



**AMGEN**<sup>®</sup>

**2022  
BIOSIMILAR  
TRENDS REPORT**

**START** 

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Amgen's 2022 Biosimilar Trends Report is a point-in-time overview of key trends in the US biosimilars marketplace, and it is intended to be a resource to help stakeholders better understand the current and future state of the biosimilars marketplace, and key considerations related to the evolving biosimilars landscape. The information provided in this report is for background and informational purposes only and is not intended to promote Amgen's products or any other products.



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# FOREWORD

## A word from our Vice President of US Value and Access

Dear Colleagues,

We are pleased to share with you the 9th edition of our **Biosimilar Trends Report**.

Key findings from this year's report emphasize that biosimilars continue to play a meaningful role in potentially expanding access to lower-cost treatment options and supporting health system resiliency.<sup>1</sup>

To date in the US, 39 biosimilars\* have received regulatory approval, and 22 products have been launched.<sup>2</sup> These launches have helped create an estimated \$21 billion in savings for the healthcare system over the past 6 years.<sup>3</sup>

This is only the beginning. We are embarking on an exciting wave of growth expected to transform the US marketplace with biosimilars. Over the next few years, the growing number of commercially available biosimilars is expected to change the treatment landscape, providing more options while creating much-needed headroom for innovation in the health system. We expect to see further expansion of biosimilars into pharmacy benefit reimbursement, launches in more therapeutic areas, and the approval of additional interchangeable biosimilars.

As biosimilars expand into new therapeutic areas and enter the pharmacy benefit, education will continue to be critical to instill patient, provider, and pharmacist confidence in the role of biosimilars as viable and integral treatment options.

As a proven biologics leader with a portfolio of 11 biosimilars, Amgen is tireless in our efforts to develop and deliver high-quality biosimilars that support a more resilient health system while ensuring that patients have access to much-needed treatment options. This report is a culmination of our biosimilars heritage and deep commitment to championing biosimilar education—grounded in four decades of biologics leadership.

We encourage you to explore the current and emerging trends in the dynamic biosimilars marketplace.



**Jen Norton**  
Vice President  
US Value and Access, Amgen



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# ABOUT AMGEN

Amgen offers 5 biosimilars across the world,\* which have the potential to expand access to high-quality biologics for patients while also delivering cost savings to healthcare systems.<sup>1,4,5</sup> Our high-quality biosimilars can potentially offer more affordable options that contribute to the sustainability of our healthcare system and allow for greater investment in new medicines for patients. We also have unique insights and a commitment to advocate for a biologics marketplace that will promote innovation and quality, while at the same time bringing more competition and meaningful cost savings to the healthcare system.

We have invested more than \$2 billion across our portfolio of 11 biosimilar candidates and marketed products intended to target serious diseases. We have reached a unique position: we have a deep and growing portfolio of innovator products as well as an already-successful commitment to developing and marketing biosimilars. With multiple US approvals and launches of biosimilars, we have a far larger stake than most companies entering the marketplace with biosimilars.



CLICK HERE FOR ADDITIONAL INFORMATION/RESOURCES

**Founded in 1980, Amgen has grown from a biotechnology pioneer into an acknowledged leader in the development of innovative biologic medicines. We are committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing, and delivering innovative human therapeutics.**



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# 2022 BIOSIMILAR TRENDS REPORT

## Key takeaways

Since the first biosimilar entered the US marketplace in 2015, **39 biosimilars have been approved, 22 of which have been launched.**<sup>2</sup> Biosimilars have gained significant share in the majority of therapeutic areas where they have been introduced.<sup>6</sup> The US marketplace is **poised to see further growth in the number of biosimilars approved and welcome many new biosimilars in the years to come.** Additional competition may lead to significant savings for the healthcare system, and these savings can be deployed to newer, innovative treatments.<sup>7</sup>



**The average sales price (ASP) is declining, due to competition, for both reference products and biosimilars.** The prices of biosimilars have decreased at a negative compound annual growth rate (CAGR) of -9% to -24%. The prices of most reference products have decreased at a negative CAGR of -4% to -21%.<sup>8</sup>



Essential components of provider and patient use of biosimilars include **addressing the clinical, economic, and operational considerations relevant to adoption as well as payer coverage.**



The cumulative reduction in drug spend for classes with biosimilar competition is estimated to have been **\$21 billion over the past 6 years.**<sup>3</sup>



Current US regulatory standards for developing and approving biosimilars, as well as for establishing interchangeability, are **scientifically appropriate to protect patient safety and support provider and payer confidence.** It is important to maintain these appropriate standards to support a sustainable marketplace with biosimilars.



The next few years will likely see **several advancements** in this space:

- Expansion of biosimilars into **pharmacy benefit reimbursement**
- Biosimilars in **more therapeutic classes**
- Additional approvals and launches of **interchangeable biosimilars in the US**



Competitive mechanisms are in place to support biosimilar uptake. For example, the Centers for Medicare & Medicaid Services (CMS) has established separate Healthcare Common Procedure Coding System (HCPCS) **codes and payment rates for biosimilars, treating them similarly to other biologics, which supports their uptake and can help lead to meaningful cost savings and a sustainable marketplace.** Additionally, Medicare reimburses for biosimilars at their ASP plus a 6% add-on of the reference biologic's ASP.<sup>9</sup>



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# CURRENT STATE OF THE MARKETPLACE



The US biosimilar marketplace is evolving. As of October 2022, 3 biosimilars have been approved with interchangeable status.<sup>10</sup> It is estimated that a significant number of biologic medications will face biosimilar competition in the next 5-10 years.<sup>11</sup> These new biosimilars have the potential to generate even more savings for the healthcare industry, which can then be deployed to newer, innovative treatments.<sup>7</sup>

Essential components of provider and patient use of biosimilars go beyond payer coverage and include addressing the clinical, operational, and economic considerations to help support adoption. Given the new therapeutic areas and types of biosimilars that will be available in the next few years, provider and pharmacist education will be critical.

While financial savings are important for helping support biosimilar uptake, it is not the only consideration for payers and providers. Other factors include manufacturing experience with biologics; reliable supply of products; understanding provider and payer clinical, economic, operational, and decision-making drivers; and experience navigating retail operations, given the pending availability of biosimilars at retail pharmacies.

On August 16, 2022, the Inflation Reduction Act was signed into law by President Biden. The Act includes several healthcare elements that impact the biopharmaceutical industry, including biosimilar manufacturers. The US Policy Update section of this report outlines key provisions that will have potential impact on the marketplace with biosimilars. Analysis of the potential impact of the Inflation Reduction Act on the marketplace with biosimilars is ongoing.

**“We anticipate biosimilars in 2022 to continue the promise of cost savings to have the potential to increase access to patients. This year will prove pivotal for the pharmacy benefit space, as providers and pharmacists navigate the first interchangeable biosimilar insulin listed as preferred on several national formularies.”**

– Beth McMahon  
Senior Vice President, Emerging Therapies & Channel Strategy, Amgen

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# THE US MARKETPLACE FOR BIOSIMILARS IS WELL-ESTABLISHED AND GROWING

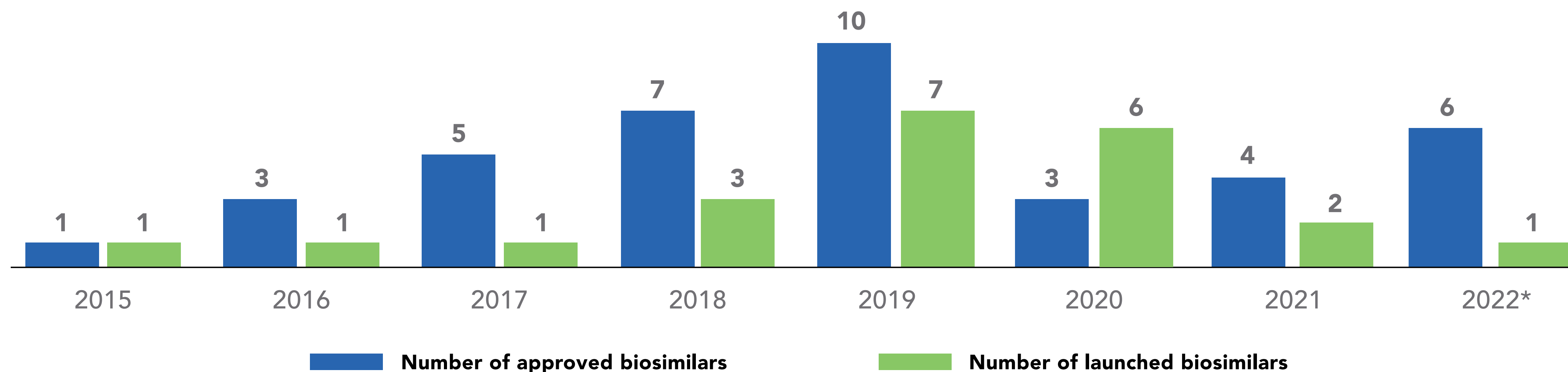
**Figure 1** shows the number of biosimilars approved and launched each year from 2015 to 2022. There was a dramatic increase in biosimilar launches from 2018 to 2020 compared to prior years.<sup>2</sup>

The slowdown of biosimilar approvals in 2020 and 2021 was likely due to several factors, some of which were pandemic related. Over the next few years, the marketplace with biosimilars should recover from this decline in activity, with new approvals and launches expected to increase to pre-2020 rates.

**39 approved biosimilars**

**22 launched biosimilars**

**Figure 1.** Number of Approved and Launched Biosimilars in the US, per Year<sup>2</sup>



Although there was an overall decline in the number of approvals during the 2020 to 2021 timeframe, the number of development programs that are participating in the FDA’s Biosimilar Development Program has continued to rise<sup>12</sup>:

**77 programs**  
in March 2019

**79 programs**  
in March 2020

**90 programs**  
in March 2021

**96 programs**  
in March 2022<sup>†</sup>

Key: BLA – Biologics License Application; FDA – Food and Drug Administration; US – United States.

\*2022 totals include latest available information (January to October 2022).

†Program totals reflect latest available data.

Note: SEMGLEE® (insulin glargine-yfgn) was approved by the FDA in June 2020 with a stand-alone BLA. The FDA subsequently approved SEMGLEE as an interchangeable biosimilar in July 2021.<sup>13,14</sup>

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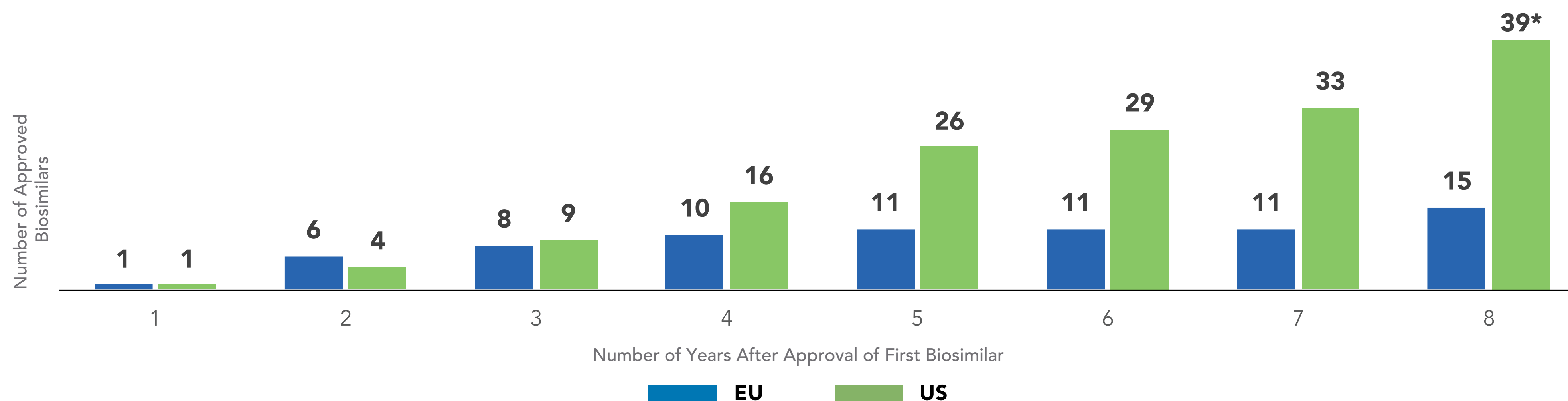
# THE US BIOSIMILAR LANDSCAPE IS ADVANCING FASTER THAN THE EU BIOSIMILAR LANDSCAPE DURING A COMPARABLE PERIOD OF TIME

**Figure 2** shows the cumulative number of biosimilars approved in the EU vs. the US, beginning with the year the first biosimilar was approved. <sup>15,16</sup> The slowdown in EU approvals between years 4 and 7 was likely due to several factors that may include length of development programs.

**In the 8 years after the EU approved the first biosimilar (2006), there were 15 approved biosimilars.** <sup>16</sup>

**By contrast, in the 8 years after the US approved the first biosimilar (2015), there were 39 approved biosimilars.** <sup>15</sup>

**Figure 2.** Comparison of Cumulative Approved Biosimilars in the EU and the US <sup>15,16</sup>



Key: EU – European Union; US – United States.  
\*Year 8 includes US approvals through October 2022.

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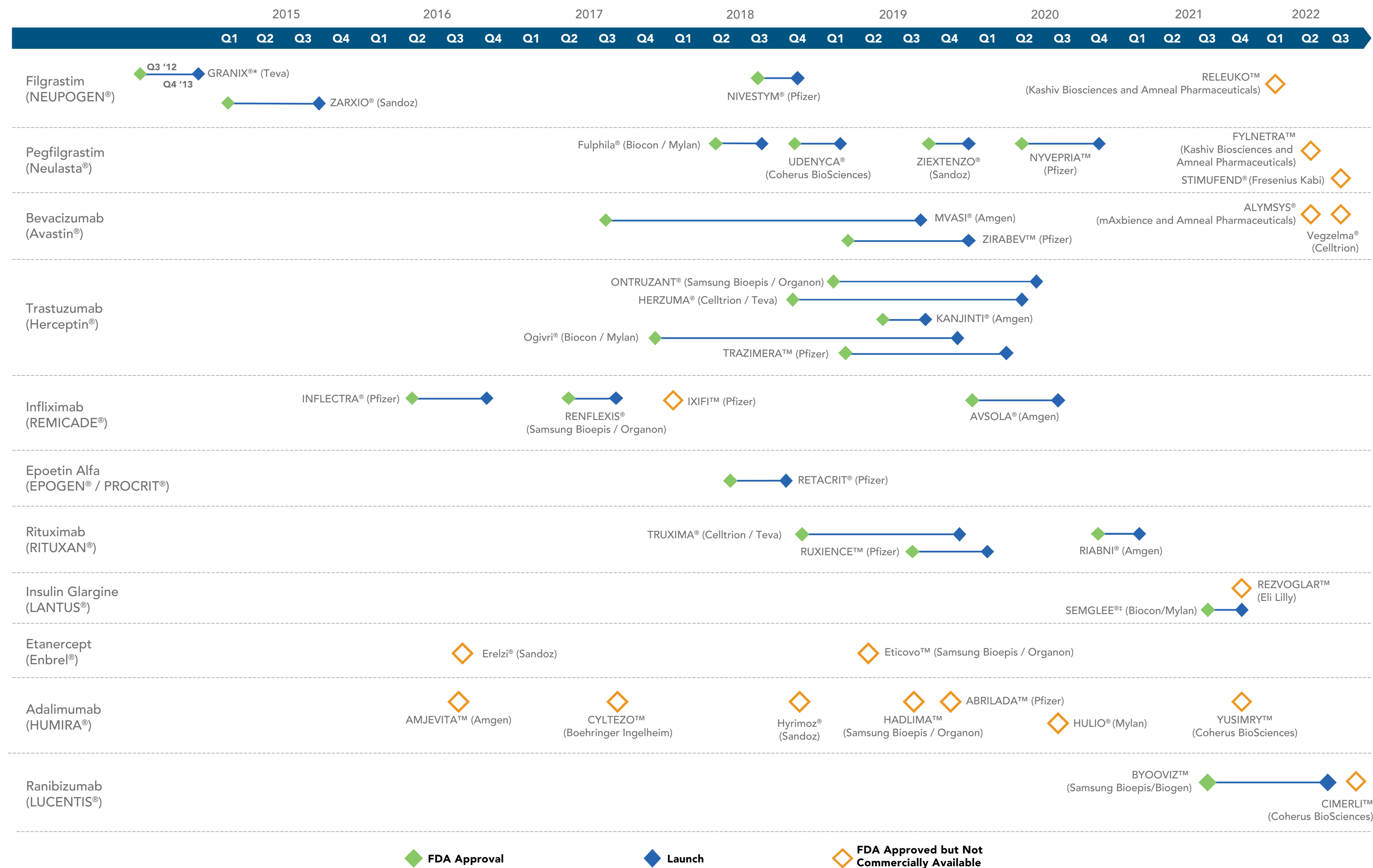
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# TIMELINE OF APPROVED BIOSIMILARS AND LAUNCH DATES



As of October 2022, the FDA has approved 39 biosimilars and 22 biosimilars have been launched in the US as shown in **Figure 3**. Currently, there are 11 reference products that have approved biosimilars.

**Figure 3.** Approved and Launched Biosimilars (including GRANIX\*) in the US<sup>2,†</sup>



Please [click here](#) for Boxed Warning information for AVSOLA, Enbrel, EPOGEN, KANJINTI, and RIABNI.

CLICK TO ENLARGE

Key: BLA – Biologics License Application; FDA – Food and Drug Administration; US – United States.  
 \*GRANIX is not a biosimilar. It was approved under a stand-alone BLA, which was submitted to the FDA before the enactment of the biosimilar approval pathway.  
 †All trademarks appearing herein are the property of their respective owners.  
 ‡SEMGLEE was approved by the FDA in June 2020 with a stand-alone BLA. The FDA subsequently approved SEMGLEE as an interchangeable biosimilar in July 2021. <sup>13,14</sup>

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# BIOSIMILARS TYPICALLY LAUNCH AT A DISCOUNT TO REFERENCE PRODUCT WAC AND ASP

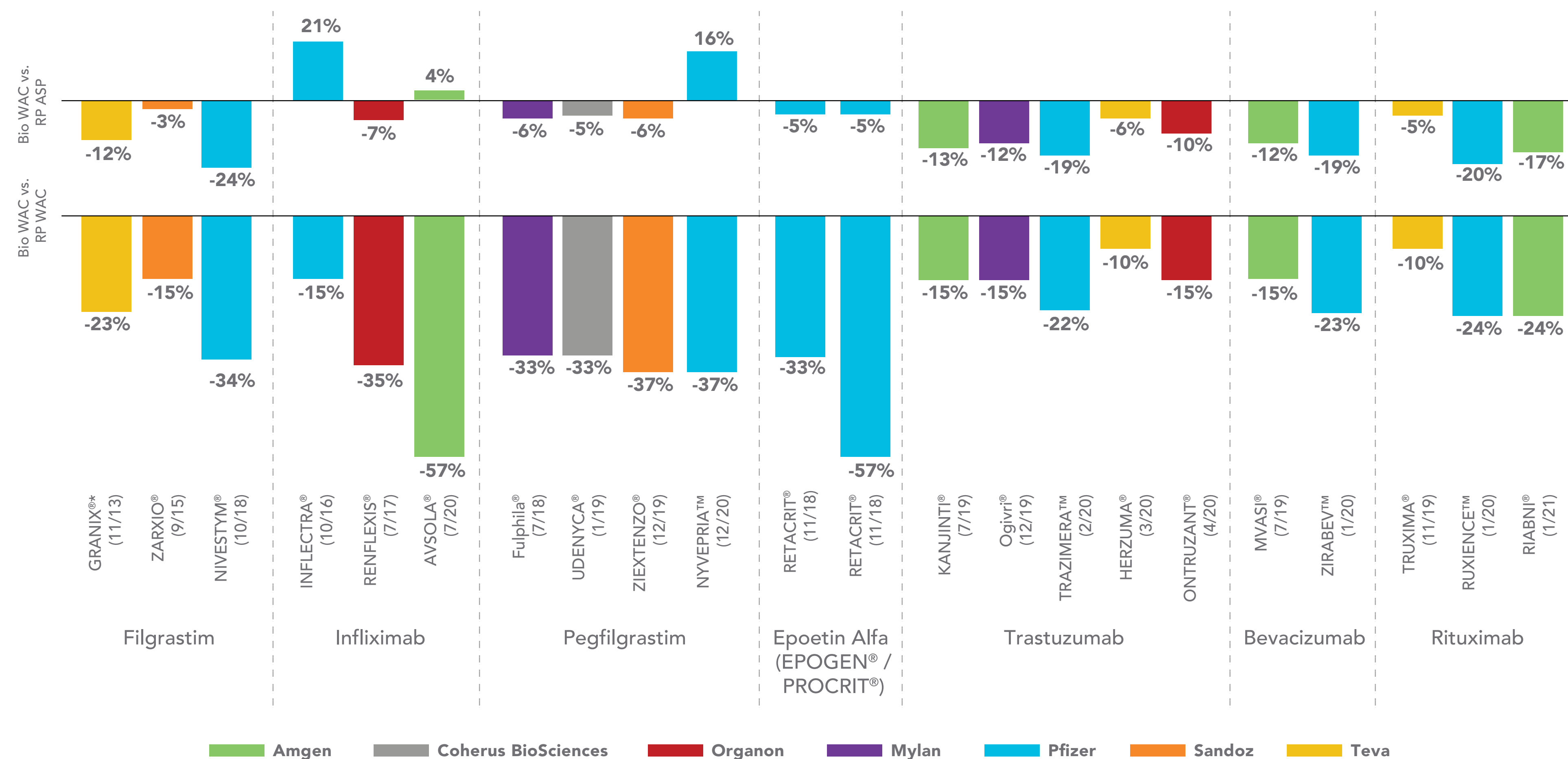
Biosimilars have the potential to reduce healthcare costs by providing significant wholesale acquisition cost (WAC) and average sales price (ASP) savings at launch and through price competition, resulting in the opportunity for additional savings over time. These reference products and their biosimilars are primarily covered under the medical benefit.

As shown in **Figure 4**, manufacturers are launching biosimilars at a WAC that is lower than that of the reference product (biosimilars' ASP becomes available 2 full quarters after launch).<sup>17</sup>

*Biosimilar WAC vs. Reference Product WAC:*

**Biosimilars primarily covered under the medical benefit typically launch at a WAC that is generally 10% to 57% lower than that of the reference product.**

**Figure 4. Price at Launch vs. Reference Product<sup>8</sup>**



Please [click here](#) for Boxed Warning information for AVSOLA, Enbrel, EPOGEN, KANJINTI, and RIABNI.

Key: ASP – average sales price; Bio – biosimilar; BLA – Biologics License Application; FDA – Food and Drug Administration; RP – reference product; WAC – wholesale acquisition cost. \*GRANIX is not a biosimilar. It was approved under a stand-alone BLA, which was submitted to the FDA before the enactment of the biosimilar approval pathway. Source: AnalySource.

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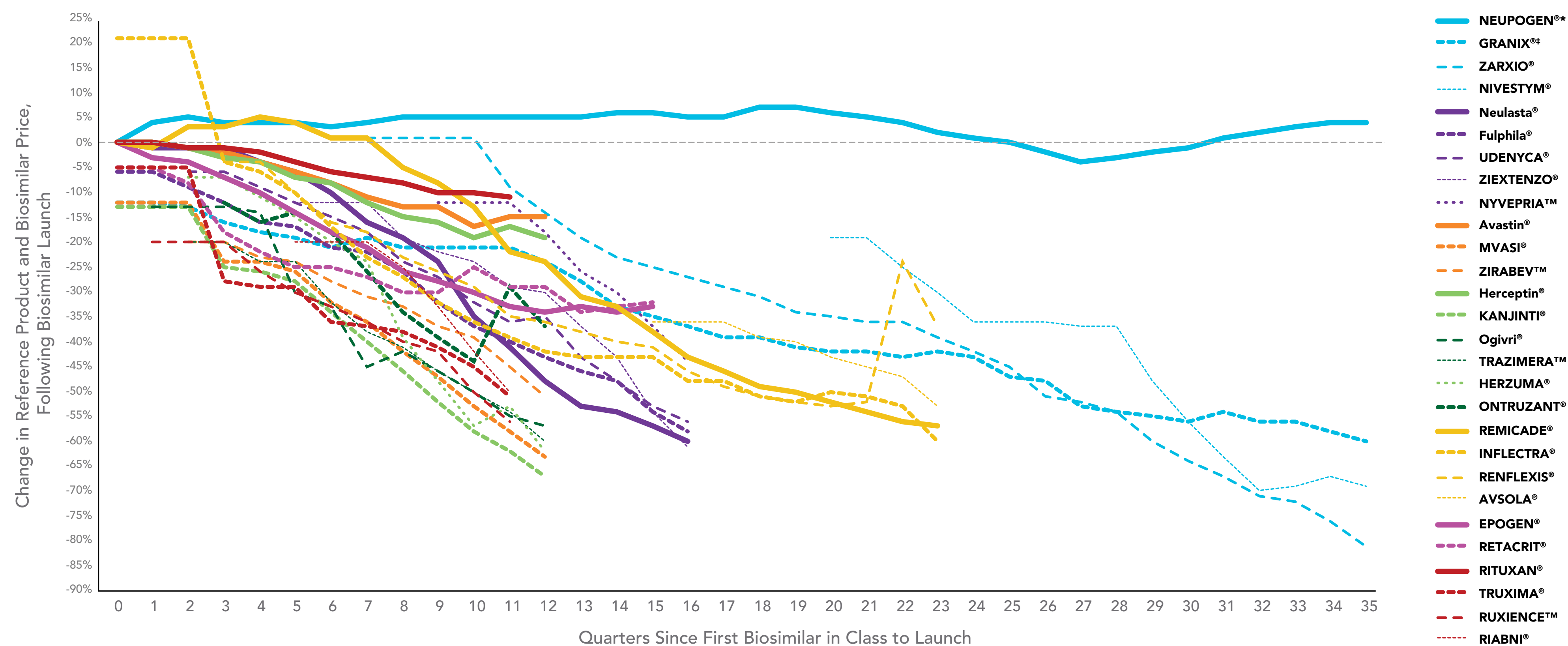
# ASPs ARE DECLINING FOR BOTH REFERENCE AND BIOSIMILAR PRODUCTS

As expected, competition usually results in lower ASP for both reference products and biosimilars, leading to additional savings. As shown in **Figure 5**, in most cases, the prices of biosimilars decline once ASP is established and continue a steady downward trend. The ASPs for reference products are also declining over time, creating additional opportunities for healthcare savings.

