used per facility is 6.0. Nearly all facilities in the sample (91%) use at least one of the biosimilars.

Utilization was similar across biosimilar categories. About two-thirds of respondent facilities utilize subsequent entry biologics for Rituxan, Neupogen, Procrit, and Avastin. Herceptin biosimilar use is slightly higher, with 79% of respondents using at least one trastuzumab biosimilar. The higher utilization may reflect the market's maturity with the first Herceptin biosimilar (Ogivri) receiving FDA approval in 2017.

WHO DOESN'T USE BIOSIMILARS?

In our sample, seven respondents indicated that they didn't use any of the biosimilars in the survey. These respondents cited provider choice, followed by reimbursement challenges, as the top reasons for this choice.

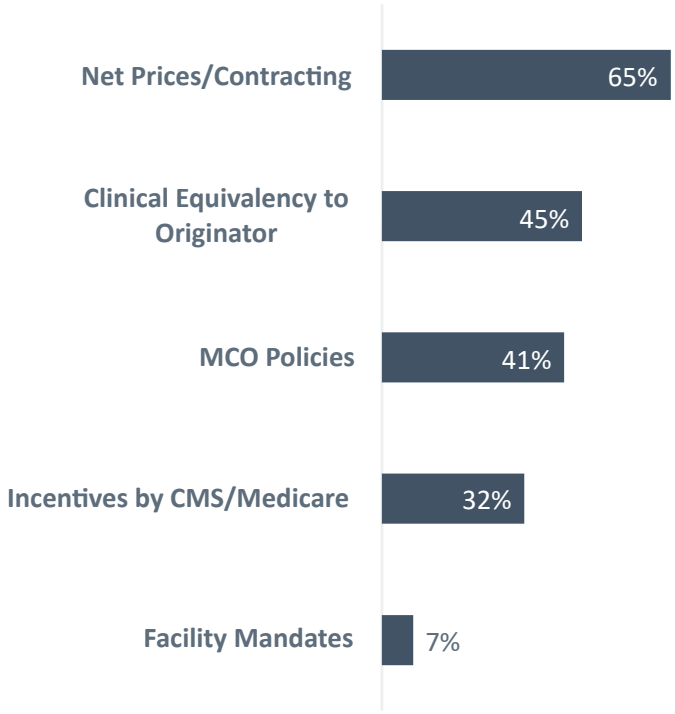
Commercial insurance is the most common payer type among no-biosimilar facilities. This may reflect the higher relevance of biosimilars for Medicare patients. These patients are more likely to have a copay or coinsurance for infused drugs and tend to be more cost-sensitive.

Additionally, facilities using no biosimilars tended to be smaller, non-academic, and located in the American South. However, our survey sample is likely too small to draw definite conclusions.

PRICE AND PAYER CONSIDERATIONS DRIVE BIOSIMILAR USE

Rationale For Use of Biosimilars; Top 2 Reasons

(Share of Respondents; n=72)



Biosimilar products' attractive net prices are the most cited rationale for their use. The second most common response was "Biosimilars seen as clinically equivalent to reference products." This response reveals a clear logic; biosimilars work as well as originator products and cost less.

Reimbursement policies from managed care organizations (MCOs) are the third most-cited rationale. Payer policies refer both to medical policies preferencing one or more biosimilars as well as reimbursement enhancements offered by some plans to encourage biosimilar use like the IRA initiative.

Interestingly, more than 30% of the panel cite reimbursement incentives offered by the Centers for Medicare and Medicaid Services (CMS) driving the use of follow-on biologics. This finding indicates that facilities are aware of the IRA's financial advantages when utilizing biosimilars for Medicare patients and may take them into consideration when making treatment decisions.

Facility Characteristics Associated with Biosimilar Utilization

(Share of Respondents; n=72)

Use MORE Biosimilars		Use FEWER Biosimilars	
8.4 Large Facilities*		**4.9** Small Facilities	
6.6 Majority Medicare Practices		**4.7** Mixed Payer Type Practices	
7.0 Buy-and-Bill Institutions		**3.4** White Bag Institutions	
10.3 Practices Owned by Private Equity		**5.9** Non-Private Equity Practices	
6.5 Traditional Facilities (not IDNs)		**4.6** Integrated Delivery Networks	

6.0 Average # of Biosimilars Used; All Facilities

> **Biosimilars have become cheaper than the brand medication and insurance companies are reimbursing more, so the hospital system is using more biosimilar products**
>
> *- Pharmacist, Academic Medical Center*

> **Reimbursement is typically more accessible; clinical trials have shown similar efficacy compared to active forms**
>
> *- Patient Services Coordinator, Community Center*

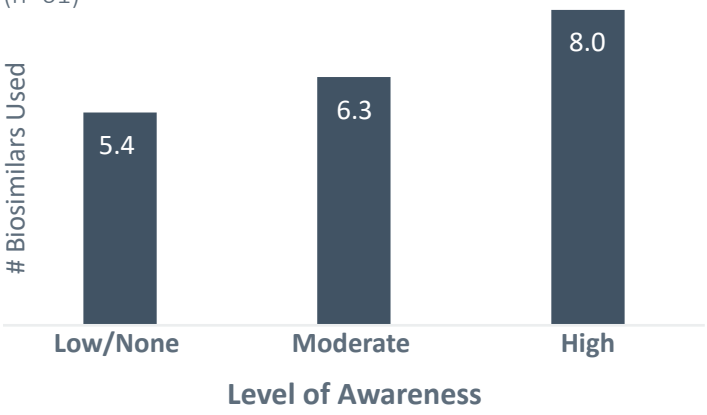
> **We are strongly in favor of using biosimilars, and they are mandatory in some cases. We try to select one partner to be single source, then work on the best net price**
>
> *- Pharmacist, DSH Hospital*

> **Our providers typically use whatever is mandated by insurance. [State Medicaid] also drives our biosimilar use**
>
> *- Pharmacist, Academic Hospital*

MORE FAMILIARITY OF IRA BIOSIMILAR ADD-ON PAYMENTS = MORE DISTINCT BIOSIMILAR PRODUCTS USED

Leadership Awareness of IRA Add-On Payment and Number of Biosimilars Used in Facility

(n=61)



One finding providing evidence of the IRA's success in bolstering biosimilar uptake is the relationship between knowledge of the reimbursement enhancement and biosimilar utilization. Facility awareness of the IRA biosimilar add-on payment and their utilization was positively correlated.

Respondents from facilities where leadership is seen as highly aware of the IRA's add-on payment use a higher number of unique biosimilar products. Strong awareness of the enhanced reimbursement may incentivize facilities to consider using biosimilars when strategically attractive.

RESPONDENTS CREDIT THE IRA REIMBURSEMENT ENHANCEMENT WITH A SMALL INCREASE IN BIOSIMILAR UTILIZATION

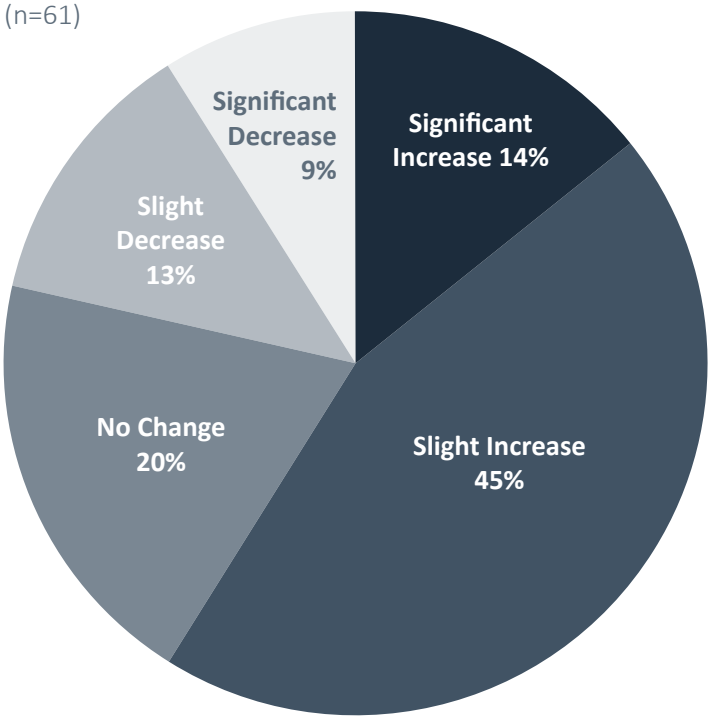
Most respondents report that their facilities slightly increased follow-on biologic utilization because of the IRA.