The prices of biosimilars have decreased at a negative CAGR of -9% to -24%.

The prices of most reference products\* have decreased at a negative CAGR of -4% to -21%.

**Figure 5.** Downward Trend in ASP for Biosimilars and Reference Products Over Time<sup>8,†</sup>



The pegfilgrastim therapeutic area saw the greatest average decline of -24% since 2021, while the infliximab therapeutic area saw the lowest average decline of -4% since 2021

Please [click here](#) for Boxed Warning information for AVSOLA, Enbrel, EPOGEN, KANJINTI, and RIABNI.

Key: ASP – average sales price; BLA – Biologics License Application; CAGR – compound annual growth rate; FDA – Food and Drug Administration.

\*NEUPOGEN®'s biosimilar price-response strategy focused on account-level provider contracting. This targeted approach modestly increased the ASP-eligible discount rate resulting in a more stable ASP trend.

†Additional research is being conducted to understand the recent spikes in ONTRUZANT and RENFLXIS.

‡GRANIX is not a biosimilar. It was approved under a stand-alone BLA, which was submitted to the FDA before the enactment of the biosimilar approval pathway.

Source: AnalySource.

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# BIOSIMILAR UPTAKE CONTINUES TO CLIMB

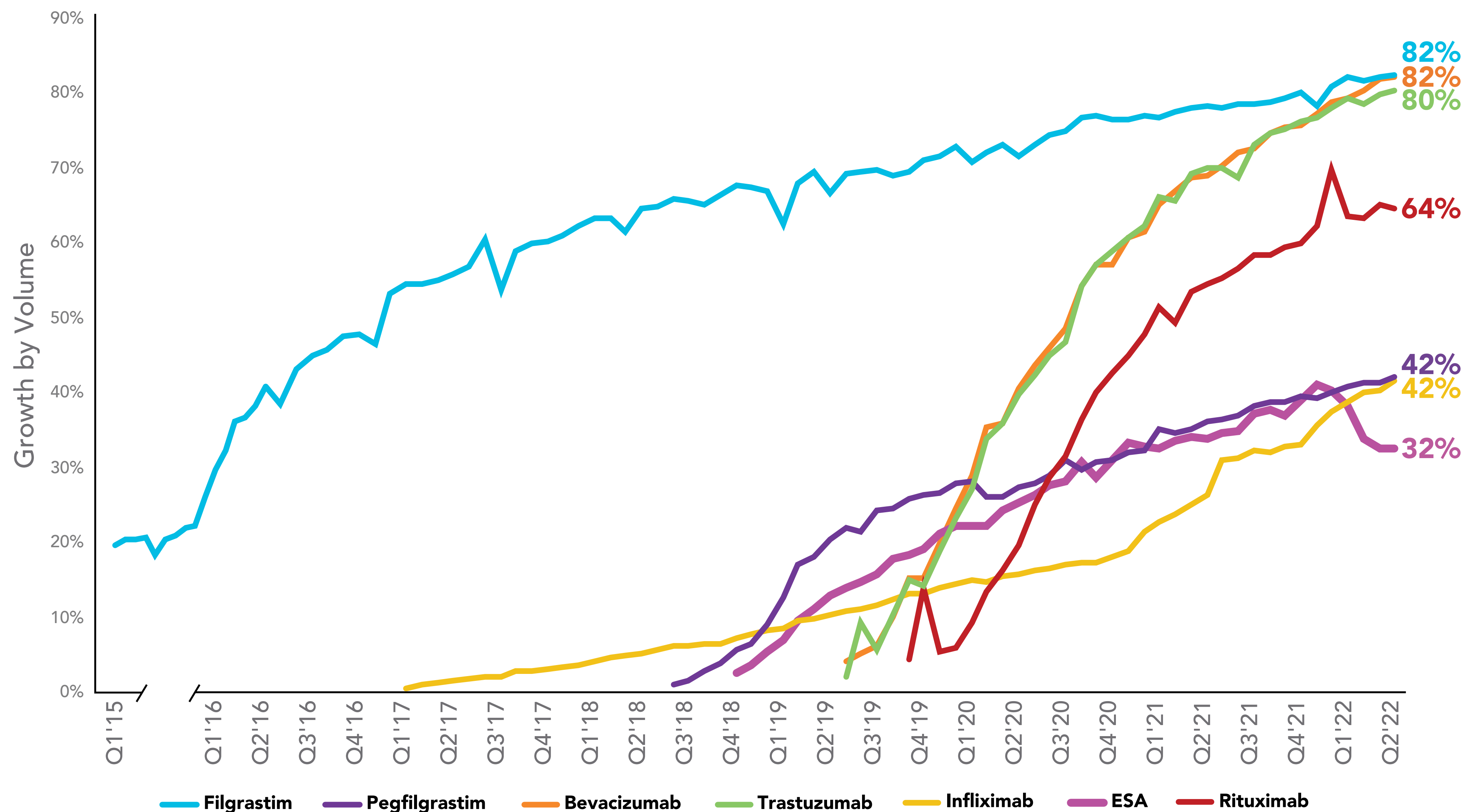


The rate of biosimilar uptake is generally increasing over time, as depicted in **Figure 6**. Biosimilars have gained significant share in the majority of therapeutic areas where they have been introduced. Additionally, first-to-launch biosimilars tend to capture a greater portion of the segment compared to later entrants.

**For therapeutic areas with biosimilars launched in the last 3 years, the average share was 75%.**

**For therapeutic areas with biosimilars launched prior to 2019, the average share after 3 years was 39%.**

**Figure 6. Biosimilars Uptake Curve<sup>6</sup>**



Key: ESA – erythropoiesis-stimulating agent.  
Source: OBU Customer Data Pack Weekly (IQVIA DDD + Chargeback).

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# BIOSIMILAR COMPETITION CONTRIBUTES TO DECREASED DRUG SPENDING

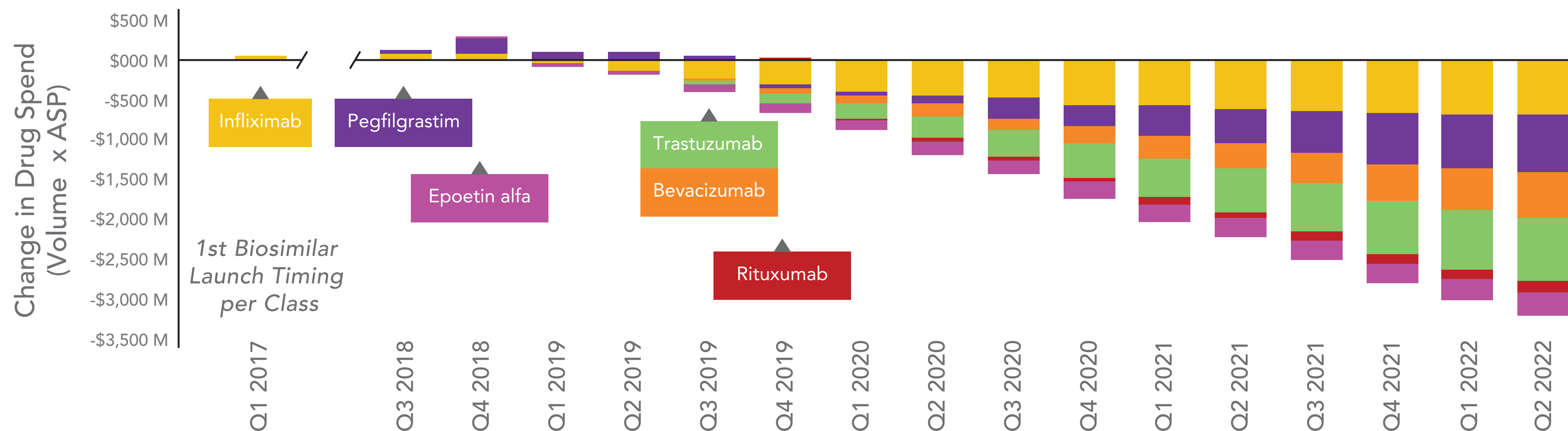


**Figure 7** shows the estimated decrease in total drug spend after biosimilar competition was introduced. The change in drug spend shown is the delta between the projected reference product spend (based on historical trend) vs. the actual spend following biosimilar launch. Beginning in Q1 2019, drug spending for most classes continues to decrease.

**The cumulative savings in drug spend for classes with biosimilar competition is estimated to have been \$21 billion over the past 6 years.**

**Trends show an increase in savings per quarter, and in Q2 2022 alone, savings in drug spend were estimated to be \$3.2 billion.**

**Figure 7. Estimated Change in Total Drug Spend After Biosimilar Competition<sup>3</sup>**



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Key: ASP – average sales price.  
 Note: Filgrastim is excluded from figure because the first biosimilar in its class was launched in 2013 and data are not available prior to Q2 2016 for normalized units.  
 The quarterly drug spend for each product is estimated as: Drug spend=ASPxNormalized unit volume. The estimated spend for the reference product (after biosimilar launch) is trended out based on historical spend for the reference product before biosimilar launch.  
 Sources: AnalySource, Integrated Weekly Sales Data (IQVIA DDD + Chargeback).

# BOXED WARNINGS FOR AMGEN PRODUCTS



## EPOGEN®

**WARNING: ESAs INCREASE THE RISK OF DEATH, MYOCARDIAL INFARCTION, STROKE, VENOUS THROMBOEMBOLISM, THROMBOSIS OF VASCULAR ACCESS AND TUMOR PROGRESSION OR RECURRENCE**

See [Full Prescribing Information](#) for complete boxed warning.

**Chronic Kidney Disease:**

- In controlled trials, patients experienced greater risks for death, serious adverse cardiovascular reactions, and stroke when administered erythropoiesis-stimulating agents (ESAs) to target a hemoglobin level of greater than 11 g/dL (5.1).
- No trial has identified a hemoglobin target level, ESA dose, or dosing strategy that does not increase these risks (2.2).
- Use the lowest EPOGEN® dose sufficient to reduce the need for red blood cell (RBC) transfusions (5.1).

**Cancer:**

- ESAs shortened overall survival and/or increased the risk of tumor progression or recurrence in clinical studies of patients with breast, non-small cell lung, head and neck, lymphoid, and cervical cancers (5.2).
- Use the lowest dose to avoid RBC transfusions (2.4).
- Use ESAs only for anemia from myelosuppressive chemotherapy (1.3).
- ESAs are not indicated for patients receiving myelosuppressive chemotherapy when the anticipated outcome is cure (1.5).
- Discontinue following the completion of a chemotherapy course (2.4).

**Perisurgery:**

- Due to increased risk of deep venous thrombosis (DVT), DVT prophylaxis is recommended (5.1).

## Enbrel®

**WARNINGS: SERIOUS INFECTIONS AND MALIGNANCIES**

See [Full Prescribing Information](#) for complete boxed warning.

**SERIOUS INFECTIONS**

- Increased risk of serious infections leading to hospitalization or death, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis), and infections due to other opportunistic pathogens. (5.1)
- Enbrel should be discontinued if a patient develops a serious infection or sepsis during treatment. (5.1)
- Perform test for latent TB; if positive, start treatment for TB prior to starting Enbrel. (5.1)
- Monitor all patients for active TB during treatment, even if initial latent TB test is negative. (5.1)

**MALIGNANCIES**

- Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with TNF-blockers, including Enbrel. (5.3)

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# BOXED WARNINGS FOR AMGEN PRODUCTS



## KANJINTI®

### **WARNING: CARDIOMYOPATHY, INFUSION REACTIONS, EMBRYO-FETAL TOXICITY, and PULMONARY TOXICITY**

See [Full Prescribing Information](#) for complete boxed warning.

Cardiomyopathy: Trastuzumab products can result in subclinical and clinical cardiac failure manifesting as CHF, and decreased LVEF, with greatest risk when administered concurrently with anthracyclines. Evaluate cardiac function prior to and during treatment. Discontinue KANJINTI for cardiomyopathy. (2.3, 5.1)

Infusion Reactions, Pulmonary Toxicity: Discontinue KANJINTI for anaphylaxis, angioedema, interstitial pneumonitis, or acute respiratory distress syndrome. (5.2, 5.4)

Embryo-Fetal Toxicity: Exposure to trastuzumab products during pregnancy can result in oligohydramnios, in some cases complicated by pulmonary hypoplasia and neonatal death. Advise patients of these risks and the need for effective contraception. (5.3, 8.1, 8.3)

## AVSOLA®

### **WARNING: SERIOUS INFECTIONS and MALIGNANCY**

See [Full Prescribing Information](#) for complete boxed warning.

- Increased risk of serious infections leading to hospitalization or death, including tuberculosis (TB), bacterial sepsis, invasive fungal infections (such as histoplasmosis) and infections due to other opportunistic pathogens.
- Discontinue AVSOLA if a patient develops a serious infection.
- Perform test for latent TB; if positive, start treatment for TB prior to starting AVSOLA. Monitor all patients for active TB during treatment, even if initial latent TB test is negative. (5.1)
- Lymphoma and other malignancies, some fatal, have been reported in children and adolescent patients treated with tumor necrosis factor (TNF) blockers, including infliximab products.
- Postmarketing cases of fatal hepatosplenic T-cell lymphoma (HSTCL) have been reported in patients treated with TNF-blockers including infliximab products. Almost all had received azathioprine or 6-mercaptopurine concomitantly with a TNF-blocker at or prior to diagnosis. The majority of cases were reported in patients with Crohn's disease or ulcerative colitis, most of whom were adolescent or young adult males. (5.2)

## RIABNI®

### **WARNING: FATAL INFUSION-RELATED REACTIONS, SEVERE MUCOCUTANEOUS REACTIONS, HEPATITIS B VIRUS REACTIVATION and PROGRESSIVE MULTIFOCAL LEUKOENCEPHALOPATHY**

See [Full Prescribing Information](#) for complete boxed warning.

- Fatal infusion-related reactions within 24 hours of rituximab infusion; approximately 80% of fatal reactions occurred with first infusion. Monitor patients and discontinue RIABNI infusion for severe reactions (5.1).
- Severe mucocutaneous reactions, some with fatal outcomes (5.2).
- Hepatitis B virus (HBV) reactivation, in some cases resulting in fulminant hepatitis, hepatic failure, and death (5.3).
- Progressive multifocal leukoencephalopathy (PML) resulting in death (5.4).

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# GLOBAL PERSPECTIVES

Access to and utilization of biosimilars continue to increase across both established and emerging regions

To create and preserve physician confidence, patient safety, and the integrity of the healthcare system, biosimilars must meet and maintain robust scientific standards before and after approval. In highly regulated regions, the regulatory pathways for biosimilar products are rigorous and approval is based on the total evidence package obtained from comparative analytical characterization and comparative preclinical and clinical studies.<sup>18-21</sup>

## European Medicines Agency (EMA) approval pathway

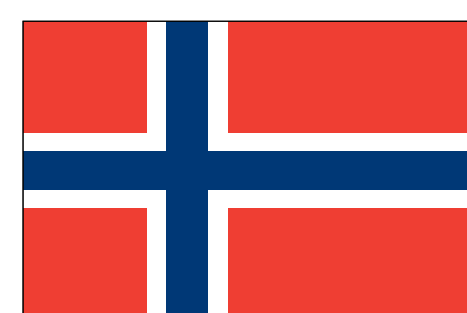
The EU was a pioneer in the regulation of biosimilar medicines by being the first to establish a regulatory framework that helped shape biosimilar development globally. Since that time, the EMA has continued to monitor and refine its approach to regulating biosimilar medicines in the EU.<sup>23</sup>

The EU established legislation for biosimilars in 2004, and EU regulators developed a regulatory approval pathway for biosimilars starting in 2005.<sup>24</sup> The EMA has reviewed 88 biosimilar applications, of which 15 have been withdrawn post-approval and 2 were refused approval. There are currently 71 biosimilars authorized for use.<sup>16</sup>

## EMA biosimilar pathway as a model of other countries

Inherently, as the first regulatory authority to formally establish a regulatory pathway for biosimilar medicines, the EMA's biosimilar guidelines often serve as a reference for other regulatory agencies to develop guidelines on biosimilar review and approval.

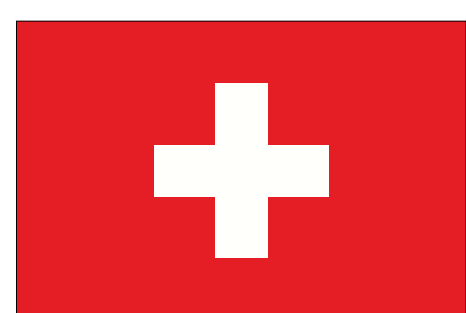
Countries that have implemented guidelines for biosimilar product approval similar to EMA guidelines include<sup>25</sup>:



Norway



Croatia



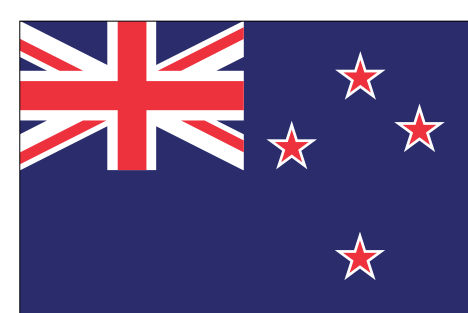
Switzerland



Turkey



Australia



New Zealand



South Africa



United Kingdom



The EU and US markets dominate the use of biosimilar medicines with 90% cumulative use (by sales); other countries have yet to harness the potential benefits of biosimilars.<sup>22</sup>

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# GLOBAL PERSPECTIVES

## Regulatory standards for biosimilars vary worldwide

Globally, established regulatory pathways and associated standards continue to vary. While some countries have specific pathways for approving biosimilars and rigorous regulatory standards, others have yet to develop laws or regulations specific to biosimilars or are still in the process of implementing a pathway based on their laws and regulations.

Many countries rely on the recommendations/approvals from regulated markets (eg, EU, US, Canada, and Japan) through the Certificate of Pharmaceutical Product (CPP) certification scheme implemented by the WHO.<sup>26</sup> Through CPP, regulatory authorities can rely on the previous thorough evaluation of the quality, safety, and efficacy of a product, and avoid certain duplicative assessment activities.

Adherence to globally accepted regulatory standards, such as the 2022 Guidelines on the Evaluation of Biosimilars, is fundamental to assuring patients and the medical community that approved biosimilar products are safe and efficacious and ensuring that adverse events can be accurately tracked and identified.<sup>27</sup>



### Global Policy Perspectives

#### World Health Organization (WHO) actions

The WHO has developed updated guidelines on the evaluation of biosimilars with the aim of aligning global requirements.<sup>27</sup> It is suggested by the WHO that global regulatory agencies use these formal guidelines as a basis for establishing national regulatory frameworks for the licensure of biosimilars.

**“We want to have a global definition of biosimilar, in terms of how it is compared with a reference product. We need to move in that direction, and make sure that those production standards are elevated globally.”<sup>28</sup>**

– Leah Christl, PhD, Executive Director,  
Global Regulatory and R&D Policy, Amgen

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# CONSIDERATIONS FOR THE GLOBAL MARKETPLACE WITH BIOSIMILARS

There are many lessons to be learned from international biosimilar marketplaces to help foster the success of biosimilars globally:



## Emphasis on biosimilar education

Several European countries and the US have launched successful educational programs to improve awareness of and comfort with the safety and efficacy of biosimilars.

The EMA has published the following materials on biosimilars to improve understanding of biosimilar medicines in the EU<sup>29</sup>:

- A video on biosimilars for the general public in the following EU languages: Dutch, French, German, Italian, Polish, Portuguese and Spanish
- The translations of the information guide on biosimilars for healthcare professionals into Dutch, French, German, Italian, Polish, Portuguese and Spanish

The EMA placed these educational materials on biosimilars, as well as the link to the Q&A for patients, on its webpage on biosimilar medicines. The organization encourages healthcare professionals to use and disseminate these materials and promote their use to help ensure that consistent public health messages on biosimilars reach EU citizens.<sup>29</sup>



## Lessons from real-world evidence from the EU

With a longer-standing biosimilar marketplace, Europe has a wealth of real-world evidence on the safety and efficacy of biosimilars.<sup>30,31</sup>

Publishing postmarketing surveillance and other observational studies of real-world evidence provides an important opportunity for manufacturers to provide physicians with additional effectiveness and safety evidence, particularly related to long-term safety, efficacy in extrapolated indications, and effects of switching.<sup>32</sup>

Additionally, real-world evidence studies may be able to provide clinicians with safety and effectiveness data and payers with cost-savings data.<sup>32</sup>



## Strong manufacturer infrastructure

A law firm analysis of the Chinese marketplace with biosimilars noted that most Chinese pharmaceutical companies had been focused on the research, development, and regulatory aspects of the biosimilar process. However, the analysis recommended that companies apply more resources to developing strong manufacturing and distribution infrastructure that is essential for the successful launch of biosimilars.

Manufacturers with long-standing, deep experience in biologics will be better positioned to help maximize the value of biosimilars.<sup>19</sup>

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# THE FUTURE OF BIOSIMILARS IN THE US



## Biosimilars are expanding into new areas

We expect growth in the number of biosimilars, both in terms of breadth and depth. As of Q2 2022, the FDA lists 96 proposed biosimilar products enrolled in the FDA’s Biosimilar Development Program, an increase of nearly 70% since October 2015.<sup>12</sup>

**Over the next few years, the growing number of biosimilars will likely lead to a rapid evolution in the US marketplace with biosimilars, including:**

 <p>Expansion of biosimilars into pharmacy benefit reimbursement</p>	 <p>Biosimilars in more therapeutic areas (autoimmune, gastroenterology, oncology, endocrinology)</p>	 <p>Approval of additional interchangeable biosimilars in the US</p>
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**This evolution in the marketplace is likely to include the following:**

 <p>Additional focus on provider and pharmacist education and comfort with prescribing and using biosimilars</p>	 <p>Use of real-world evidence to inform the future of the marketplace and enhance pharmacovigilance</p>
---	---



**These efforts are likely to further support biosimilars as viable and integral US treatment options. Biosimilars will become accessible to new prescriber specialties, pharmacists, payers, and patients. These developments may lead to changes to the patient support program landscape, interactions at the pharmacy counter, and product-administration devices.**

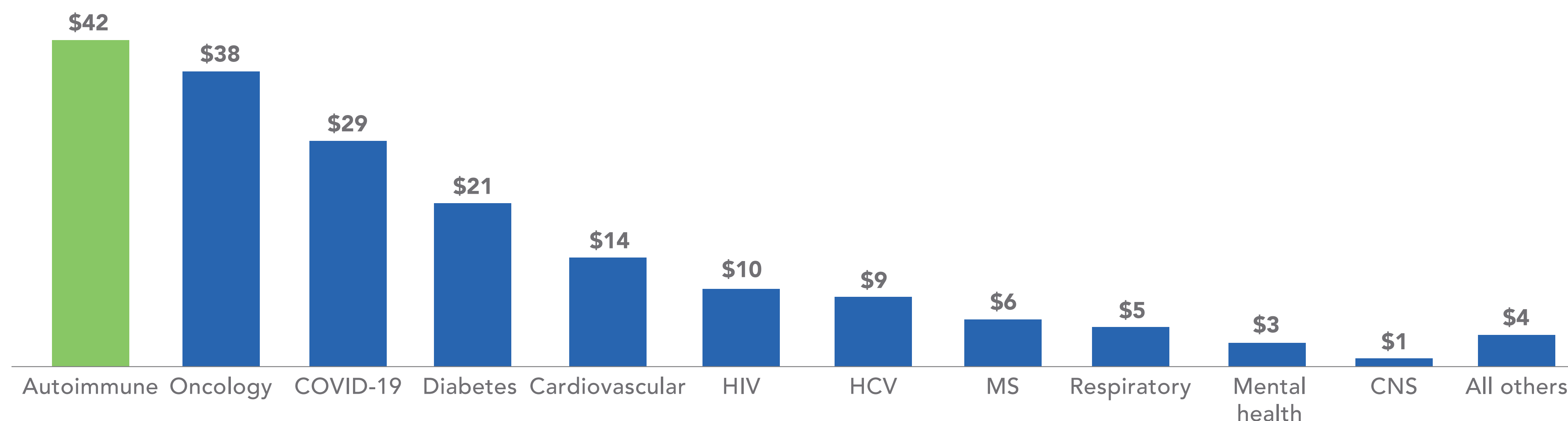
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# NEW AUTOIMMUNE BIOSIMILARS WILL CONTINUE TO EXPAND THE FASTEST GROWING THERAPEUTIC AREA

As shown in **Figure 8**, spending on new and existing autoimmune products exceeded any other therapeutic area, reaching \$42 billion over the past 5 years.<sup>34</sup>

**Autoimmune therapies had the largest growth of any category from 2017 to 2021.**<sup>34</sup>

**Figure 8.** US Medicine Net Spending Growth 2017–2021 for New Brands and Protected Brands Volume, in Billions<sup>34</sup>



## Potential biosimilar launches

Within the autoimmune space, the planned launches of biosimilars to HUMIRA in 2023 could be a pivotal moment. HUMIRA has the highest number of anticipated biosimilar launches in the US over the next few years when compared to reference products in other categories.