Facilities that have not increased biosimilar use because of the enhanced reimbursement, cited the following key reasons:

- Lack of awareness among providers and/or facility leadership
- Institutional inertia (e.g. slow implementation processes, siloed decision-making)
- Contracts between facilities and originator products

Impact of IRA Add-On Payments on Biosimilar Utilization

(n=61)



89% Believe **Biosimilar Utilization Will Increase** in The Next Five Years

74% Believe **IRA Add-On Payments Will Be a Factor** in The Increase

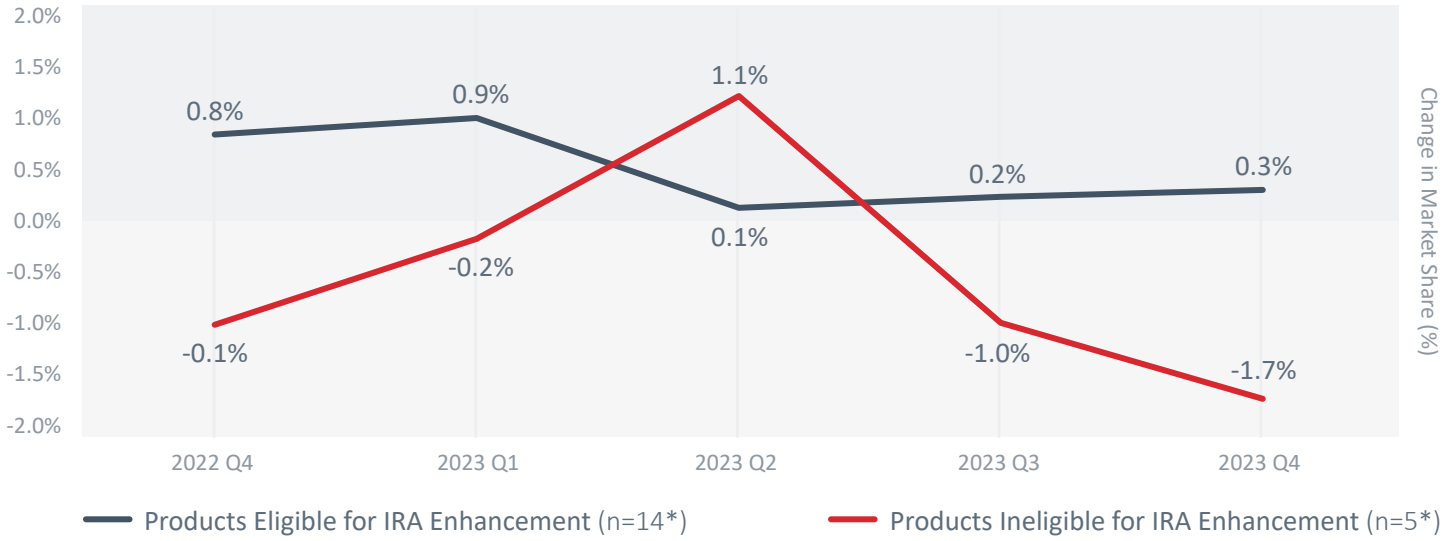
Most respondents expect biosimilar use to increase moving forward for all reference products tested.

About two-thirds of respondents anticipate increases in their facility's use of Avastin, Neupogen, Remicade, and Rituxan biosimilars. About half expect an increase in the use of Herceptin follow-on biologics. As mentioned previously, this exception may reflect the maturity of the trastuzumab biosimilar market.

LIMITED MARKET DATA SUGGESTS THAT THE IRA ENHANCEMENT MAY HAVE SLIGHTLY INCREASED UPTAKE

Publicly-available data is limited due to the short period the provision has been in place and the small set of therapies eligible for the IRA biosimilar boost. Nevertheless, our secondary research supports the survey's findings that the law has slightly increased biosimilar utilization.

Change In Market Share Based on Eligibility for IRA Enhancement (n=17 products)



	Products Eligible for IRA Enhancement (n=14*)	Products Ineligible for IRA Enhancement (n=5*)
2022 Q4	0.8%	-1.0%
2023 Q1	0.9%	-0.2%
2023 Q2	0.1%	1.1%
2023 Q3	0.2%	-1.0%
2023 Q4	0.3%	-1.7%
Average	0.4%	-0.5%