More biosimilars to treat autoimmune conditions will be coming to market this decade, offering an opportunity to inject competition and reduce healthcare costs.

**Table 1.** Top-Selling Autoimmune Drugs in 2021<sup>35-37</sup>

Product	Manufacturer	2021 global sales (billions)
<b>HUMIRA (adalimumab)</b>	AbbVie	\$20.7
<b>STELARA (ustekinumab)</b>	Janssen	\$9.1
<b>Enbrel (etanercept)</b>	Amgen	\$4.4
<b>REMICADE (infliximab)</b>	Janssen	\$3.2

Please [click here](#) for Boxed Warning information for Enbrel.

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# ANTICIPATED ENTRY OF HUMIRA BIOSIMILARS IS EXPECTED TO INCREASE COMPETITION FOR THE TOP-SELLING AUTOIMMUNE DRUG IN THE US

HUMIRA® (adalimumab) makes up nearly a third of autoimmune sales

As shown in **Table 2**, there are currently 7 FDA-approved biosimilars for the reference product HUMIRA, with the possibility of 7 or more launches in 2023. Based on the history of pricing for biosimilar and reference products seen in other areas, the entry of additional biosimilars is expected to lead to greater price declines across all products within the class.

**Table 2.** FDA Approval and EU Launch Status of Biosimilars to HUMIRA<sup>2,16</sup>

Company	Drug	FDA approved	Launched in the EU
Amgen	AMJEVITA*	✓	✓
Samsung Bioepis/Organon	HADLIMA†	✓	✓
Boehringer Ingelheim	CYLTEZO	✓	
Coherus BioSciences	YUSIMRY	✓	
Viartis-Fuji	HULIO	✓	✓
Sandoz	HYRIMOZ	✓	✓
Pfizer	ABRILADA	✓	
Fresenius Kabi	IDACIO		✓
Alvotech‡	AVT02		✓
Celltrion	Yuflyma		✓

## A Closer Look: Impact of biosimilars of HUMIRA in the EU offers insight into potential biosimilar adoption in the US

The manufacturer of HUMIRA generated **83.7% of its product's sales in 2021 from the US market.**<sup>38</sup> As a result, global HUMIRA sales in 2023 and beyond will depend heavily on competition from its biosimilars in the US.

HUMIRA biosimilars have acquired strong market share in Europe. Within a year and a half, **the availability of adalimumab biosimilars in Europe resulted in HUMIRA's manufacturer reporting a 31.1% decrease in net revenue in 2019.**<sup>39</sup>

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Data current as of Q1 2022.

Key: EU – European Union; FDA – Food and Drug Administration; US – United States.

\*This is for informational purposes only. This is not an offer for sale. AMJEVITA™ is currently not available commercially and will not be commercially available in the United States until on or after January 31, 2023. AMGEVITA® has launched in Europe.

†HADLIMA is marketed as IMRALDI in the EU and manufactured/marketed by Samsung Bioepis/Biogen.

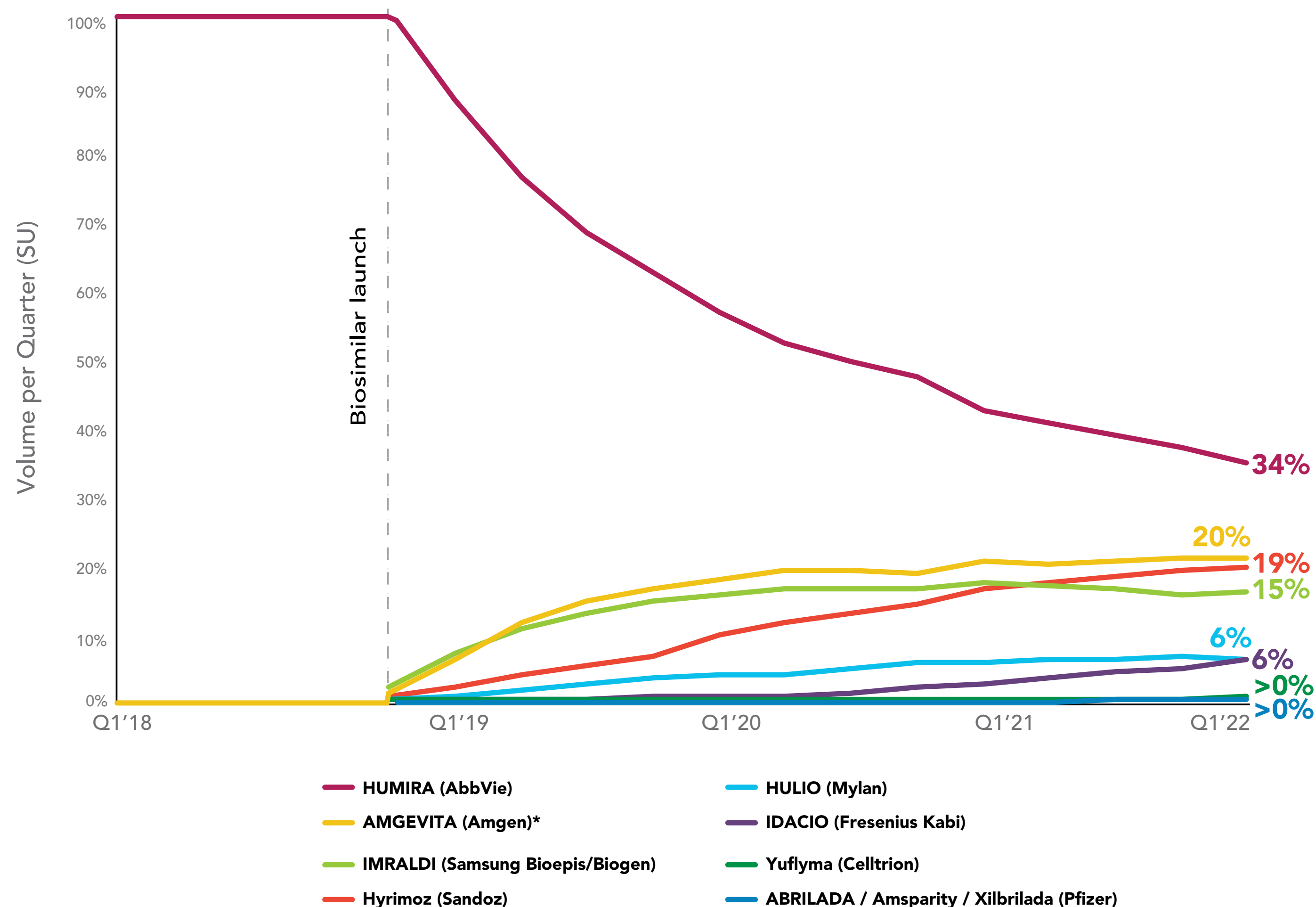
‡STADA Arzneimittel AG has exclusive commercialization rights to AVT02 in all key European markets under the names HUKYNDRA and LIBMYRIS.

# LESSONS FOR THE FUTURE FROM 4 YEARS' EXPERIENCE

Uptake of biosimilars to HUMIRA (adalimumab) in the EU has been steady since 2019

As shown in **Figure 9**, HUMIRA's share has declined in the EU since the introduction of biosimilar competition. At the time of publication, HUMIRA had a 34% share, while AMGEVITA – the first biosimilar in the market – had a 20% share, followed by Hyrimoz (19%) and IMRALDI (15%).<sup>40</sup>

**Figure 9.** Adalimumab Volume Analysis in the EU<sup>40</sup>



Adoption of adalimumab biosimilars is higher in some EU countries due to varying healthcare systems and government policies. For example, the AMGEVITA share differs by country, with:

- 41% share in the UK
- 20% share in Germany
- 19% share in France<sup>40</sup>

**Uptake of biosimilars to HUMIRA in the EU has been strong, and biosimilar products now make up nearly 66% of the adalimumab share.**

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# REAL-WORLD EVIDENCE (RWE) FURTHER SUPPORTS USE OF AUTOIMMUNE BIOSIMILARS



Data on biosimilars in the real-world setting are increasing as clinical experience with biosimilars to treat autoimmune conditions such as inflammatory bowel disease, psoriasis, and rheumatoid arthritis grows. Studies using RWE from the EU help support the effectiveness, safety, and tolerability of biosimilars in patients.

*Analysis of several recent RWE studies on autoimmune biosimilars in the EU shows:*



Results are largely consistent with the evidence from randomized controlled trials <sup>41-43</sup>



Real-life data confirm both efficacy and safety of biosimilars based on large-scale studies <sup>44</sup>



Outcomes were generally consistent, regardless of whether patients were biologic-naïve or switched from another biologic <sup>41</sup>

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# FUTURE CONSIDERATIONS FOR STAKEHOLDERS



## Payers/PBMs

- Payers and PBMs often put greater emphasis on cost minimization, when outcomes are equal or assumed to be equal<sup>45</sup>
- Their concern is typically on balancing risk and ensuring that premiums are low enough to attract/retain members while providing adequate access to benefits
- Non-cost differentiators such as product portfolio, category experience, supply chain, and the ability to pull through coverage decisions may resonate here



## Employers

- Escalating specialty drug costs present a challenge for employers trying to provide healthcare for their employees
- Employers are uniquely motivated to ensure continued health and productivity while considering cost-effectiveness
- Competition between reference products and biosimilars may bring cost savings to the system, benefiting employers that are facing soaring healthcare expenses

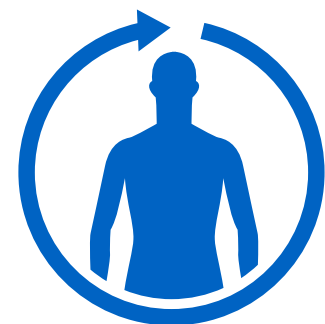
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# FUTURE CONSIDERATIONS FOR STAKEHOLDERS



## Pharmacists

- Many pharmacists may be introduced to biosimilars for the first time with the launch of biosimilars that are processed under the pharmacy benefit in the US market
- As of October 2022, 3 biosimilars with interchangeable designations are approved in the US<sup>10</sup>
- All 50 states plus Puerto Rico and DC allow pharmacists to substitute an FDA-approved, interchangeable biosimilar for a prescribed reference product, consistent with state law<sup>46</sup>
- Public information is [available](#) to assist pharmacists in evaluating biosimilars for formulary inclusion
- Pharmacists will likely need education to become more knowledgeable and comfortable discussing biosimilars with patients. Science-based educational outreach can promote pharmacist confidence in dispensing biosimilars



## Patients

- Patient support programs can help patients initiate and adhere to therapy, and can also help those struggling to afford their medications
- A manufacturer with a strong supply-chain history and reputation can assuage patients' concerns about disruptions to their medication regimen

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# ONCOLOGY THERAPEUTICS

The biosimilars available for oncology therapeutics consist of **trastuzumab**, **bevacizumab**, and **rituximab** products. For each, we discuss:

- **WAC and ASP of the biosimilar at launch compared to the reference product**

---

- **ASP for the reference product and biosimilars since launch**

---

- **Biosimilar uptake**

---

- **Estimated difference in total drug spend after biosimilar competition**

Biologics account for half of the pharmacological products in oncology; however, their high cost is a result of greater costs of development and production compared to small molecules.<sup>47</sup> Biosimilars can help drive down that high cost with 10 oncology biosimilars now available.<sup>2</sup>

As this section demonstrates, biosimilars available for oncology therapeutics have exhibited strong growth. For example, both trastuzumab and bevacizumab biosimilars account for nearly 80% of sales by volume. The rituximab biosimilars are comparatively newer, though they still account for 64% of sales by volume.<sup>6</sup>

**“The price takes its own toll on cancer patients with [more] patients facing out-of-pocket costs. It becomes hard for them to sustain the level of cancer care. I think biosimilars definitely help assimilate some of that kind of challenge.”<sup>48</sup>**

– Kashyap Patel, MD  
CEO, Carolina Blood and Cancer Care



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# ONCOLOGY THERAPEUTICS

## Trastuzumab

Five biosimilars have launched since 2019 to the reference product Herceptin (trastuzumab):

Launched at a price<sup>8</sup>

**KANJINTI**<sup>®</sup>  
(trastuzumab-anns)  
For Injection 420mg/vial multiple dose

✓ **15%** less than Herceptin's WAC

✓ **13%** less than Herceptin's ASP

**Ogivri**<sup>®</sup>  
(trastuzumab-dkst)  
Injection 420mg | 150mg

✓ **15%** less than Herceptin's WAC

✓ **12%** less than Herceptin's ASP

INJECTION  
**Trazimera**<sup>™</sup>  
*trastuzumab-qyyp*

✓ **22%** less than Herceptin's WAC

✓ **19%** less than Herceptin's ASP

**Herzuma**<sup>®</sup>  
(trastuzumab-pkrb)  
For Injection • 420 mg/vial • 150 mg/vial

✓ **10%** less than Herceptin's WAC

✓ **6%** less than Herceptin's ASP

**Ontruzant**<sup>®</sup>  
trastuzumab-dttb  
for injection, for intravenous use 21 mg/mL

✓ **15%** less than Herceptin's WAC

✓ **10%** less than Herceptin's ASP



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Please [click here](#) for Boxed Warning information for KANJINTI.  
See [Full Prescribing Information](#) for complete risk information.

Key: ASP – average sales price; WAC – wholesale acquisition cost.



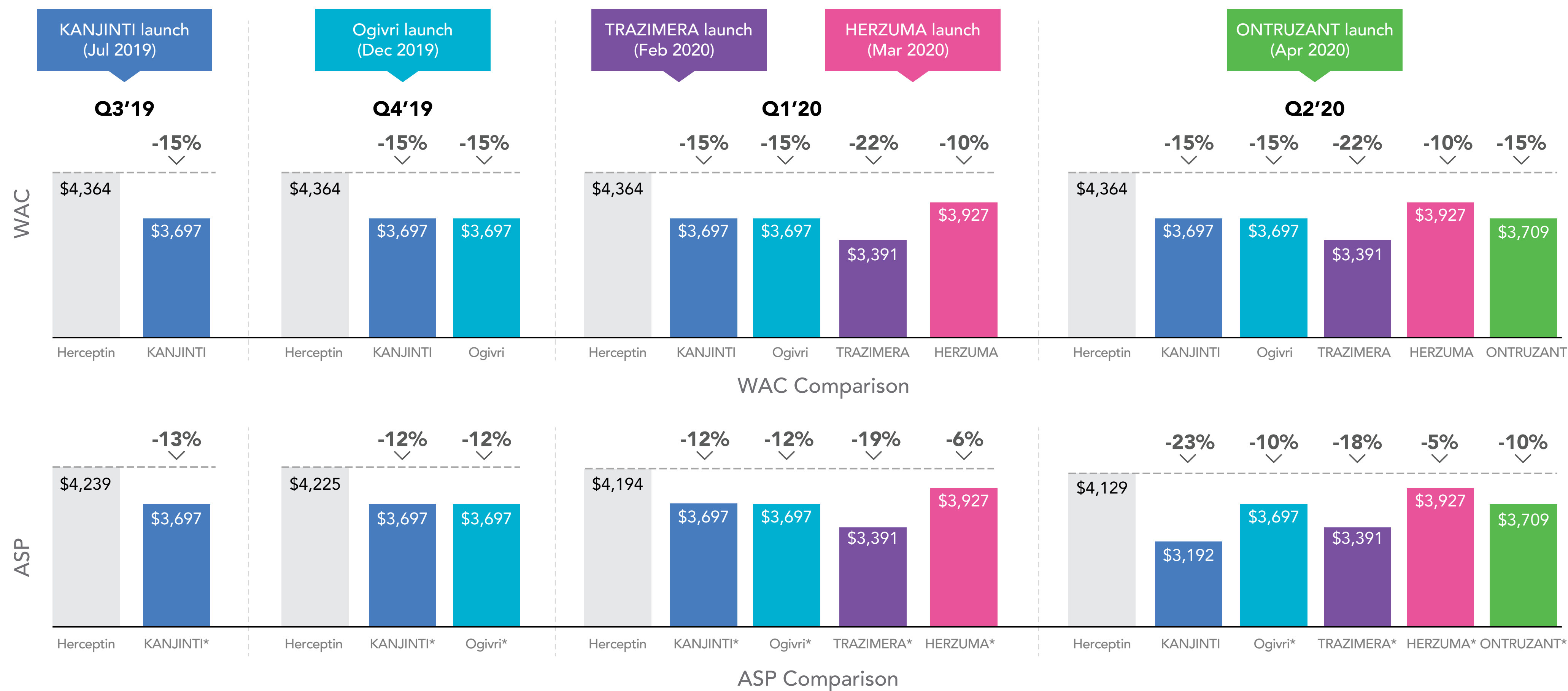
# ONCOLOGY THERAPEUTICS

## Trastuzumab



As **Figure 10** shows, all 5 biosimilars launched at WAC and ASP discounts to the reference product with some launching at discounts below their predecessors.

**Figure 10. WAC and ASP of Trastuzumab Biosimilars Relative to Reference Product at Launch<sup>8</sup>**



Please [click here](#) for Boxed Warning information for KANJINTI.  
See [Full Prescribing Information](#) for complete risk information.

Key: ASP – average sales price; WAC – wholesale acquisition cost.  
\*ASP was not available for these products at the time of comparison. WAC is used to compare with reference product ASP.  
Source: AnalySource.

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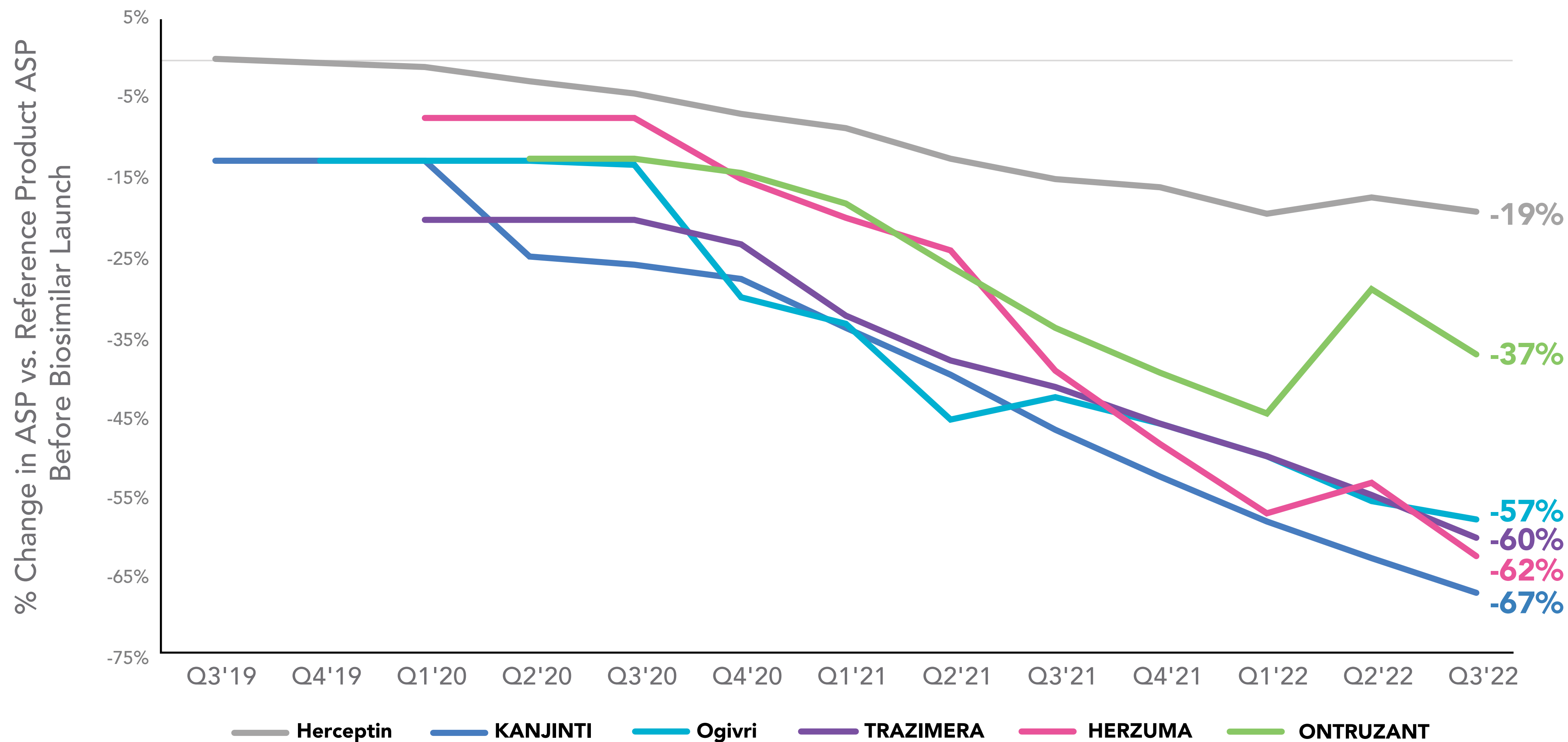
# ONCOLOGY THERAPEUTICS

## Trastuzumab

**Figure 11** shows the percentage change in the price of biosimilars over time when compared to the reference product's ASP at the time that the first trastuzumab biosimilar launched.

**The reference product Herceptin's price has declined by 19% in the last 3 years since the first trastuzumab biosimilar was launched.**

**Figure 11.** ASP of Trastuzumab Products at Biosimilars' Launches<sup>8</sup>



Please [click here](#) for Boxed Warning information for KANJINTI.

See [Full Prescribing Information](#) for complete risk information.

Key: ASP – average sales price; WAC – wholesale acquisition cost.  
 Biosimilar WAC is used for comparing against reference product ASP until biosimilar ASP is available.  
 Source: AnalySource.



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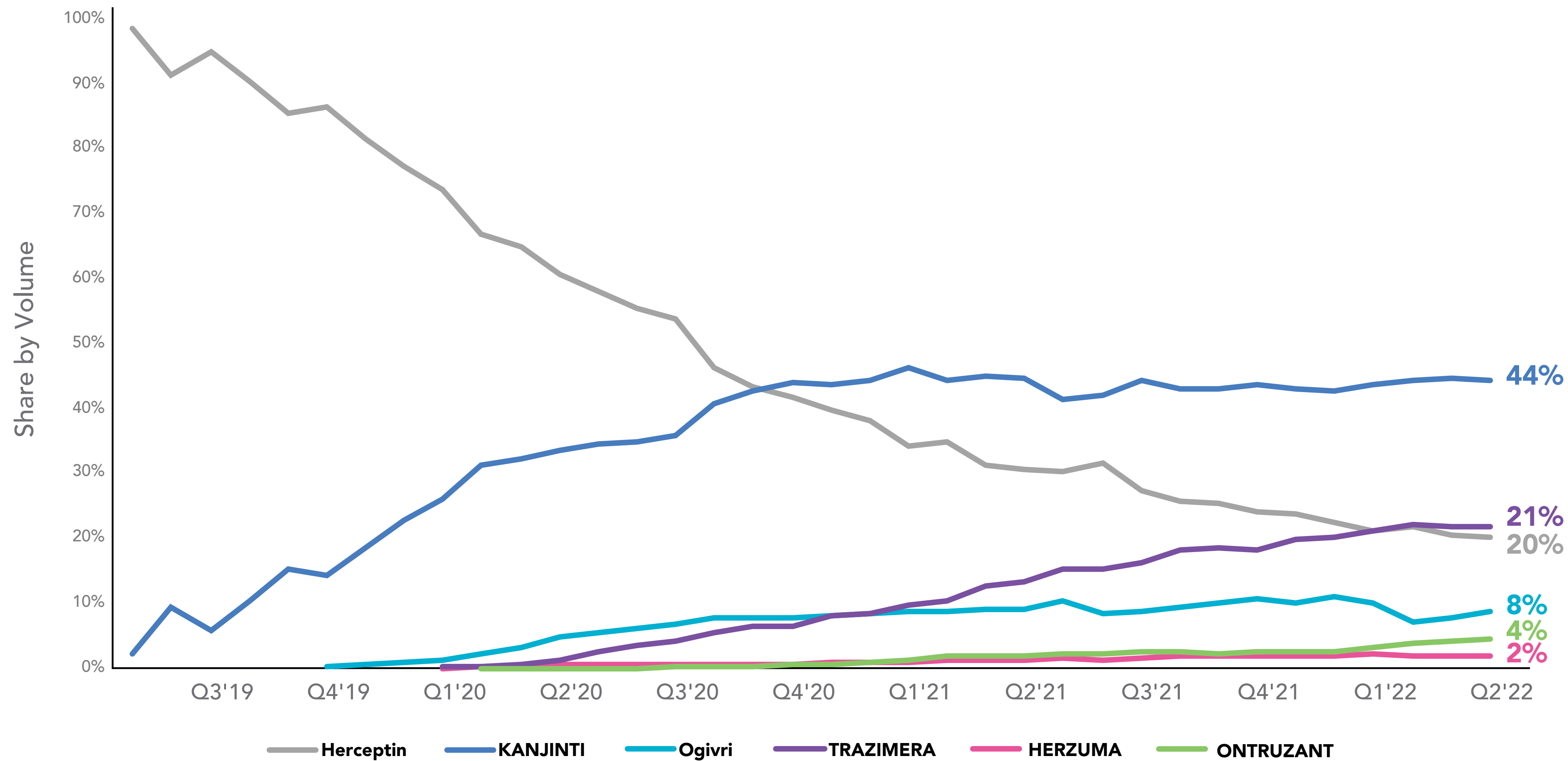
# ONCOLOGY THERAPEUTICS

## Trastuzumab

As seen in **Figure 12**, there has been a strong adoption of trastuzumab biosimilars. Within 18 months after launching, KANJINTI captured more share than the reference product Herceptin.

**Three years after the first launch, biosimilars now account for 80% share of all trastuzumab products.**

**Figure 12.** Biosimilar Uptake Curve for Trastuzumab Products<sup>6</sup>



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# ONCOLOGY THERAPEUTICS

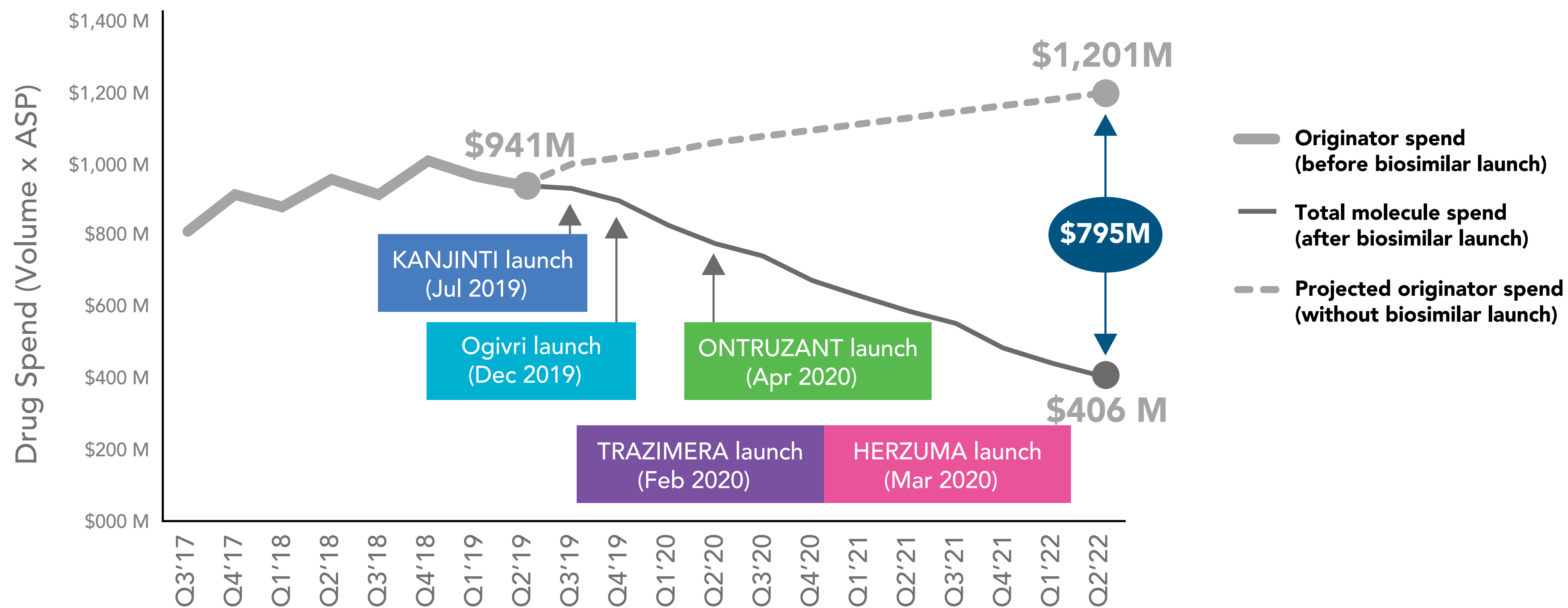
## Trastuzumab

**Figure 13** shows the total drug spend for trastuzumab with biosimilar launches, compared to the projected drug spend in the absence of biosimilar competition.

**The cumulative savings in drug spend for trastuzumab from the Herceptin biosimilar launch in Q3 2019 to Q2 2022 is estimated to be \$5.3 billion to date.**

**Without biosimilar competition, projected spending on trastuzumab could have been more than \$790M higher in Q2 2022.**

**Figure 13.** Comparison of Estimated Trastuzumab Drug Spend With vs. Without Biosimilar Competition<sup>3</sup>



Please [click here](#) for Boxed Warning information for KANJINTI.  
See [Full Prescribing Information](#) for complete risk information.

Key: ASP – average sales price.  
The quarterly drug spend for each product is estimated as: Drug spend=ASPxNormalized unit volume. The estimated spend for the reference product (after biosimilar launch) is trended out based on historical spend for the reference product before biosimilar launch.  
Sources: AnalySource, Integrated Weekly Sales Data (IQVIA DDD + Chargeback).



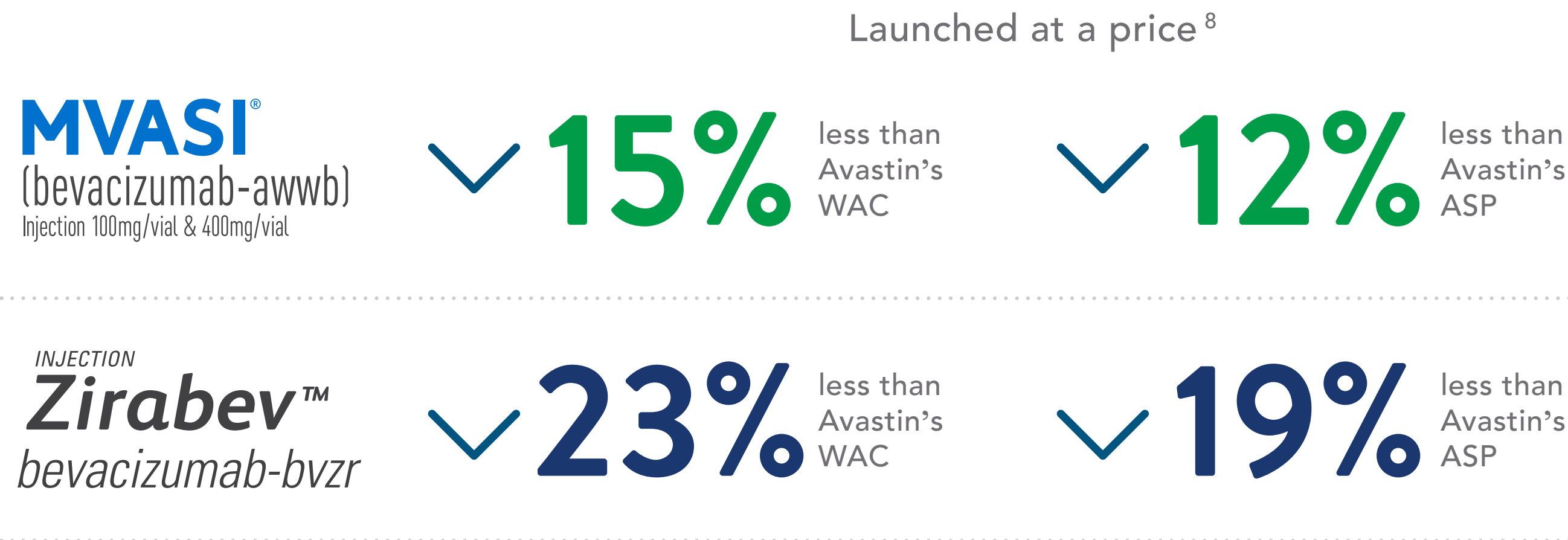
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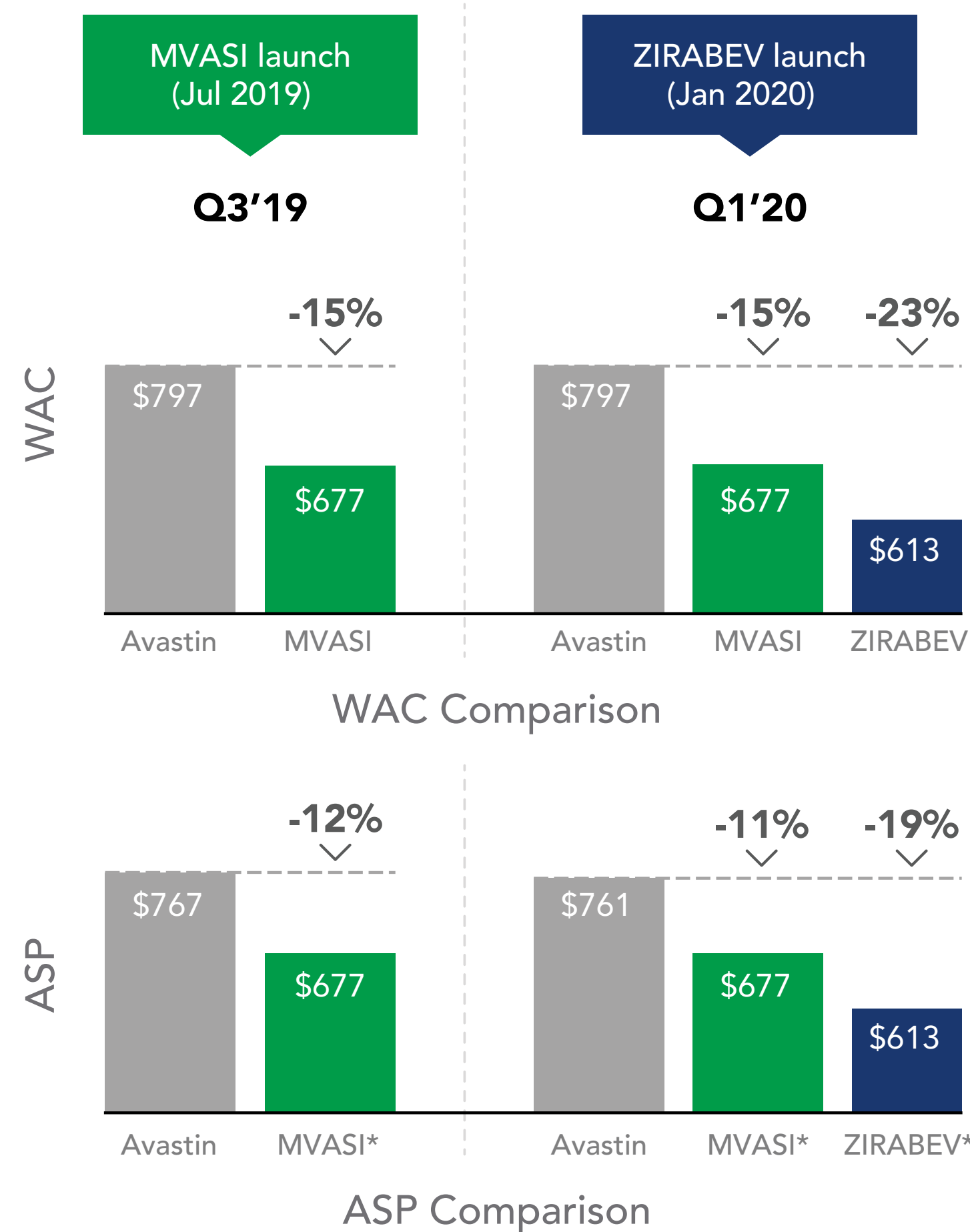
## Bevacizumab



Since 2019, 2 biosimilars have launched to the reference product Avastin (bevacizumab):



**Figure 14.** WAC and ASP of Bevacizumab Biosimilars Relative to Reference Product at Launch<sup>8</sup>



Key: ASP – average sales price; WAC – wholesale acquisition cost.  
\*ASP was not available for these products at the time of comparison. WAC is used to compare with reference product ASP.  
Source: AnalySource.

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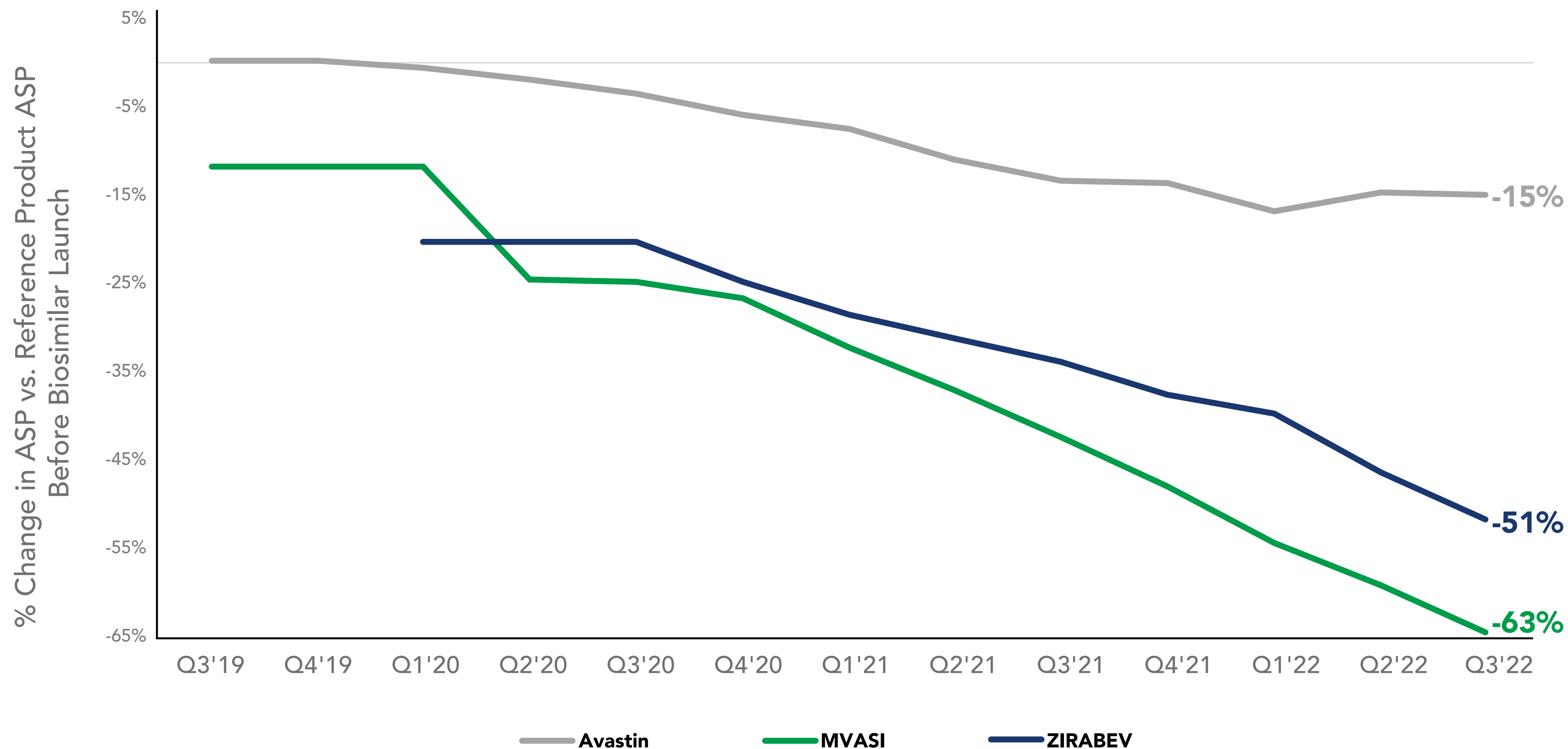
# ONCOLOGY THERAPEUTICS

## Bevacizumab

**Figure 15** shows the percentage change in the price of biosimilars over time when compared to the reference product's ASP at the time that the first biosimilar to Avastin was launched.

**The reference product Avastin's price has declined by 15% in the last 3 years since the first bevacizumab biosimilar was launched.**

**Figure 15.** ASP of Bevacizumab Products at Biosimilars' Launches<sup>8</sup>



Key: ASP – average sales price; WAC – wholesale acquisition cost.  
 Biosimilar WAC is used for comparing against reference product ASP until biosimilar ASP is available.  
 Source: AnalySource.



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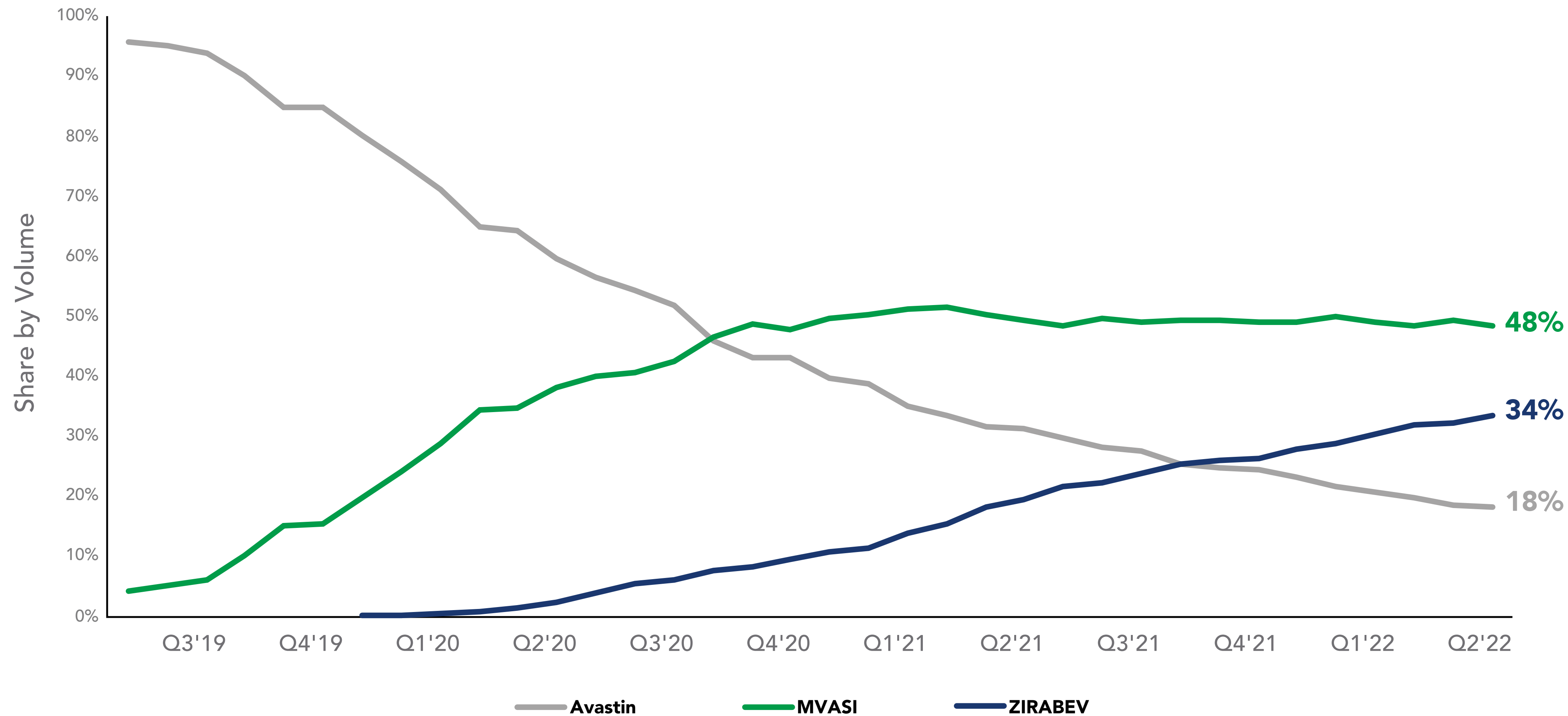
# ONCOLOGY THERAPEUTICS

## Bevacizumab

As seen in **Figure 16**, there has been a strong adoption of bevacizumab biosimilars. Within 16 months after launching, MVASI captured more share than the reference product Avastin.

**Three years after the first launch, biosimilars now account for 82% share of all bevacizumab products.**

**Figure 16.** Biosimilar Uptake Curve for Bevacizumab Products<sup>6</sup>



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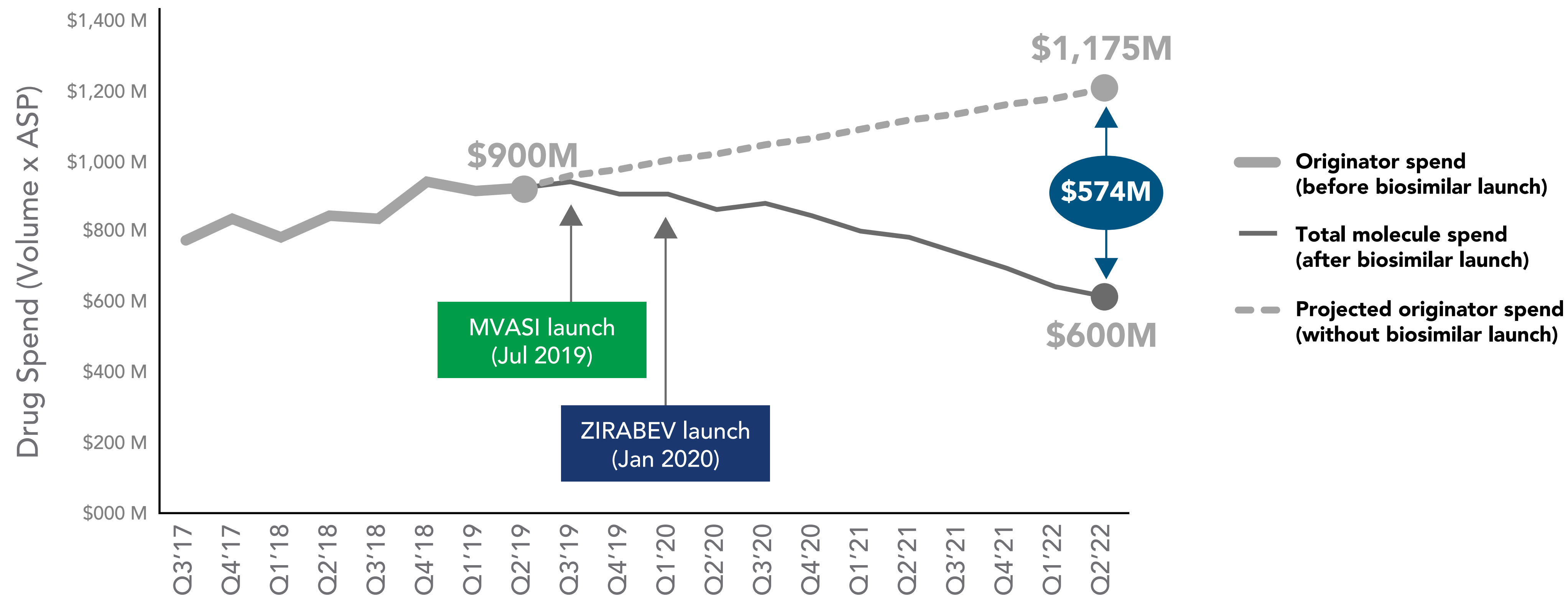
## Bevacizumab

**Figure 17** shows the total drug spend for bevacizumab with biosimilar launches, compared to the projected drug spend in the absence of biosimilar competition.

**The cumulative savings in drug spend for bevacizumab from the first Avastin biosimilar launch in Q3 2019 to Q2 2022 is estimated to be \$3.3 billion to date.**

**Without biosimilar competition, projected spending on bevacizumab could have been more than \$570M higher in Q2 2022.**

**Figure 17.** Comparison of Estimated Bevacizumab Drug Spend With vs. Without Biosimilar Competition<sup>3</sup>



Key: ASP – average sales price.  
 The quarterly drug spend for each product is estimated as: Drug spend=ASPxNormalized unit volume. The estimated spend for the reference product (after biosimilar launch) is trended out based on historical spend for the reference product before biosimilar launch.  
 Sources: AnalySource, Integrated Weekly Sales Data (IQVIA DDD + Chargeback).