**Eligibility for some products varies by quarter*

Source: CMS ASP Pricing Files

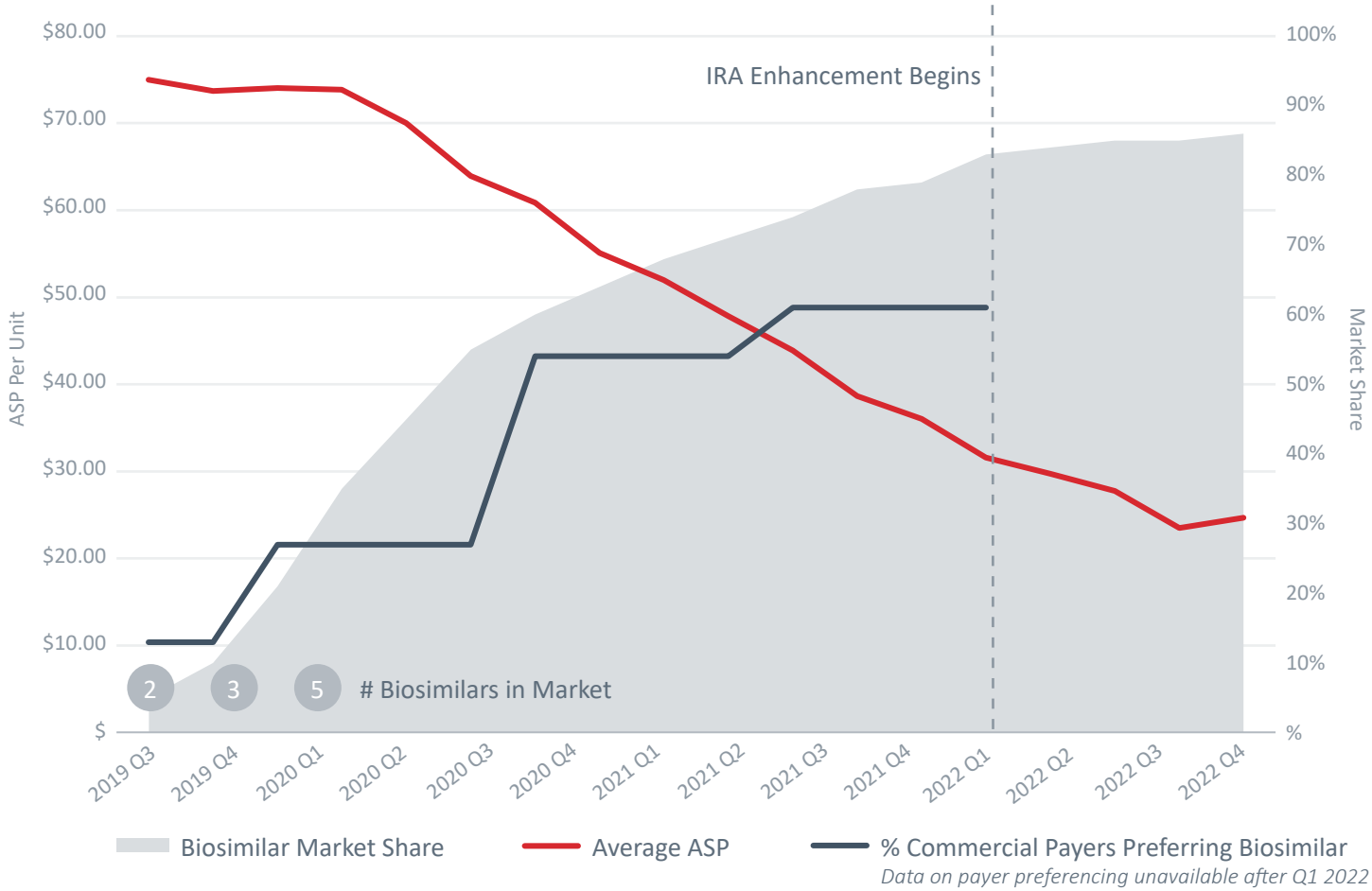
The chart above tracks the change in market share for subsequent entry biologics that are eligible for the IRA enhancement versus ineligible products. Dissecting the difference between enhanced reimbursement and net price is difficult since eligibility for the former is based on the latter. Nevertheless, products eligible for enhanced reimbursement show increased market share vs. ineligible products.

Overall, however, the results are underwhelming. An increase of less than 1% hardly argues a great success. Examining the distinctions between the biosimilars currently available for the reimbursement boost and the next wave of biosimilar launches, however, provides cause for optimism that the biosimilar boost may have a greater impact over the remaining three years of its existence.

THE EVOLUTION OF THE BIOSIMILAR MARKET APPEARS TO CONFIRM RESPONDENTS' ASSESSMENTS OF THE MOST IMPORTANT DRIVERS OF UPTAKE

As discussed previously, respondents cite cost savings and payer policies as the most important factors driving biosimilar utilization. Data on biosimilar market share, ASP change, and commercial payer policies appear to confirm these findings.

Biosimilar Market Evolution: Herceptin (Trastuzumab)



Source: CMS ASP Pricing Files, Samsung Bioepis Biosimilar Market Report, Drug Channels

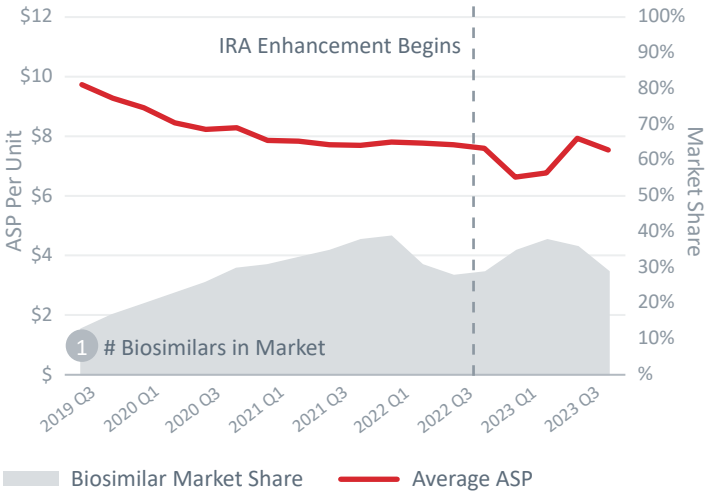
The data for Herceptin and its biosimilars reveals a strong link between the drop in average ASP and the biosimilar market share. As ASPs drop (driven by discounts given by manufacturers of biosimilars and the originator product), use increases nearly proportionally.

Payer policies and utilization of biosimilars are correlated as measured by market share. The data are unavailable on a product-specific basis and are only available through 2022. Still, as commercial policies preferencing one or more biosimilars over the brand become more common, market shares of Herceptin biosimilars rise.

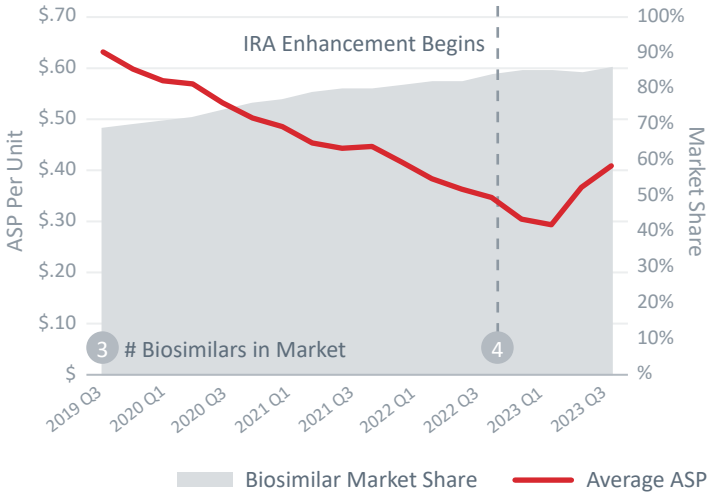
Of course, formulary policies and prices are not independent factors. Rebates provided to payers to preference biosimilars decrease ASP. Lower prices may also encourage payers to favor the lower-priced biosimilars over higher-priced originator products.