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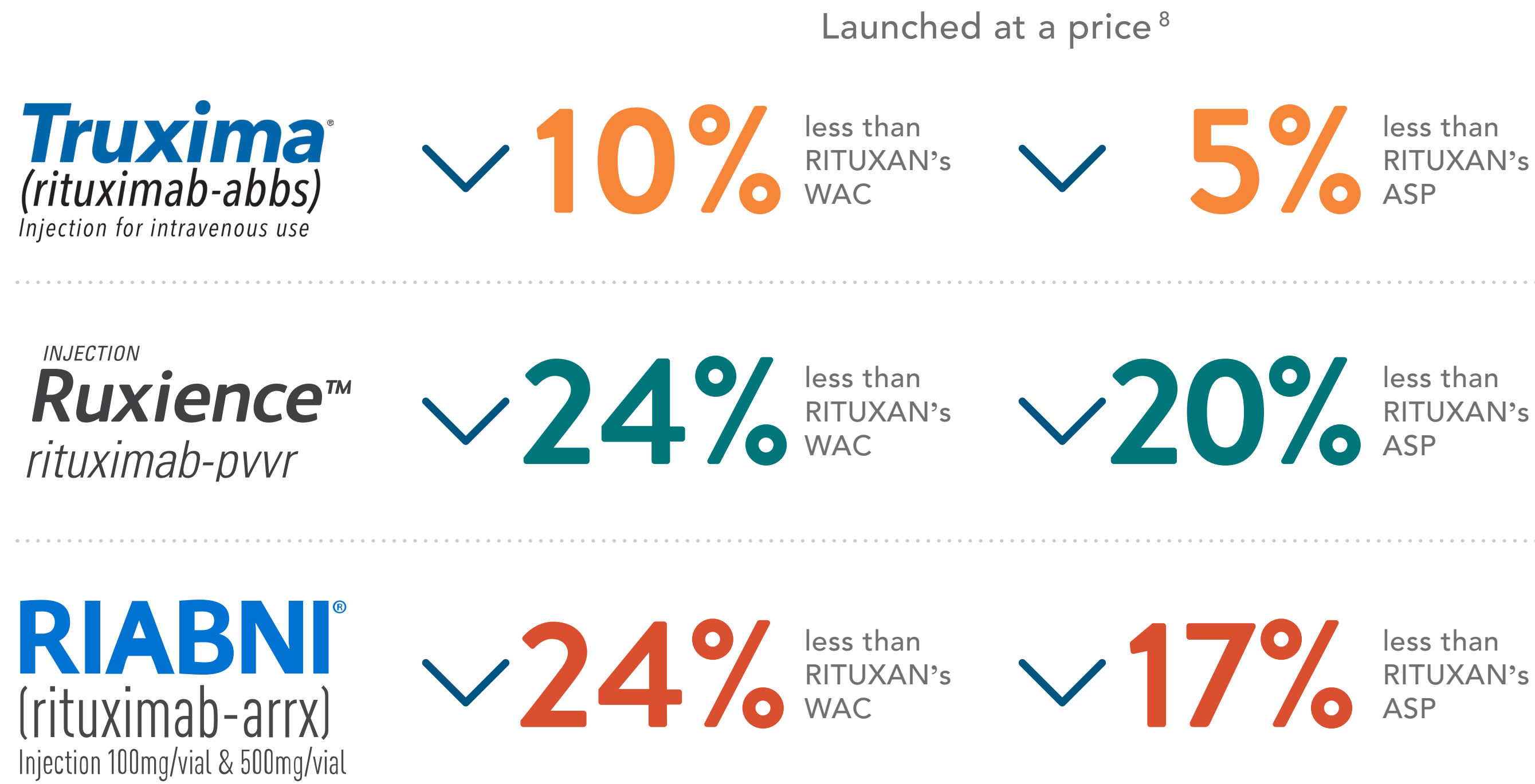


# ONCOLOGY THERAPEUTICS

## Rituximab



Three biosimilars have launched—in 2019, 2020, and 2021—to the reference product RITUXAN (rituximab):



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Please [click here](#) for Boxed Warning information for RIABNI.  
See [Full Prescribing Information](#) for complete risk information.

Key: ASP – average sales price; WAC – wholesale acquisition cost.

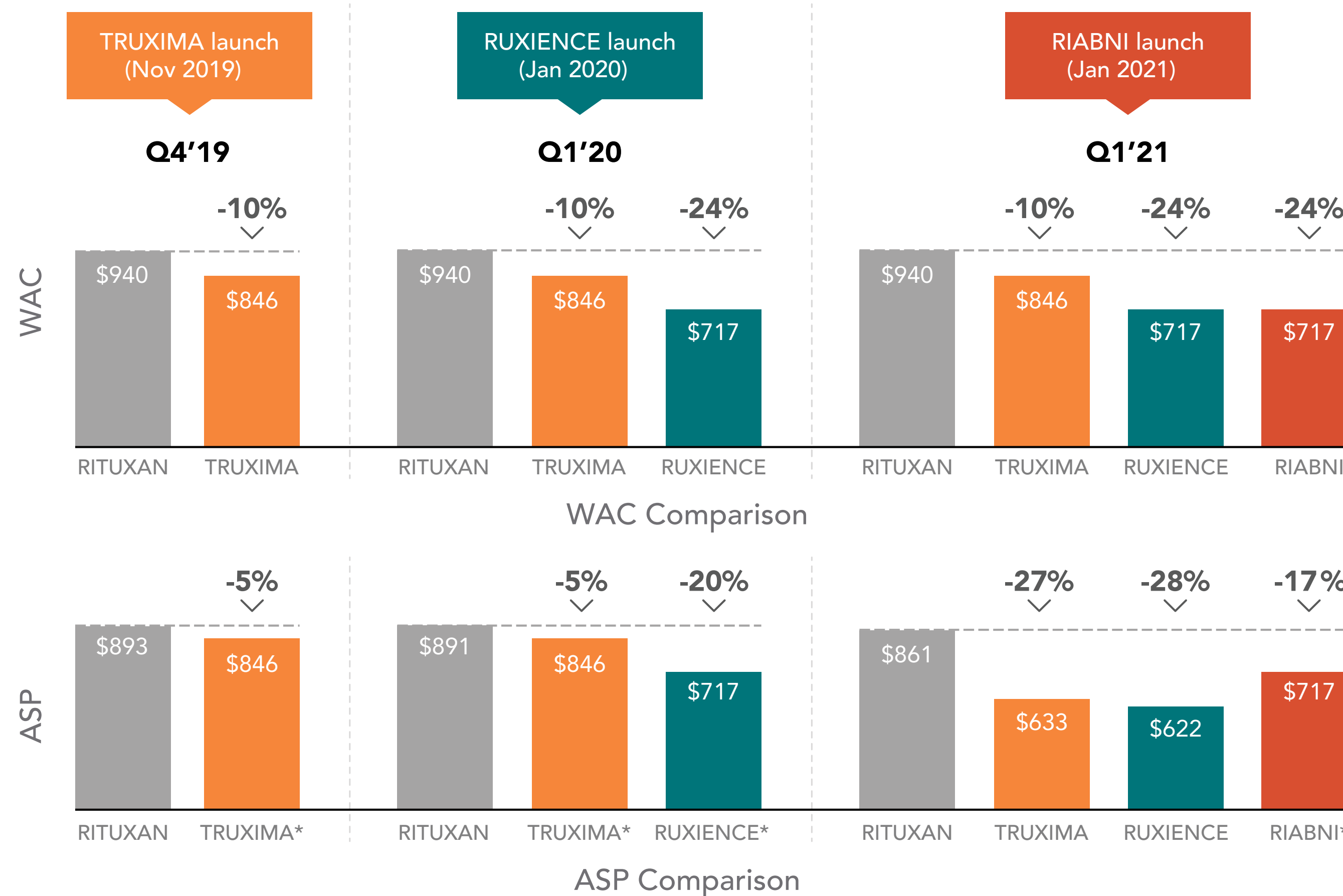
# ONCOLOGY THERAPEUTICS

## Rituximab



As **Figure 18** shows, in addition to all biosimilars launching at WAC and ASP discounts to the reference product, subsequent biosimilars launching after 2019 did so at a discount to the first rituximab biosimilar, TRUXIMA.

**Figure 18.** WAC and ASP of Rituximab Biosimilars Relative to Reference Product at Launch<sup>8</sup>



Please [click here](#) for Boxed Warning information for RIABNI.  
See [Full Prescribing Information](#) for complete risk information.

Key: ASP – average sales price; WAC – wholesale acquisition cost.  
\*ASP was not available for these products at the time of comparison. WAC is used to compare with reference product ASP.  
Source: AnalySource.

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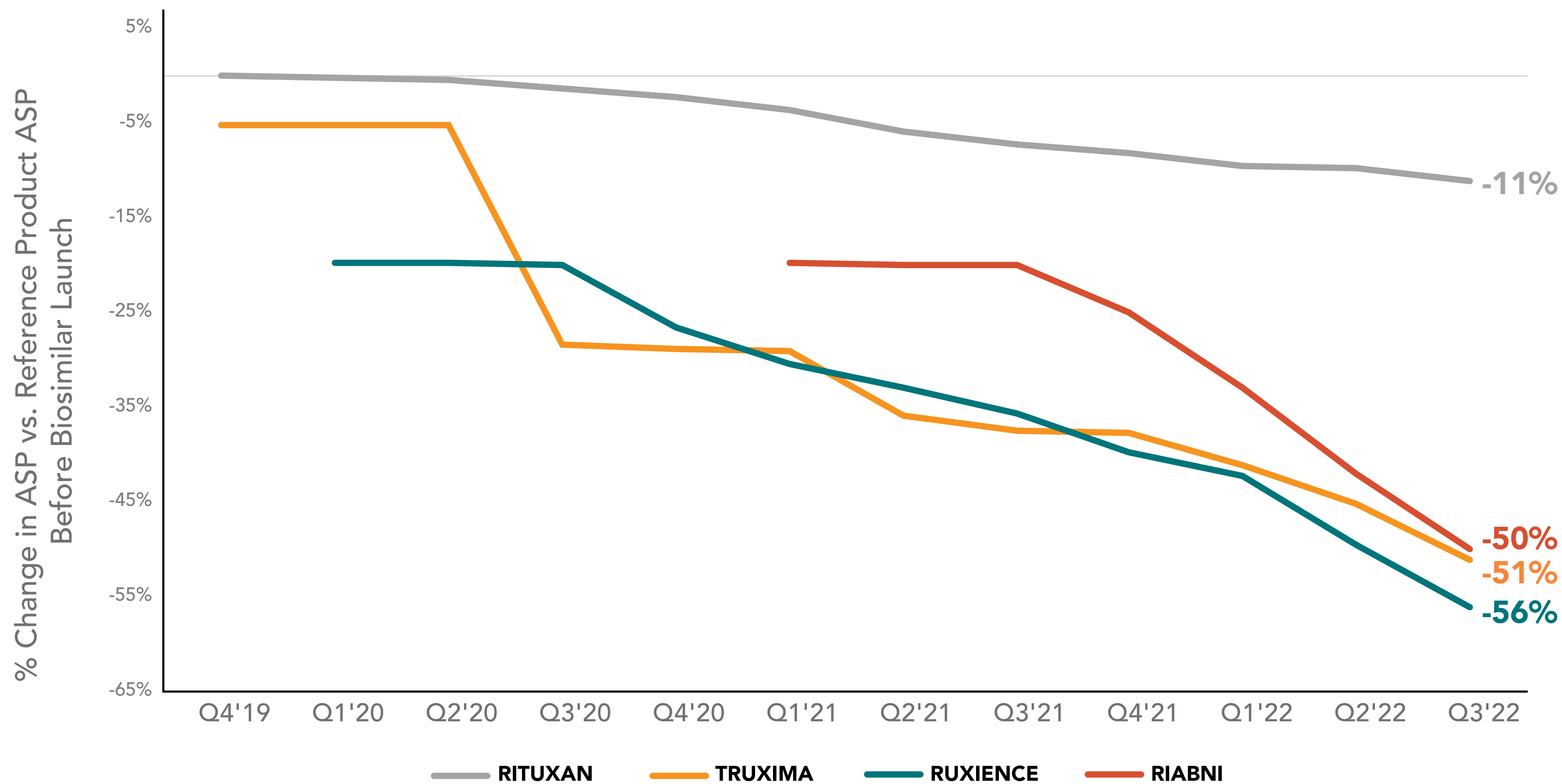
## Rituximab



**Figure 19** shows the percentage change in the price of biosimilars over time when compared to the reference product's ASP at the time that the first rituximab biosimilar launched.

**In under 3 years after the first launch, the price of rituximab biosimilars is now 50% to 56% lower than the price of their reference product RITUXAN in Q3 2022.**

**Figure 19.** ASP of Rituximab Products at Biosimilars' Launches<sup>8</sup>



Please [click here](#) for Boxed Warning information for RIABNI.  
See [Full Prescribing Information](#) for complete risk information.

Key: ASP – average sales price; WAC – wholesale acquisition cost.  
Biosimilar WAC is used for comparing against reference product ASP until biosimilar ASP is available.  
Source: AnalySource.

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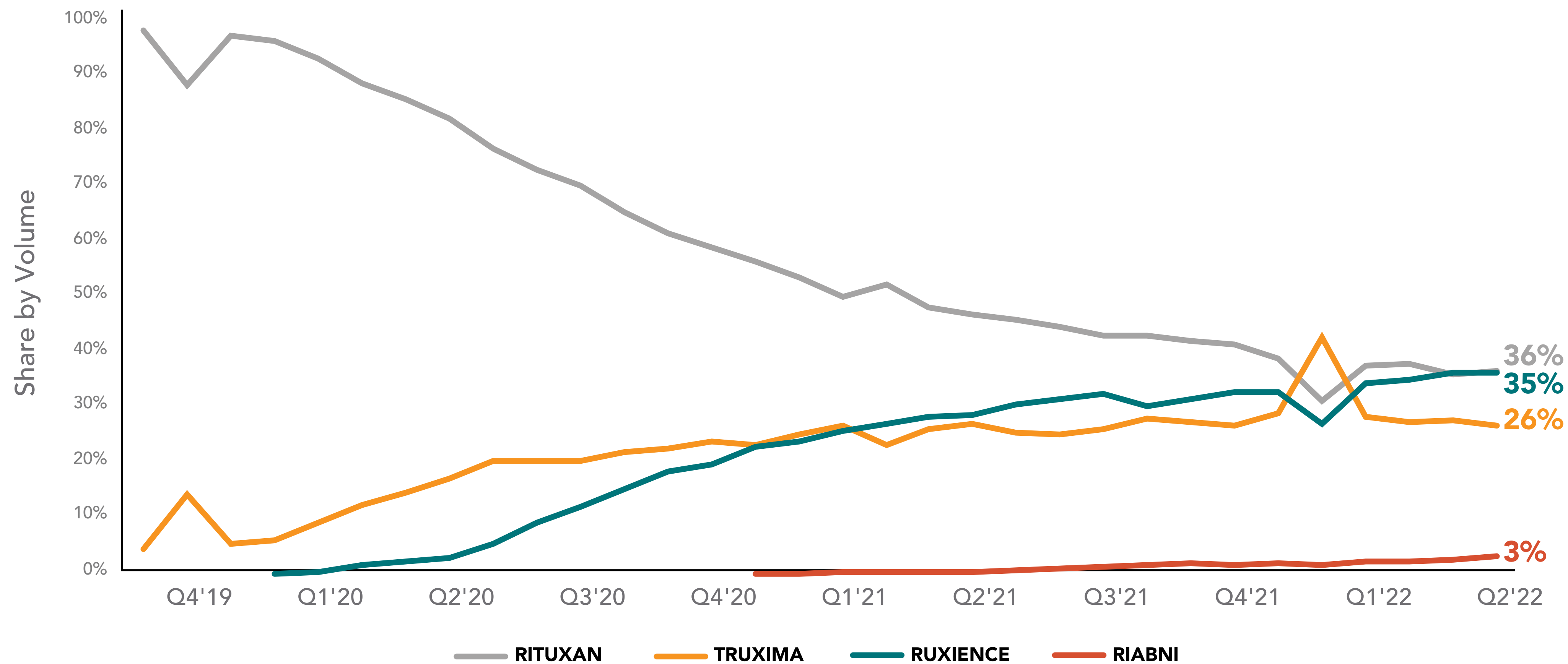
# ONCOLOGY THERAPEUTICS

## Rituximab

As seen in **Figure 20**, there has been a strong adoption of rituximab biosimilars, particularly after the second and third biosimilars launched beginning in 2020.

**In under 3 years after the first launch, biosimilars now account for 64% share of all rituximab products.**

**Figure 20.** Biosimilar Uptake Curve for Rituximab Products<sup>6</sup>



Please [click here](#) for Boxed Warning information for RIABNI.  
See [Full Prescribing Information](#) for complete risk information.

Source: OBU Customer Data Pack Weekly (IQVIA DDD + Chargeback).



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# ONCOLOGY THERAPEUTICS

## Rituximab

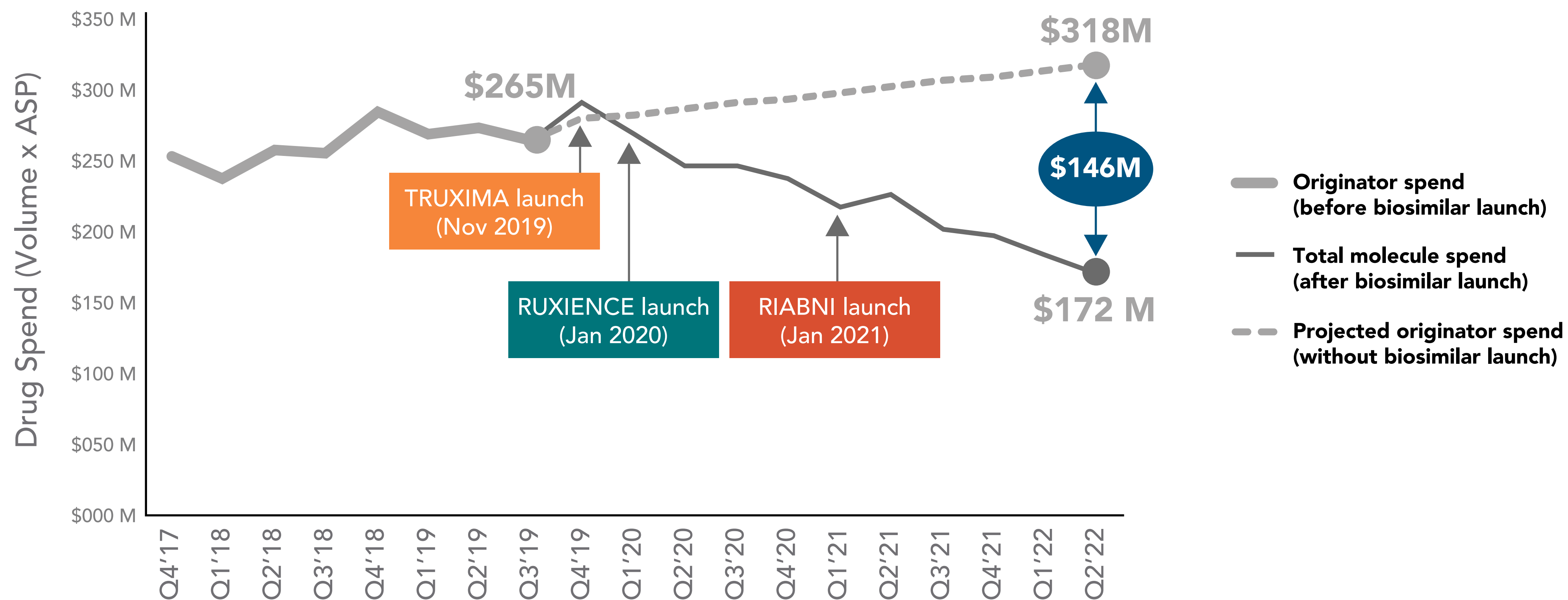


**Figure 21** shows the total drug spend for rituximab with biosimilar launches, compared to the projected drug spend in the absence of biosimilar competition. The total spend for rituximab started to decline following the launch of the first RITUXAN biosimilar TRUXIMA in Q4 2019, and continued to decline after the second biosimilar launch in Q1 2020.

**Spending on rituximab has decreased following the launch of RITUXAN biosimilars in Q4 2019, contributing to an estimated \$793 million in cumulative savings to date.**

**Without biosimilar competition, projected spending on rituximab could have been more than \$140M higher in Q2 2022.**

**Figure 21.** Comparison of Estimated Rituximab Drug Spend With vs. Without Biosimilar Competition <sup>3</sup>



Please [click here](#) for Boxed Warning information for RIABNI.  
See [Full Prescribing Information](#) for complete risk information.

Key: ASP – average sales price.  
The quarterly drug spend for each product is estimated as: Drug spend=ASPxNormalized unit volume. The estimated spend for the reference product (after biosimilar launch) is trended out based on historical spend for the reference product before biosimilar launch.  
Sources: AnalySource, Integrated Weekly Sales Data (IQVIA DDD + Chargeback).

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# ONCOLOGY SUPPORTIVE CARE



The biosimilars available for oncology supportive care consist of **pegfilgrastim** and **filgrastim** products. For each, we discuss:

- **WAC and ASP of the biosimilar at launch compared to the reference product**

---

- **ASP for the reference product and biosimilars since launch**

---

- **Biosimilar uptake**

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- **Estimated difference in total drug spend after biosimilar competition**



*Oncology supportive care is the most mature US biosimilar category.*

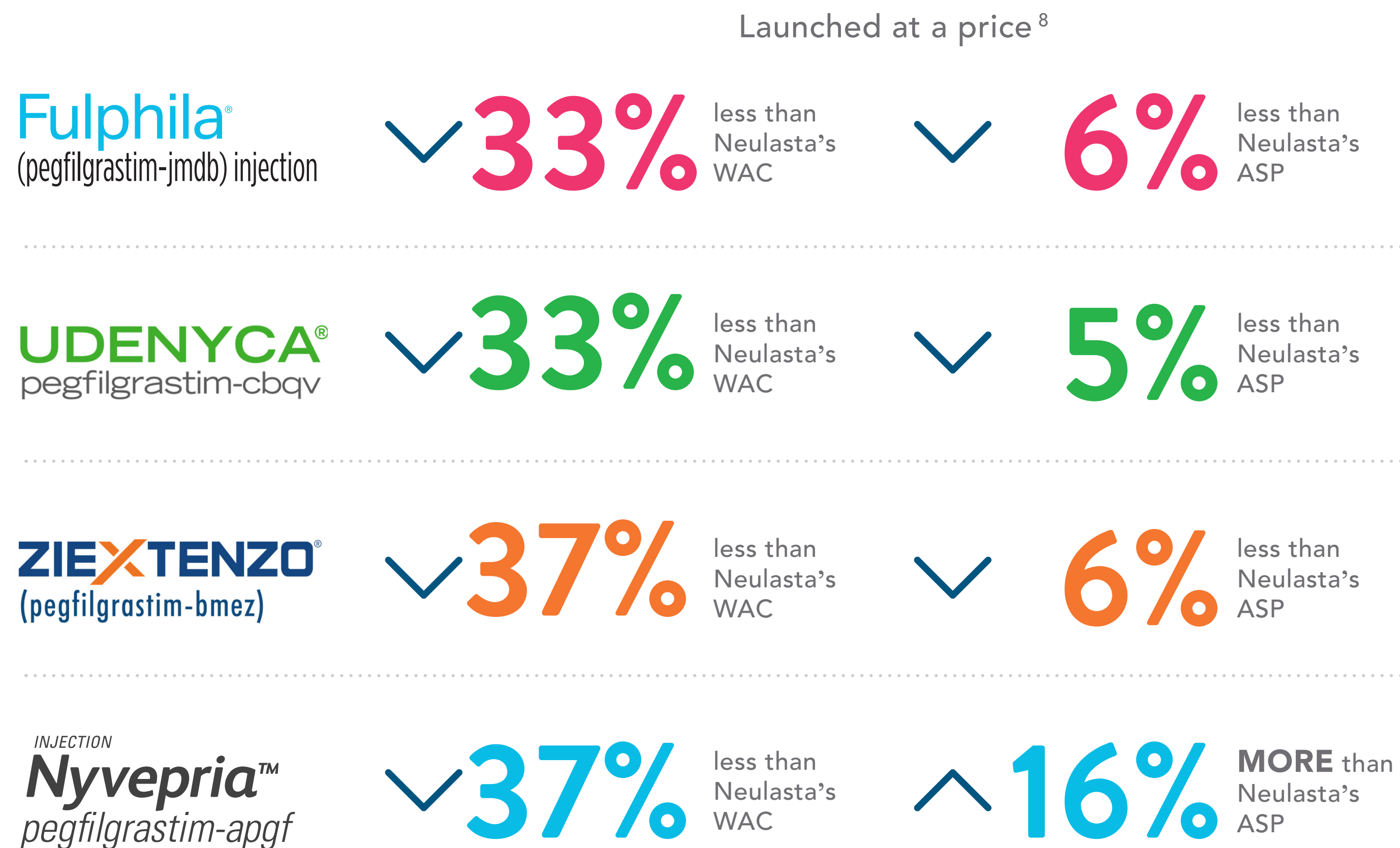
The FDA approved GRANIX in 2012, though not as a biosimilar under the pathway created in the US by the Biologics Price Competition and Innovation Act (BPCIA).<sup>49</sup> It was approved under a stand-alone Biologics License Application, which was submitted to the FDA before the enactment of the biosimilar approval pathway.<sup>49</sup> ZARXIO was the first biosimilar approved in the US (in 2015) and also the first biosimilar to become commercially available (also in 2015).<sup>50</sup> As such, this category provides insights into how biosimilars and their reference products may change over time, as well as how biosimilars may gain share over a period of 5 years.

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# ONCOLOGY SUPPORTIVE CARE

## Pegfilgrastim

Four biosimilars have launched since 2018 to the reference product Neulasta (pegfilgrastim):



See Neulasta [Full Prescribing Information](#) for complete risk information.

Key: ASP – average sales price; WAC – wholesale acquisition cost.