ONCOLOGY BIOSIMILARS SAW SUBSTANTIAL UPTAKE AND ASP EROSION BEFORE THE IRA'S IMPLEMENTATION

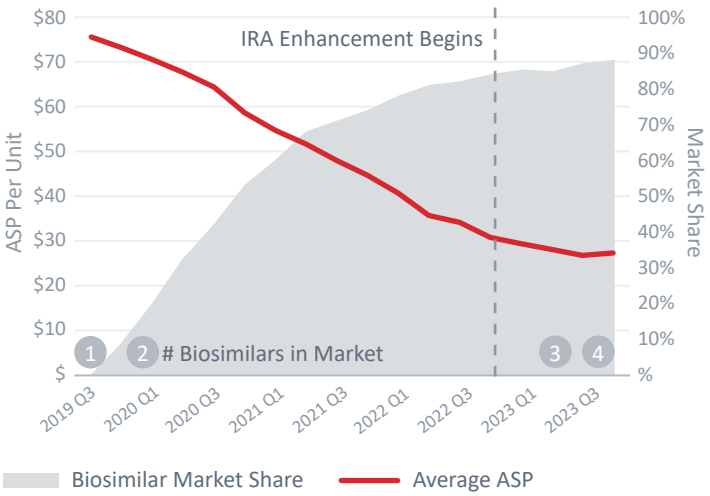
Biosimilar Market Evolution: Epogen/Procrit
(Epoetin Alfa)



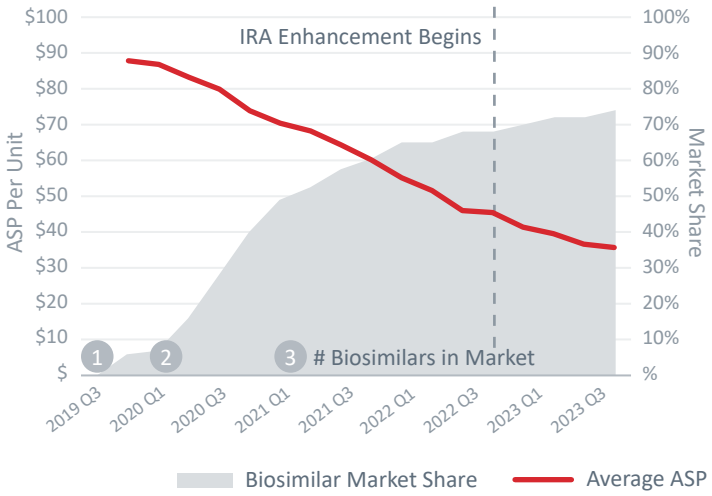
Biosimilar Market Evolution: Neupogen
(Filgrastim)



Biosimilar Market Evolution: Avastin
(Bevacizumab)



Biosimilar Market Evolution: Rituxan
(Rituximab)



Source: CMS ASP Pricing Files, Samsung Bioepis Biosimilar Market Report

Reviewing market data for the other biosimilar categories included in the survey, another factor becomes clear: the number of competitors. Markets with two or more biosimilar competitors (Avastin, Neupogen, Rituxan) see much more substantial changes in ASP and biosimilar market share than the Epogen/Procrit market, which has a single biosimilar.

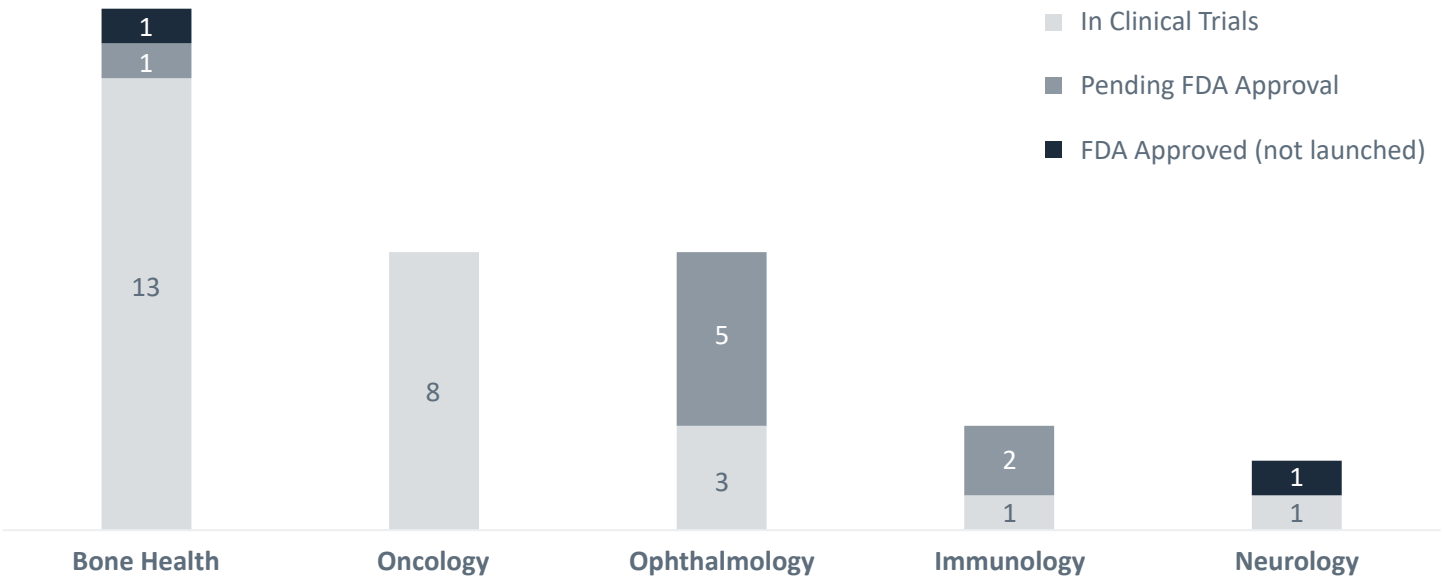
Several characteristics of the site of care for the biosimilars tested in our survey make it less susceptible to some of the "perverse incentives" to use higher-priced drugs that the IRA's reimbursement boost attempts to overcome. The most important characteristic is the relevance of cost recovery in the hospital/clinic vs. in physician offices.

THE FINAL THREE YEARS OF THE INITIATIVE WILL BE THE REAL TEST FOR THE IRA BIOSIMILAR BOOST'S IMPACT

In the next three years, as more biosimilars enter markets where net cost recovery is a significant revenue source, the IRA add-on payment may have a more significant impact. This is specifically applicable to bone health and ophthalmology therapies.

Number of Biosimilars in Development, By Phase

Includes only products where originator has no biosimilar competition and is not self-administered



Source: Cardinal Health, 2024 Biosimilars Report

Compared to biosimilars used in the hospital setting, these markets have more factors discouraging use of biosimilars, as outlined in the table below, which compares IV oncology drugs and injectable ophthalmology drugs:

	IV Oncology Drugs (Hospital)	**Injectable Ophthalmology Drugs** (Physician Office)
Importance of acquisition cost to provider	More important, due to high volumes of drugs purchased and potential for wastage	Less important, given the lower volume of drugs purchased and lower potential for wastage
Provider negotiating power regarding payer policy for biosimilars	Moderate- given the broad range of services provided, drug choice is less prominent than other payer topics	Strong, given limited pool of injecting ophthalmologists and retina specialists
Importance of cost-recovery to overall practice revenue	Low considering breadth of services provided	Moderate, especially if practice focuses on retina only and not general ophthalmology and optometry
Physician compensation	Majority of providers are salaried; compensation is not linked to treatment choice	Often linked to practice revenue
Implication	Stronger appetite for biosimilars	Lower appetite for biosimilars

CONCLUSIONS

Oncology and supportive care biosimilars have achieved significant market share, saving the US healthcare system millions of dollars. While most of these savings are attributable to other causes, our primary research and market data analysis suggest that the IRA's Medicare reimbursement boost for qualifying biosimilars is a small but measurable contributing factor.

The legislation's limited impact to date is likely attributable to the oncology/supportive care market dynamics that fostered competition for biosimilars before the IRA's implementation. Over the next three years, the real test of the provision will be if it can overcome the perverse incentives to use higher-priced originator products over biosimilars.

KEY TAKEAWAYS

- Oncology biosimilars are widely used and accepted, and growth is anticipated to increase
- Stakeholders are relatively well informed of the IRA's enhanced biosimilar reimbursement
- Facilities with greater leadership awareness of the IRA biosimilar add-on payments use a higher number of biosimilar products
- Respondents attribute a small increase in their facilities' use of survey biosimilars to the IRA reimbursement enhancement. However, price and payer considerations are top drivers
- Market data suggests that the IRA enhancement may have slightly increased uptake of oncology/supportive care biosimilars
- The impact of the legislation to date may have been blunted by the substantial uptake and ASP erosion for oncology/supportive care biosimilars and originator products before the implementation of IRA. In addition, market dynamics in this treatment category foster a competitive biosimilars market
- The final three years of the IRA biosimilar boost will test the legislation's impact as more biosimilars enter markets where net cost recovery generates significant revenue

Connect with Certara's experts for your market access needs and questions related to the Inflation Reduction Act (IRA).

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[1] Reference Sources

- Average Selling Price (ASP)
- Qualification for 8% of Reference Add-On
- Market Shares of Reference and Biosimilars
- Trends in US Commercial Health Plan Coverage of Biosimilars