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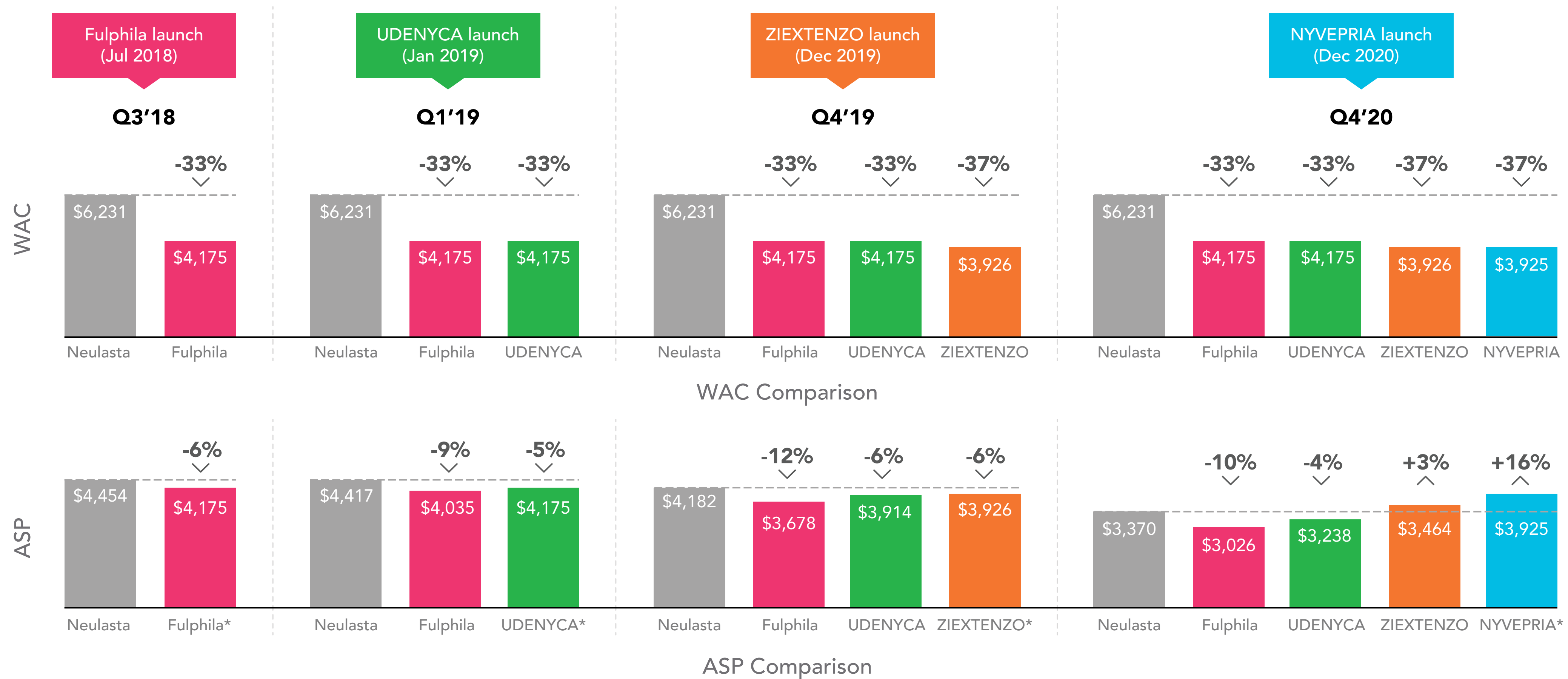
# ONCOLOGY SUPPORTIVE CARE

## Pegfilgrastim



As **Figure 22** shows, all 4 biosimilars launched between a 33% to 37% discount to the reference product Neulasta's WAC. While the first 3 pegfilgrastim biosimilars launched at discounts, the fourth pegfilgrastim biosimilar launched at a premium to the ASP of the reference product. The second, third, and fourth pegfilgrastim biosimilars also launched at premiums to the ASP of Fulphila (the first pegfilgrastim biosimilar).

**Figure 22.** WAC and ASP of Pegfilgrastim Biosimilars Relative to Reference Product at Launch<sup>8</sup>



See Neulasta [Full Prescribing Information](#) for complete risk information.

Key: ASP – average sales price; WAC – wholesale acquisition cost.  
 \*ASP was not available for these products at the time of comparison. WAC is used to compare with reference product ASP.  
 Source: AnalySource.

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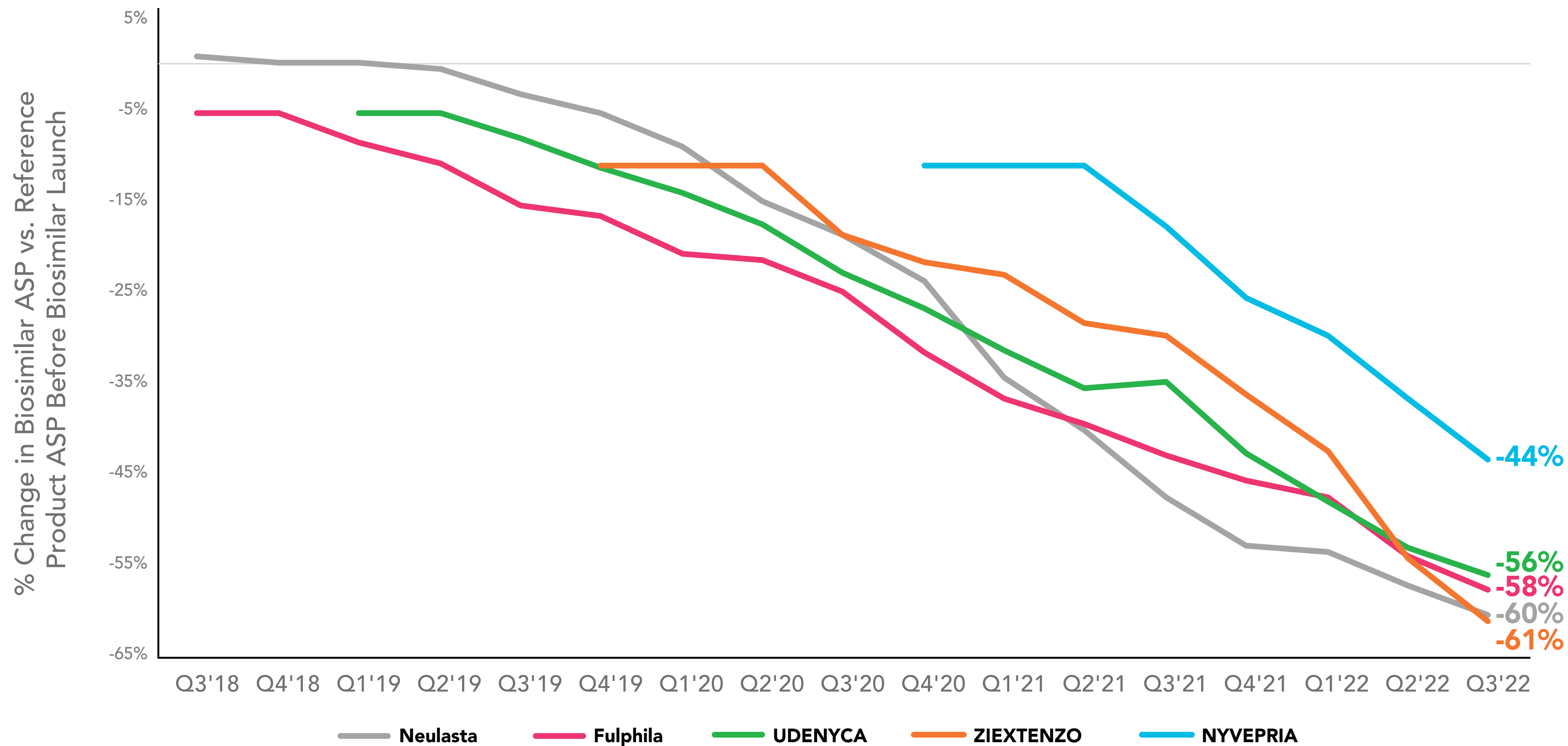
# ONCOLOGY SUPPORTIVE CARE

## Pegfilgrastim

**Figure 23** shows the percentage change in the price of biosimilars over time when compared to the reference product's ASP at the time that the first pegfilgrastim biosimilar launched.

**ASPs for all pegfilgrastim products have continued to decline over time, particularly in the last 2 years with 2 additional biosimilar launches. The reference product Neulasta's price has declined by 60% over the last 4 years since the first pegfilgrastim biosimilar was launched.**

**Figure 23.** ASP of Pegfilgrastim Products at Biosimilars' Launches<sup>8</sup>



See Neulasta [Full Prescribing Information](#) for complete risk information.

Key: ASP – average sales price; WAC – wholesale acquisition cost.  
Biosimilar WAC is used for comparing against reference product ASP until biosimilar ASP is available.  
Source: AnalySource.



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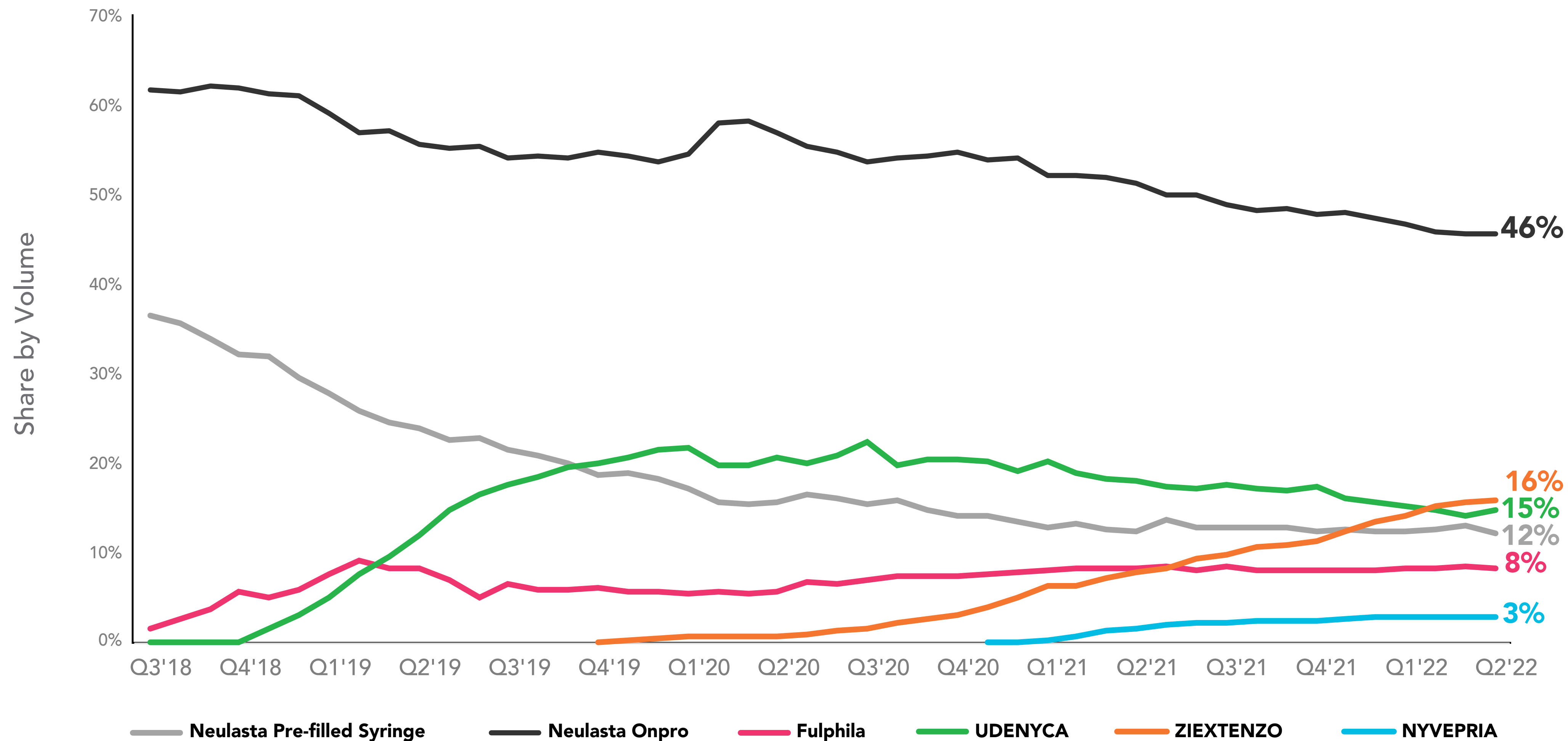
# ONCOLOGY SUPPORTIVE CARE

## Pegfilgrastim

As seen in **Figure 24**, pegfilgrastim biosimilars show a different uptake pattern than other biosimilars, where the first biosimilar to launch captured the most share. By comparison, the leading pegfilgrastim biosimilar by share was UDENYCA, which was the second pegfilgrastim biosimilar to launch, until Q2 2022 when ZIEXTENZO captured more share.

**With 4 biosimilars now launched and available in the US, biosimilars account for 42% of all pegfilgrastim products.**

**Figure 24.** Biosimilar Uptake Curve for Pegfilgrastim Products<sup>6</sup>



See Neulasta [Full Prescribing Information](#) for complete risk information.

Key: US – United States.  
Source: OBU Customer Data Pack Weekly (IQVIA DDD + Chargeback).



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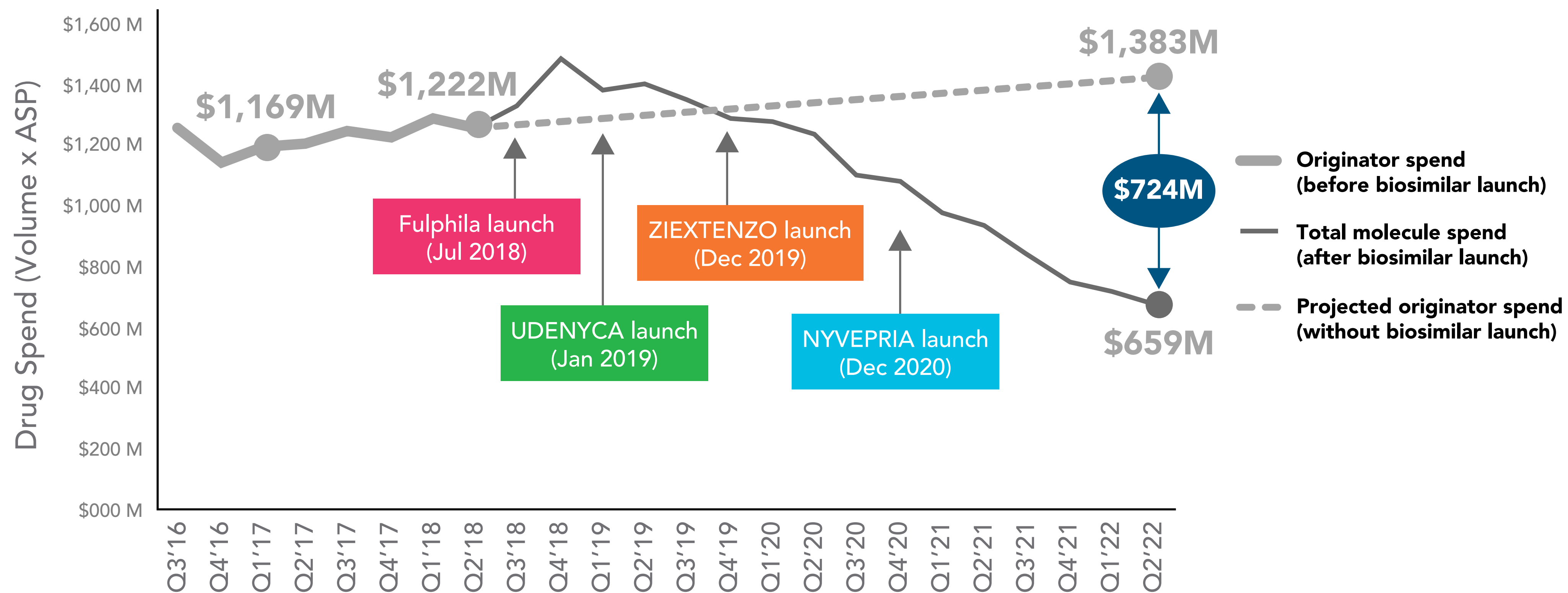
## Pegfilgrastim

**Figure 25** shows the total drug spend for pegfilgrastim with biosimilar launches, compared to the projected drug spend in the absence of biosimilar competition.

**After an initial increase, drug spend for pegfilgrastim has steadily declined overall since Q4 2018, resulting in an estimated cumulative savings of \$3.6 billion to date.**

**Without biosimilar competition, projected spending on pegfilgrastim could have been more than \$720M higher in Q2 2022.**

**Figure 25.** Comparison of Estimated Pegfilgrastim Drug Spend With vs. Without Biosimilar Competition<sup>3</sup>



See Neulasta [Full Prescribing Information](#) for complete risk information.

Key: ASP – average sales price.  
 The quarterly drug spend for each product is estimated as: Drug spend=ASPxNormalized unit volume. The estimated spend for the reference product (after biosimilar launch) is trended out based on historical spend for the reference product before biosimilar launch.  
 Sources: AnalySource, Integrated Weekly Sales Data (IQVIA DDD + Chargeback).



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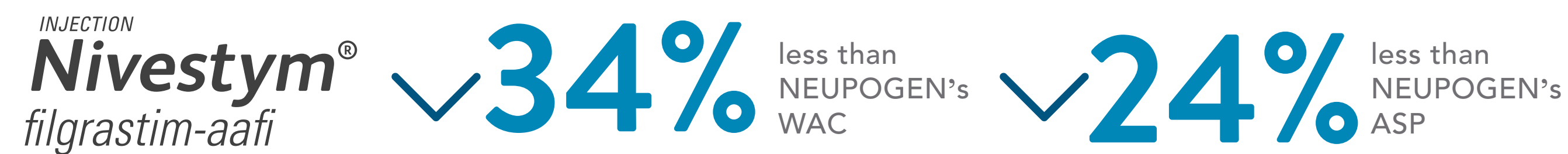
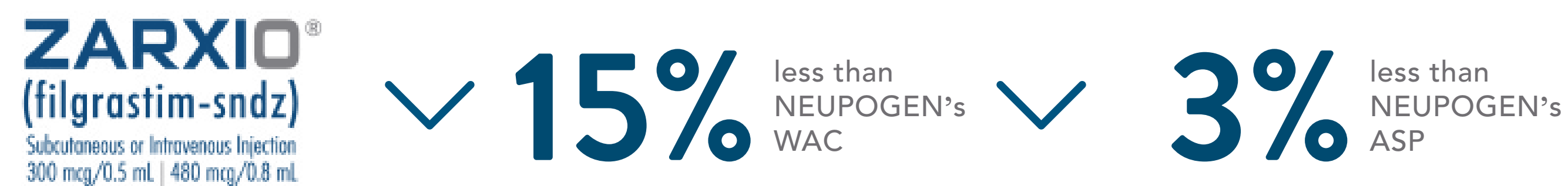
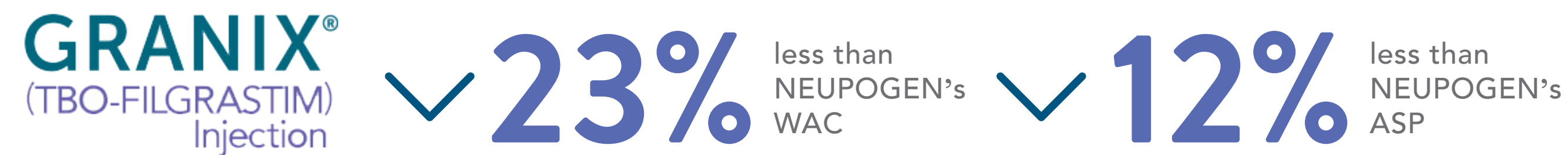
# ONCOLOGY SUPPORTIVE CARE

## Filgrastim



Two biosimilars to the reference product NEUPOGEN (filgrastim) have been launched since 2015, as well as GRANIX in 2013:

Launched at a price<sup>8</sup>



**GRANIX is not a biosimilar. It was approved under a stand-alone Biologics License Application, which was submitted to the FDA before the enactment of the biosimilar approval pathway.<sup>49</sup>**

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See NEUPOGEN [Full Prescribing Information](#) for complete risk information.

Key: ASP – average sales price; FDA – Food and Drug Administration; WAC – wholesale acquisition cost.

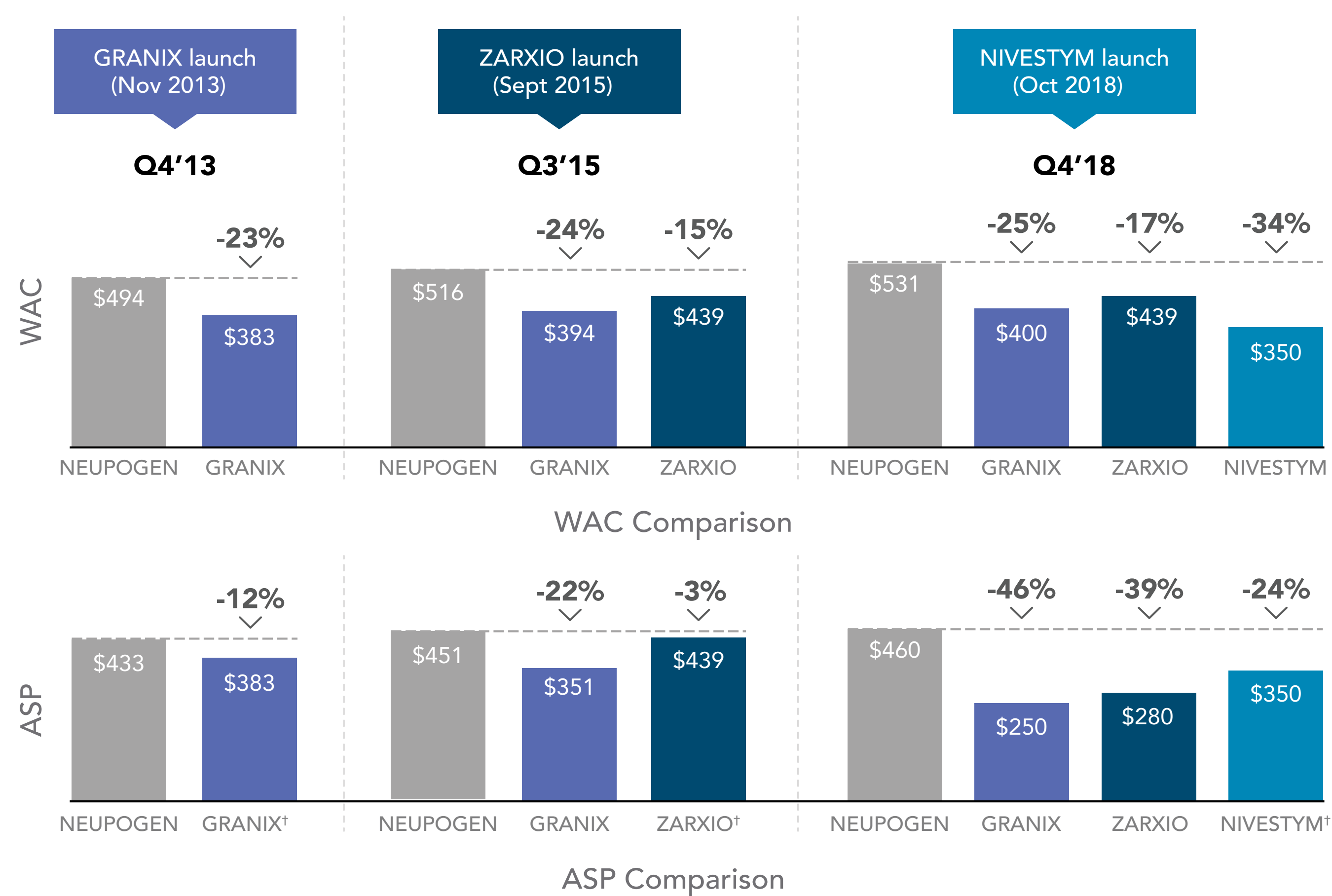
# ONCOLOGY SUPPORTIVE CARE

## Filgrastim



As **Figure 26** shows, in addition to both biosimilars and GRANIX\* launching at WAC and ASP discounts to the reference product, biosimilar NIVESTYM launched at a discounted WAC compared to the first biosimilar, ZARXIO.

**Figure 26.** WAC and ASP of GRANIX and Filgrastim Biosimilars Relative to Reference Product at Launch<sup>8</sup>



See **NEUPOGEN Full Prescribing Information** for complete risk information.

Key: ASP – average sales price; BLA – Biologics License Application; FDA – Food and Drug Administration; WAC – wholesale acquisition cost.

\*GRANIX is not a biosimilar. It was approved under a full BLA, which was submitted to the FDA before the enactment of the biosimilar approval pathway.

†ASP was not available for these products at the time of comparison. WAC is used to compare with reference product ASP.

Source: AnalySource.

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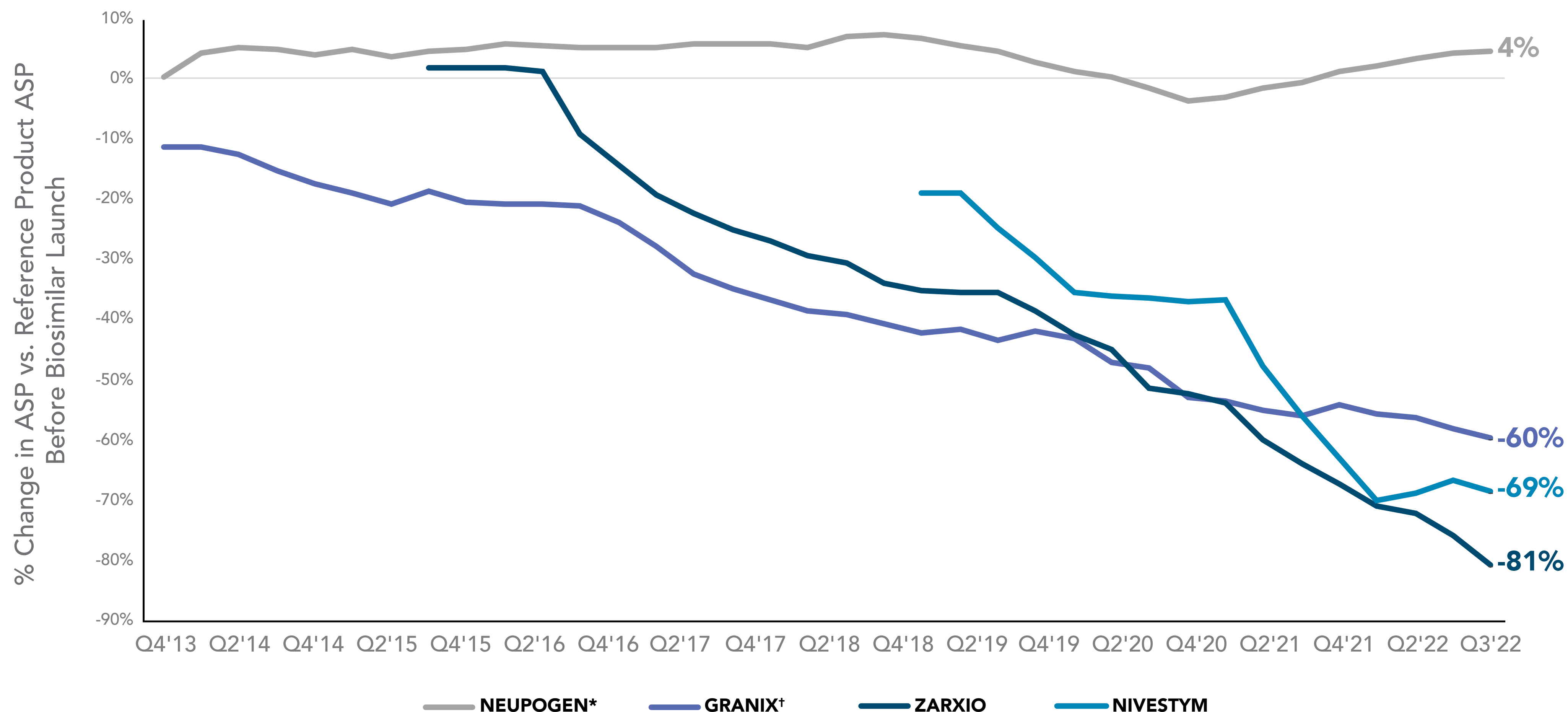
# ONCOLOGY SUPPORTIVE CARE

## Filgrastim

**Figure 27** shows the percentage change in price over time when compared to NEUPOGEN's ASP at the time GRANIX launched. By 2021, both filgrastim biosimilars and GRANIX saw significant decreases in their ASPs, while the ASP for reference product NEUPOGEN has remained relatively stable.

**The price of filgrastim biosimilars is now 60% to 81% lower than the price of reference product NEUPOGEN in Q3 2022.**

**Figure 27.** ASP of Filgrastim Products at Biosimilars' Launches<sup>8</sup>



See **NEUPOGEN Full Prescribing Information** for complete risk information.

Key: ASP – average sales price; BLA – Biologics License Application; FDA – Food and Drug Administration; WAC – wholesale acquisition cost.  
 \*NEUPOGEN's biosimilar price-response strategy focused on account-level provider contracting. This targeted approach modestly increased the ASP-eligible discount rate, resulting in a more stable ASP trend.  
 †GRANIX is not a biosimilar. It was approved under a full BLA, which was submitted to the FDA before the enactment of the biosimilar approval pathway.  
 Biosimilar WAC is used for comparing against reference product ASP until biosimilar ASP is available.  
 Source: AnalySource.



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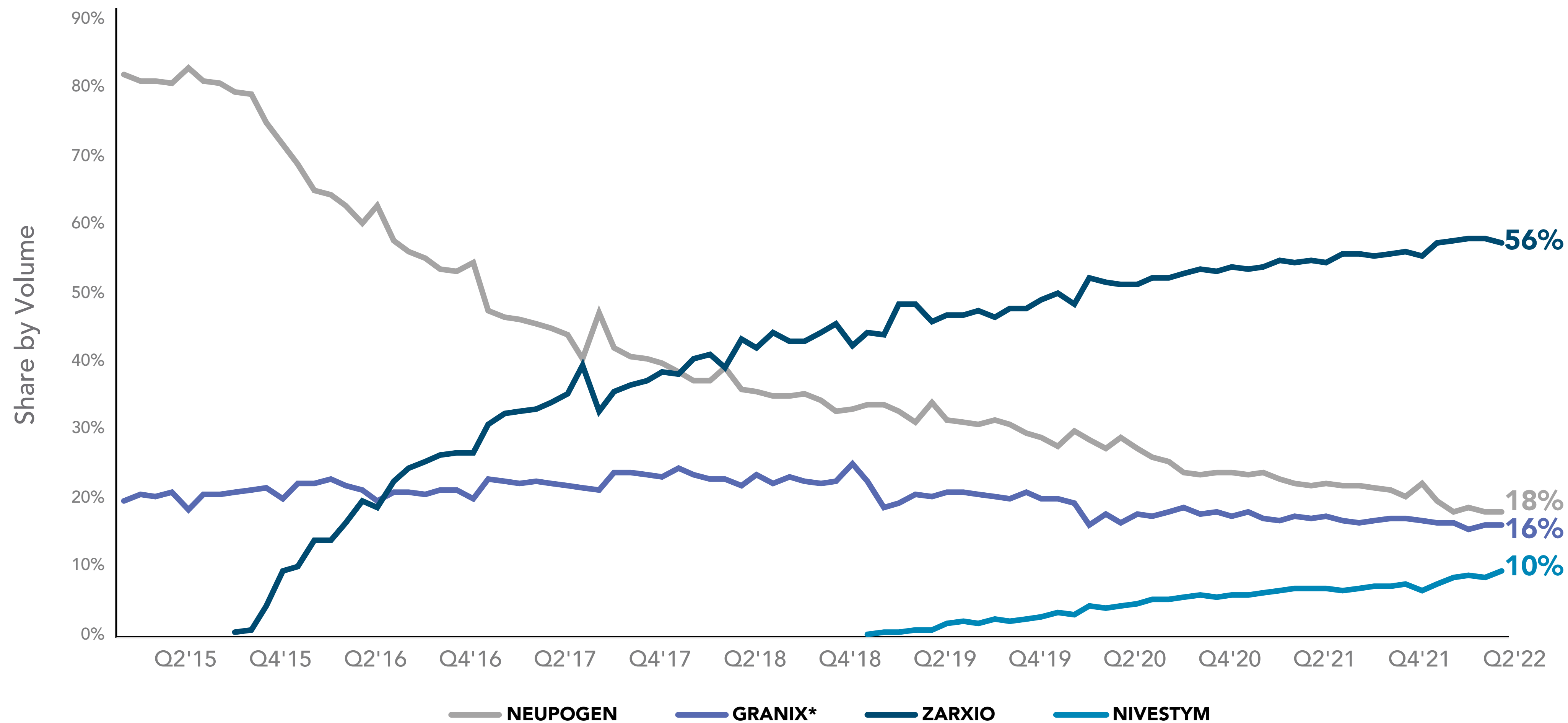
# ONCOLOGY SUPPORTIVE CARE

## Filgrastim

As seen in **Figure 28**, filgrastim biosimilars account for a majority of share when compared to reference product NEUPOGEN. After 2.5 years, the first filgrastim biosimilar ZARXIO captured more share than the reference product NEUPOGEN.

**As of Q2 2022, biosimilars and GRANIX account for 82% share of all filgrastim products.**

**Figure 28. Uptake Curve for Filgrastim Products<sup>6</sup>**



See **NEUPOGEN Full Prescribing Information** for complete risk information.

Key: BLA – Biologics License Application; FDA – Food and Drug Administration.  
 \*GRANIX is not a biosimilar. It was approved under a full BLA, which was submitted to the FDA before the enactment of the biosimilar approval pathway.  
 Source: OBU Customer Data Pack Weekly (IQVIA DDD + Chargeback).



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# NEPHROLOGY/ONCOLOGY SUPPORTIVE CARE



For nephrology/oncology supportive care, we look at **epoetin alfa** products. We discuss:

- WAC and ASP of the biosimilar at launch compared to the reference product

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- ASP for the reference product and biosimilars since launch

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- Biosimilar uptake

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- Estimated difference in total drug spend after biosimilar competition



***EPOGEN and PROCRIT are the same molecule; however, they are marketed by 2 different companies in separate therapeutic areas. In addition, they have independent WACs but the same ASP.***

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Please [click here](#) for Boxed Warning information for EPOGEN. See [Full Prescribing Information](#) for complete risk information.

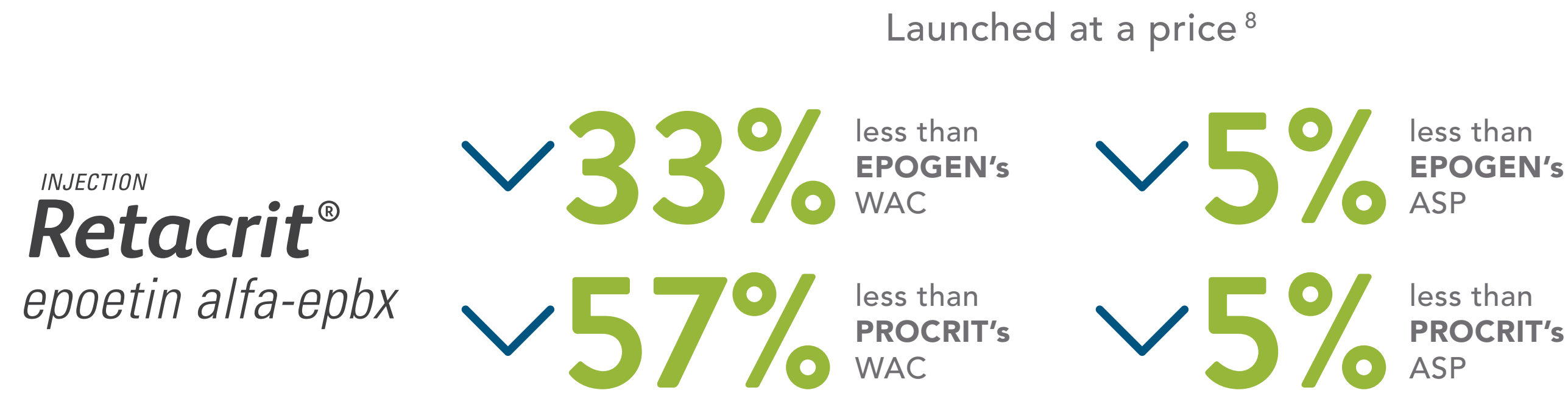


# NEPHROLOGY/ONCOLOGY SUPPORTIVE CARE

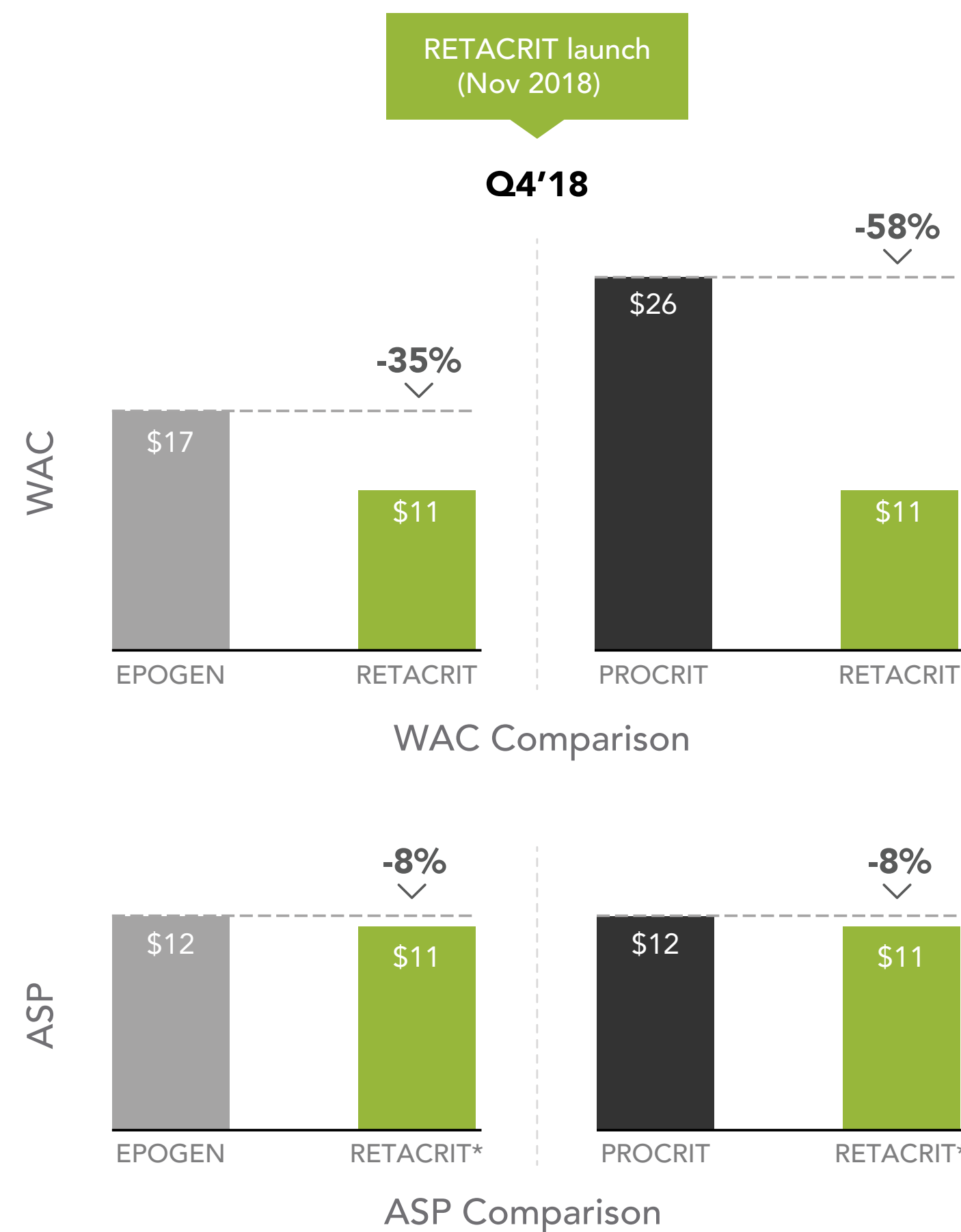
## Epoetin alfa



One biosimilar has launched since 2018 to the reference products EPOGEN and PROCIT (epoetin alfa):



**Figure 29.** WAC and ASP of Epoetin Alfa Biosimilar Relative to Reference Products at Launch<sup>8</sup>



Please [click here](#) for Boxed Warning information for EPOGEN.  
See [Full Prescribing Information](#) for complete risk information.

Key: ASP – average sales price; WAC – wholesale acquisition cost.  
\*ASP was not available for these products at the time of comparison. WAC is used to compare with reference product ASP.  
Source: AnalySource.

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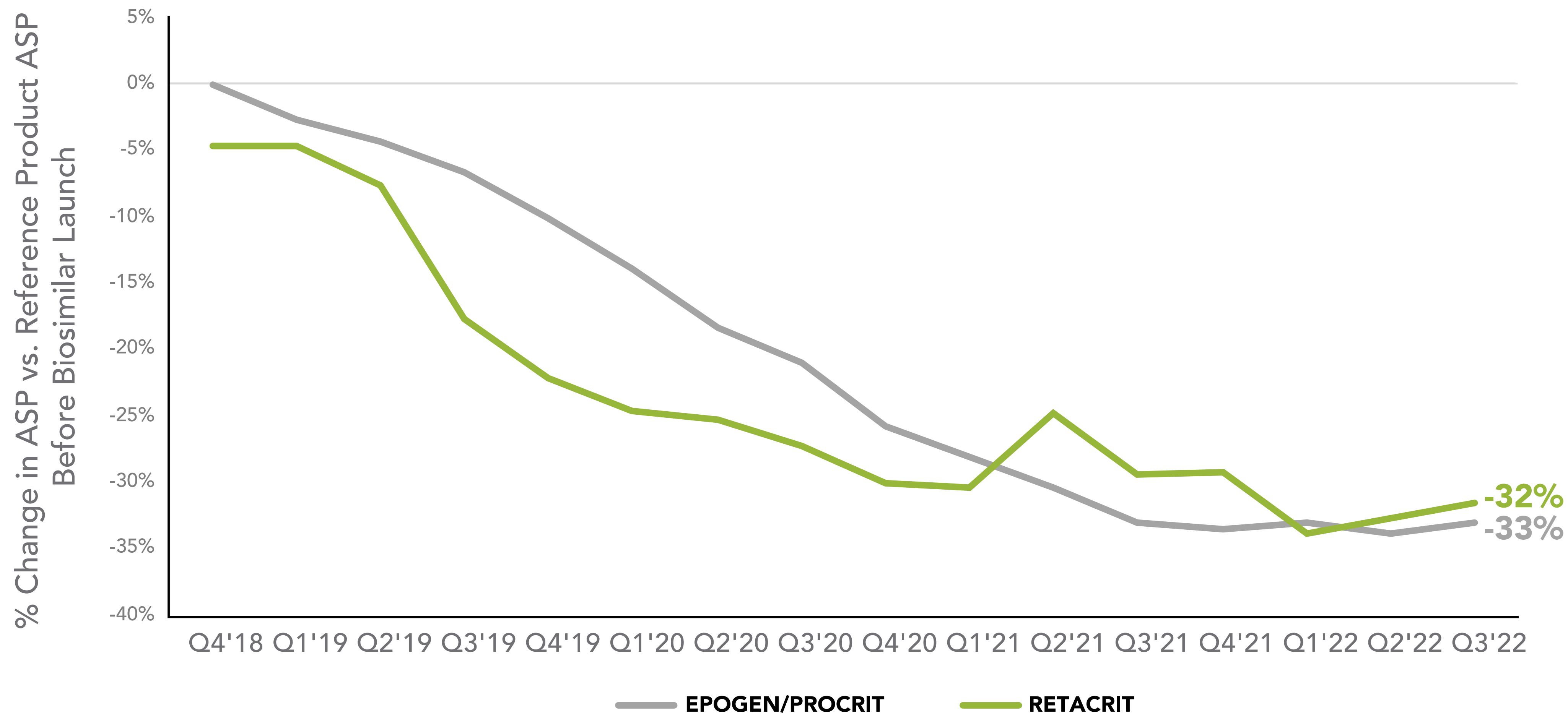


## Epoetin alfa

**Figure 30** shows the percentage change in the price of the biosimilar over time when compared to the reference products' ASP at the time that the first epoetin alfa biosimilar launched. Following the establishment of RETACRIT's ASP in April 2019, it declined dramatically, then increased in Q2 2021, then mostly continued to trend lower since then.

**The reference product EPOGEN/PROCRIT's price has declined by 33% since the first epoetin alfa biosimilar was launched.**

**Figure 30.** ASP of Epoetin Alfa Products at Biosimilar's Launch<sup>8</sup>



Please [click here](#) for Boxed Warning information for EPOGEN.  
See [Full Prescribing Information](#) for complete risk information.

Key: ASP – average sales price; WAC – wholesale acquisition cost.  
Biosimilar WAC is used for comparing against reference product ASP until biosimilar ASP is available.  
Source: AnalySource.

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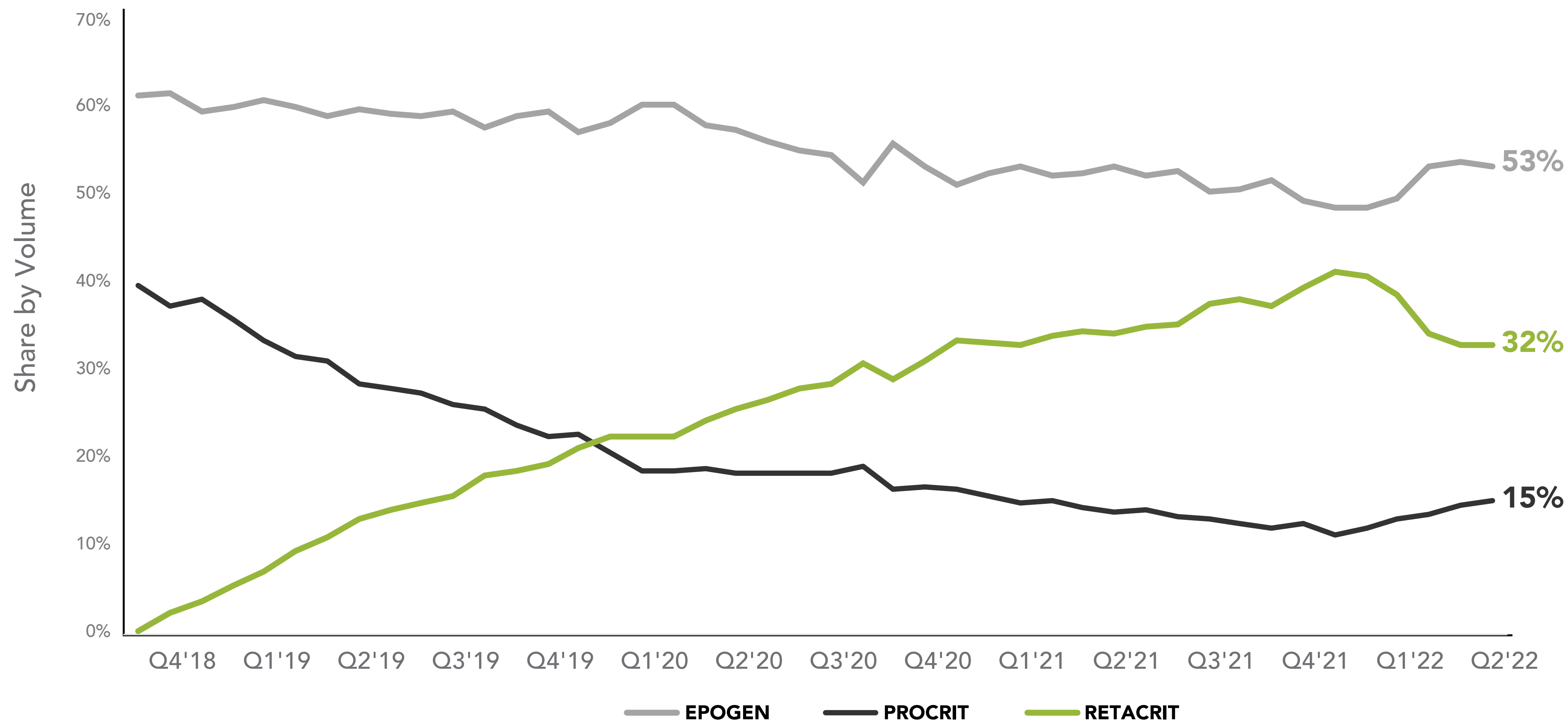


## Epoetin alfa

As seen in **Figure 31**, the epoetin alfa biosimilar RETACRIT has continued to increase its share over time, while reference products EPOGEN and PROCIT's share have remained relatively stable or declined, respectively. By Q1 2020 (5 quarters after its launch), RETACRIT had captured more share than the reference product PROCIT.

**As of Q2 2022, RETACRIT has now captured 32% share among epoetin alfa products.**

**Figure 31.** Biosimilar Uptake Curve for Epoetin Alfa Products<sup>6</sup>



Please [click here](#) for Boxed Warning information for EPOGEN. See [Full Prescribing Information](#) for complete risk information.

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# NEPHROLOGY/ONCOLOGY SUPPORTIVE CARE



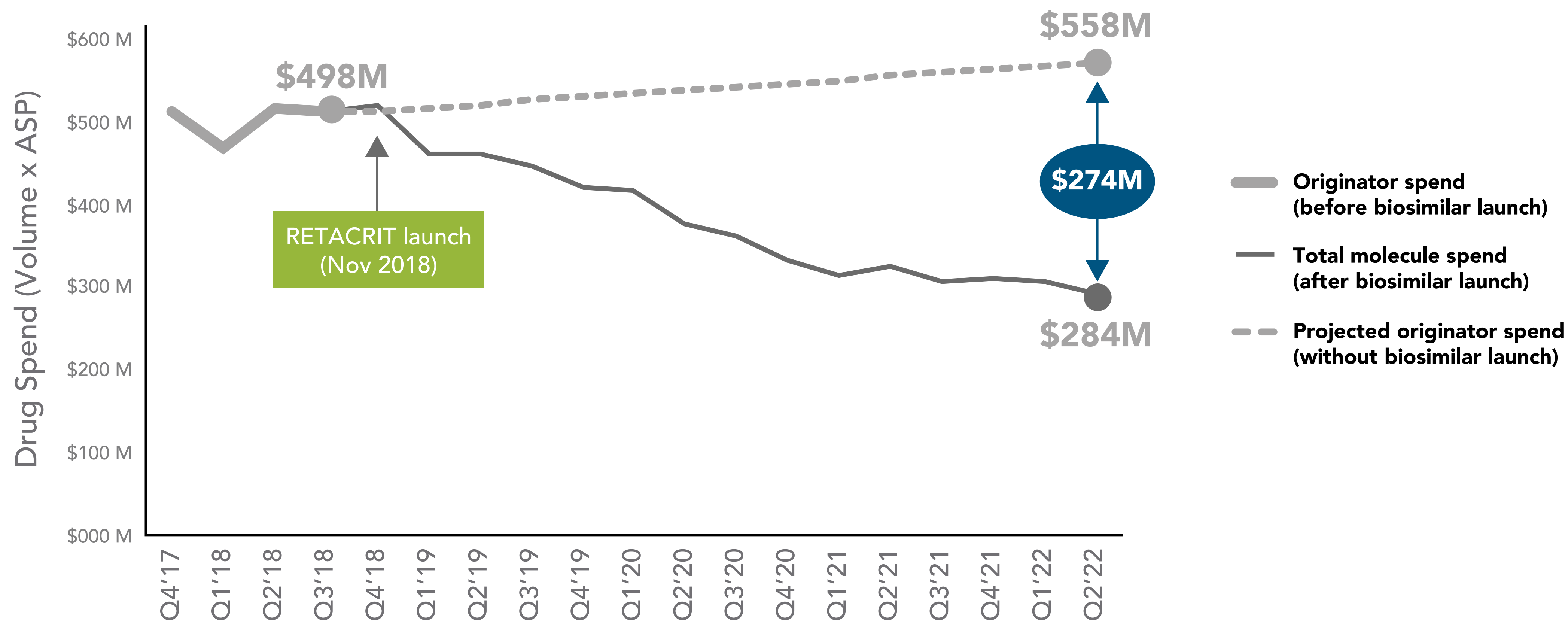
## Epoetin alfa

**Figure 32** shows the total drug spend for epoetin alfa with biosimilar launches, compared to the projected drug spend in the absence of biosimilar competition.

**The cumulative savings in drug spend for epoetin alfa from the first EPOGEN/PROCRIT biosimilar launch in Q4 2018 to Q2 2022 is estimated to be \$2.4 billion to date.**

**Without biosimilar competition, projected spending on epoetin alfa could have been more than \$270M higher in Q2 2022.**

**Figure 32.** Comparison of Estimated Epoetin Alfa Drug Spend With vs. Without Biosimilar Competition<sup>3</sup>



Please [click here](#) for Boxed Warning information for EPOGEN.  
See [Full Prescribing Information](#) for complete risk information.

Key: ASP – average sales price.  
The quarterly drug spend for each product is estimated as: Drug spend=ASPxNormalized unit volume. The estimated spend for the reference product (after biosimilar launch) is trended out based on historical spend for the reference product before biosimilar launch.  
Sources: AnalySource, Integrated Weekly Sales Data (IQVIA DDD + Chargeback).

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# INFLAMMATION

For inflammation, we look at **infliximab** products. We discuss:

- **WAC and ASP of the biosimilar at launch compared to the reference product**

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- **ASP for the reference product and biosimilars since launch**

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- **Biosimilar uptake**

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- **Estimated difference in total drug spend after biosimilar competition**

In the next few years, patients with inflammation diseases will likely have access to more treatment options due to increasing biosimilar availability. Based on historical performance of biosimilar competition in other disease states, this may lead to cost savings for the healthcare system.



*Two of the 10 best-selling medicines are anti-inflammatory biologics, neither of which has biosimilar competition in the US.<sup>35</sup>*



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# INFLAMMATION

## Infliximab

Three biosimilars (and one unbranded infliximab product\*) have launched—in 2016, 2017, 2020, and 2022—to the reference product REMICADE (infliximab):



Please [click here](#) for Boxed Warning information for AVSOLA.  
 See [Full Prescribing Information](#) for complete risk information.

Key: ASP – average sales price; WAC – wholesale acquisition cost.  
 \*In 2021, Janssen (manufacturer of REMICADE) released unbranded infliximab in the market. This specific unbranded infliximab is not a biosimilar. It is REMICADE sold under a different name.<sup>51</sup>  
<sup>†</sup>The unbranded infliximab product launched at the same ASP as REMICADE.



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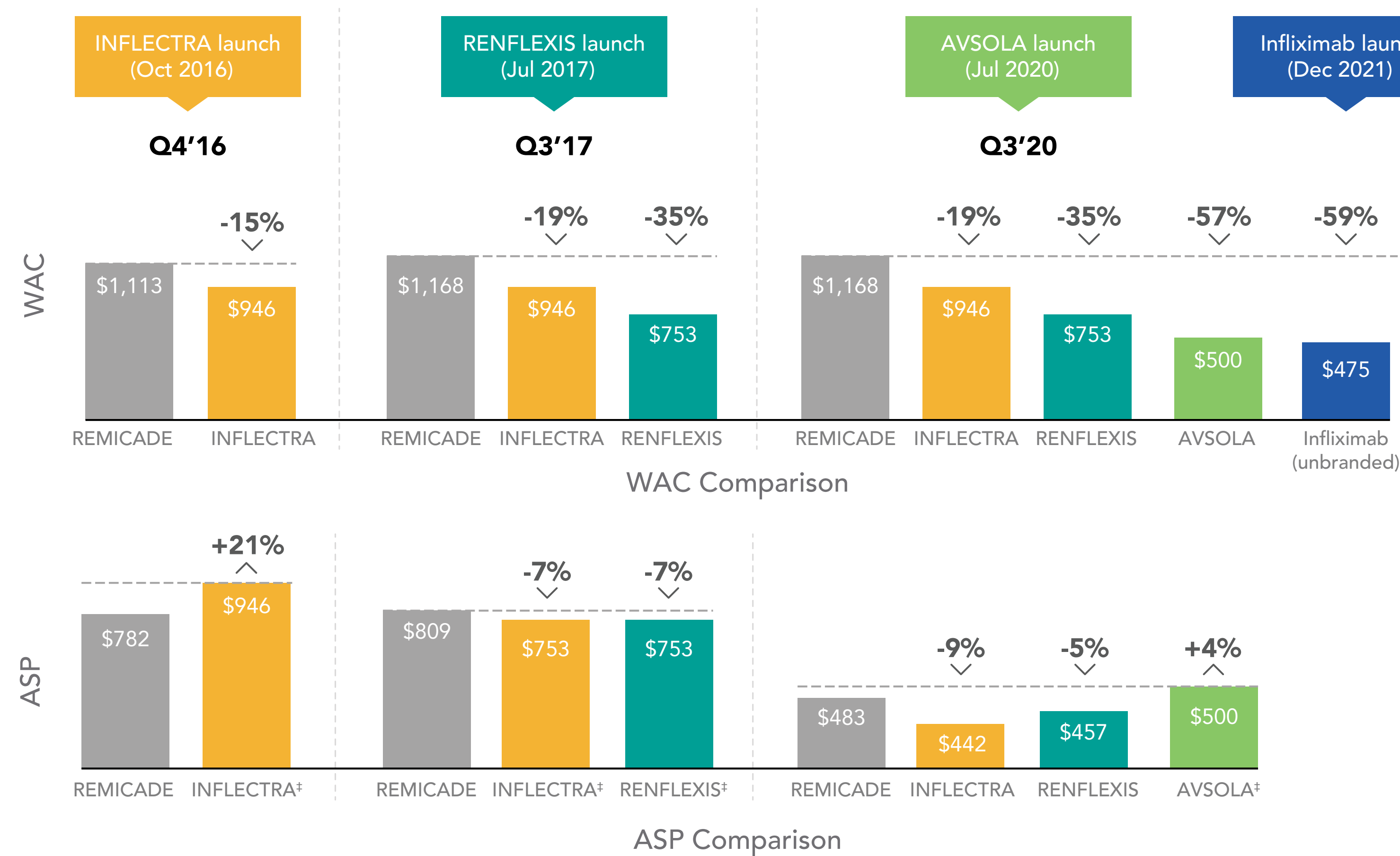
# INFLAMMATION

## Infliximab



As **Figure 33** shows, all infliximab biosimilars launched at WAC discounts to the reference product. The majority of biosimilars in the US have launched with discounts to the reference product's ASP; however, INFLECTRA and AVSOLA launched at a premium to the reference product REMICADE's ASP. The infliximab (unbranded) product launched at the same price as REMICADE's ASP.\* RENFLEXIS also launched at a WAC discount to the first biosimilar, INFLECTRA, and provided WAC and ASP discounts compared with the reference product.

**Figure 33. WAC and ASP of Infliximab Biosimilars Relative to Reference Product at Launch<sup>8</sup>**



Please [click here](#) for Boxed Warning information for AVSOLA.  
See [Full Prescribing Information](#) for complete risk information.

Key: ASP – average sales price; US – United States; WAC – wholesale acquisition cost.  
\*In 2021, Janssen (manufacturer of REMICADE) released unbranded infliximab in the market. This specific unbranded infliximab is not a biosimilar. It is REMICADE sold under a different name.<sup>51</sup>  
<sup>†</sup>The unbranded infliximab product launched at the same ASP as REMICADE.  
<sup>‡</sup>ASP was not available for these products at the time of comparison. WAC is used to compare with reference product ASP.  
Source: AnalySource.

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# INFLAMMATION

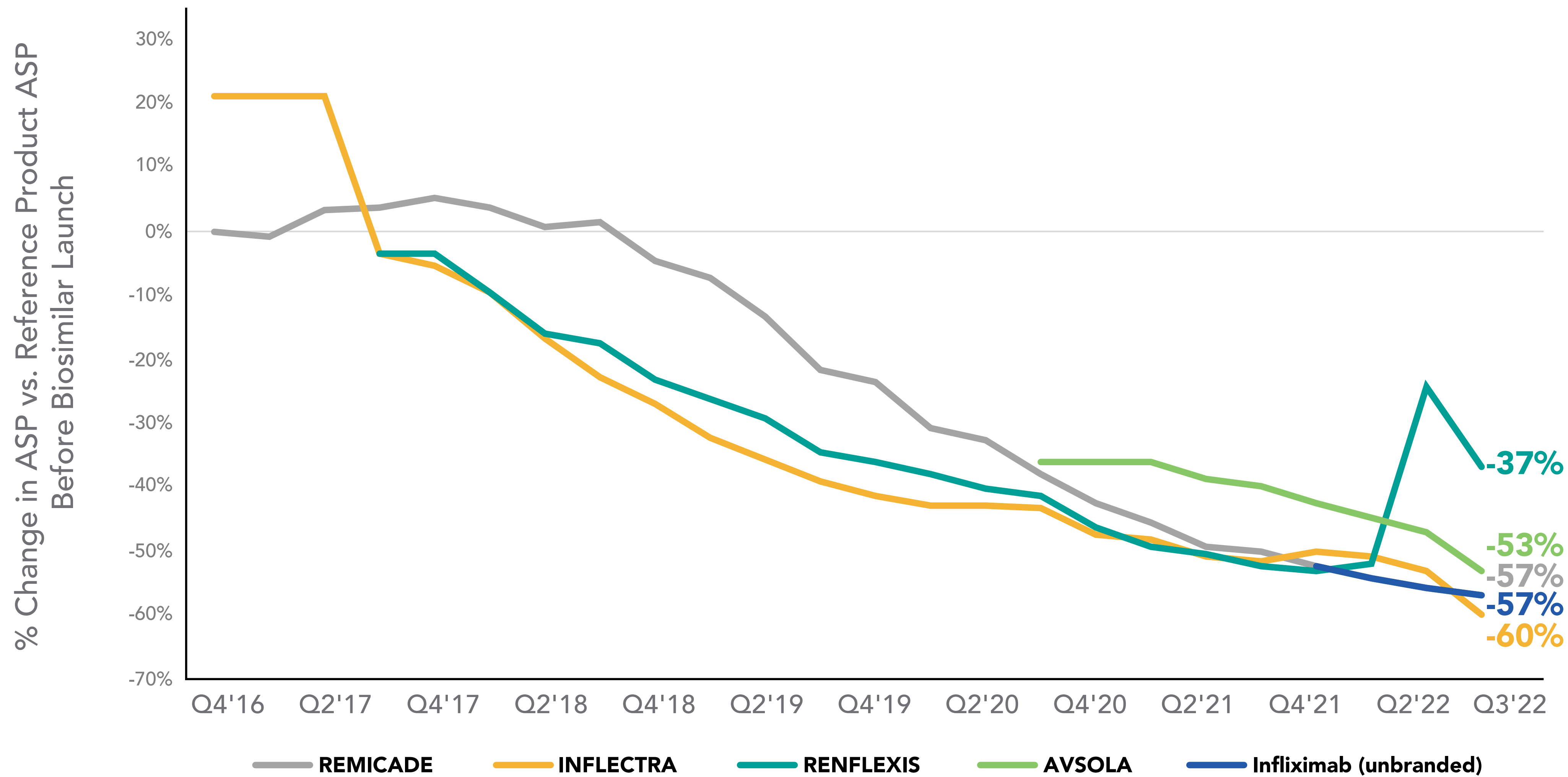
## Infliximab



**Figure 34** shows the percentage change in the price of biosimilars and Janssen’s unbranded infliximab over time when compared to the reference product’s ASP at the time that the first infliximab biosimilar launched.\* Despite launching at a premium to the reference product’s ASP, INFLECTRA’s price quickly declined to be lower than REMICADE once its ASP was established 3 quarters after launch.

**The reference product REMICADE’s price has declined by 57% since the first infliximab biosimilar was launched.**

**Figure 34.** ASP of Infliximab Products at Biosimilars’ Launches<sup>8,†</sup>



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See [Full Prescribing Information](#) for complete risk information.

Key: ASP – average sales price; WAC – wholesale acquisition cost.  
Biosimilar WAC is used for comparing against reference product ASP until biosimilar ASP is available.  
Source: AnalySource.

\*In 2021, Janssen (manufacturer of REMICADE) released unbranded infliximab in the market. This specific unbranded infliximab is not a biosimilar. It is REMICADE sold under a different name.<sup>51</sup>  
†The unbranded infliximab product launched at the same ASP as REMICADE.

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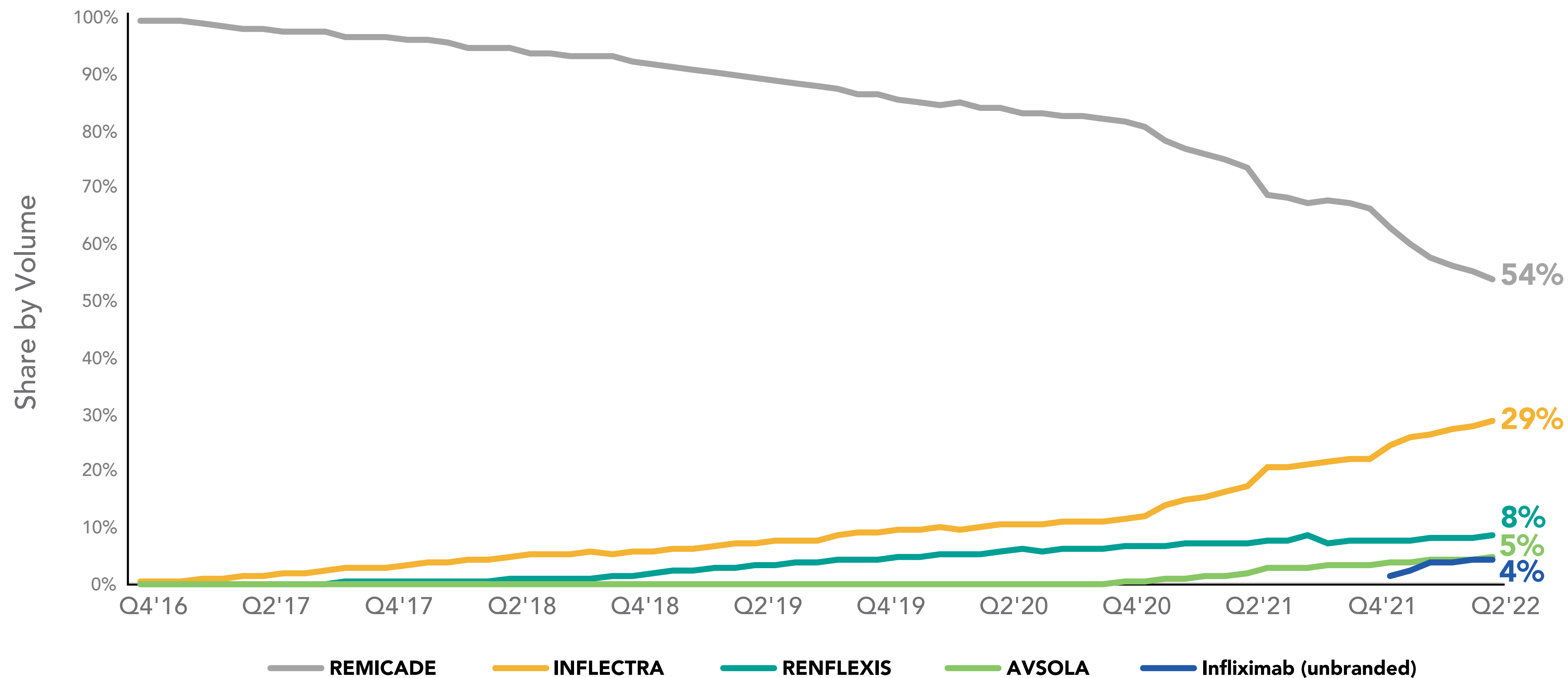
# INFLAMMATION

## Infliximab

As seen in **Figure 35**, biosimilar share is growing. As more biosimilars become available, reference product manufacturers are frequently willing to lower prices. Price competition from the reference product REMICADE and physician caution around changing medicines for chronic conditions like autoimmune diseases may have contributed to the slow start in capturing share for infliximab biosimilars.<sup>52,53</sup>

**After slow starts, infliximab biosimilars have gained 42% share by Q2 2022, while the reference product REMICADE has a 54% share.\***

**Figure 35.** Biosimilar Uptake Curve for Infliximab Products<sup>6</sup>



Please [click here](#) for Boxed Warning information for AVSOLA. See [Full Prescribing Information](#) for complete risk information.

Source: OBU Customer Data Pack Weekly (IQVIA DDD + Chargeback).

\*In 2021, Janssen (manufacturer of REMICADE) released unbranded infliximab in the market. This specific unbranded infliximab is not a biosimilar. It is REMICADE sold under a different name.<sup>51</sup>



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# INFLAMMATION

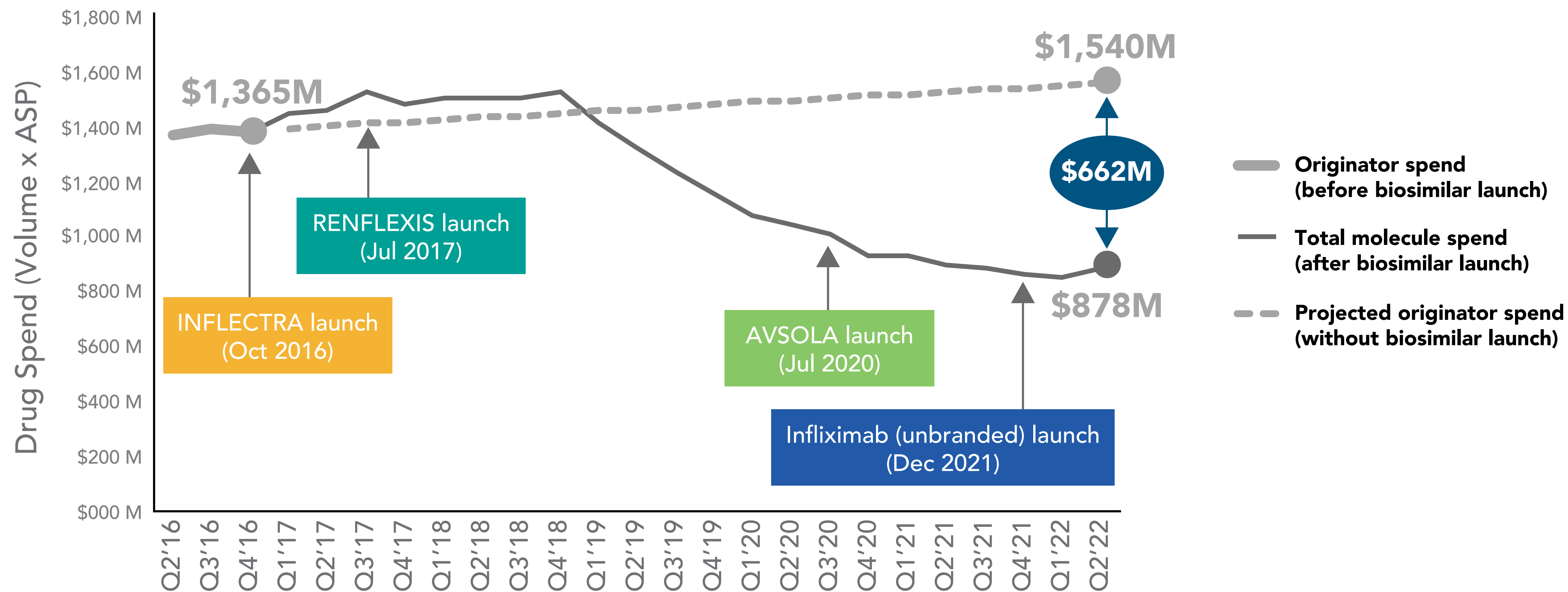
## Infliximab

**Figure 36** shows the total drug spend for infliximab with biosimilar launches, compared to the projected drug spend in the absence of biosimilar competition.

**The cumulative savings in drug spend for infliximab from Q4 2016 to Q2 2022 is estimated to be \$6 billion to date.**

**Without biosimilar competition, projected spending on infliximab could have been more than \$660M higher in Q2 2022.**

**Figure 36.** Comparison of Estimated Infliximab Drug Spend With vs. Without Biosimilar Competition<sup>3</sup>



Please [click here](#) for Boxed Warning information for AVSOLA. See [Full Prescribing Information](#) for complete risk information.

Key: ASP – average sales price. The quarterly drug spend for each product is estimated as: Drug spend=ASPxNormalized unit volume. The estimated spend for the reference product (after biosimilar launch) is trended out based on historical spend for the reference product before biosimilar launch. Sources: AnalySource, Integrated Weekly Sales Data (IQVIA DDD + Chargeback).



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  - Payers and IDNs
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  - Patients

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# HEALTHCARE SYSTEMS



Biosimilars offer potential benefits to every stakeholder in the healthcare system

Biosimilars may lower spending by offering potentially lower-cost treatment options and fostering competition, which may lead to savings that can be redeployed toward spending on new, innovative therapies.

## Two factors driving potential savings:



**ABBREVIATED APPROVAL PATHWAY**

Developing a biosimilar costs less than a reference biologic because of the abbreviated FDA approval pathway

Biosimilars are expected to **cost between \$130 million and \$270 million** (adjusted to 2022 dollars) to develop compared to an estimate of \$2.6 billion for developing a new drug or biologic.<sup>54,55</sup> As a result, manufacturers have fewer expenses to recoup, which theoretically contributes to the possibility of biosimilars having lower list prices.



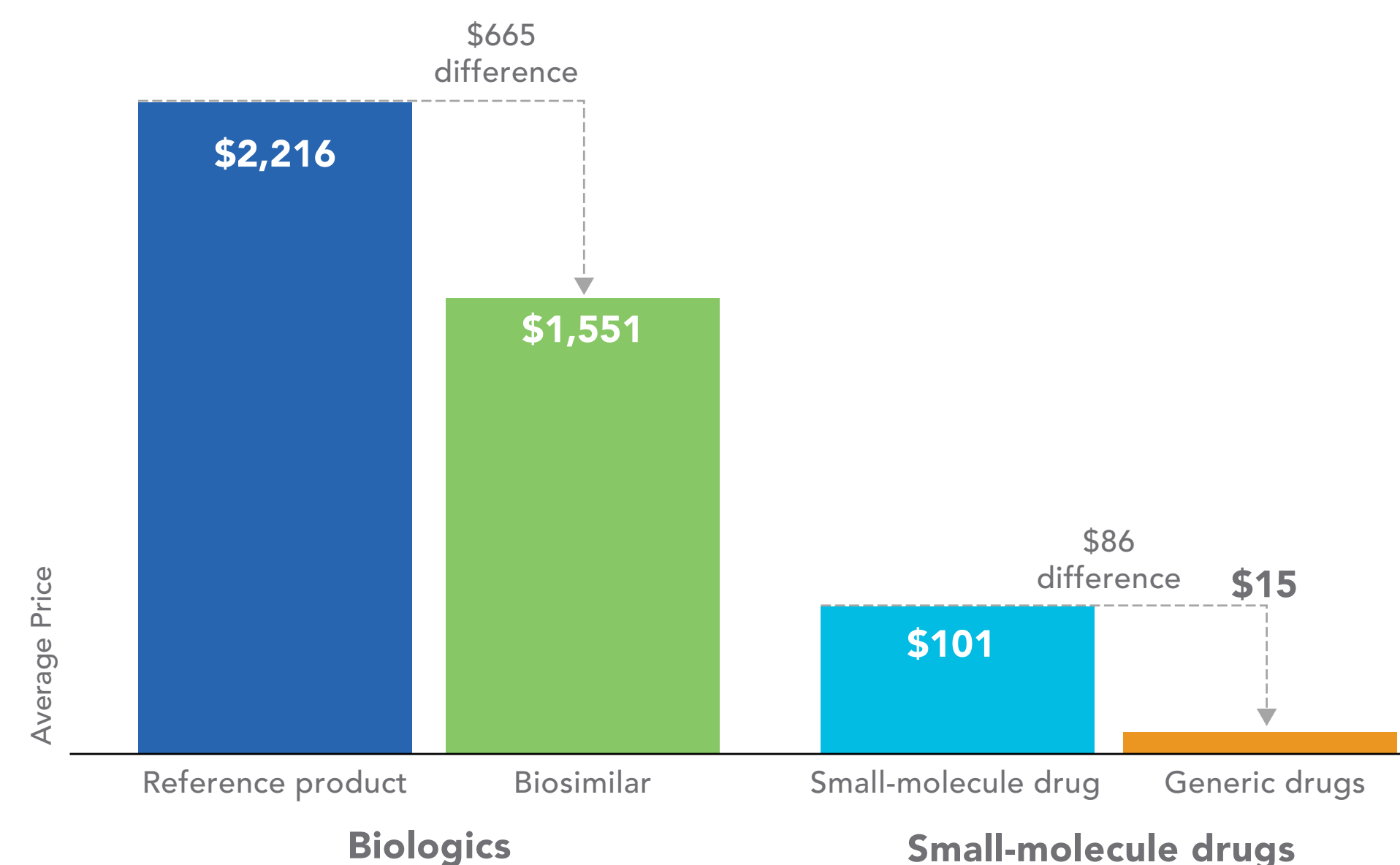
**CREATION OF COMPETITION**

Biosimilars contribute to competition in the healthcare system

As the number of treatment choices increases for a particular disease or condition, **manufacturers may be incentivized to lower the prices of their products** to remain competitive.<sup>56</sup>

## Biosimilar competition compared to generic competition

Due to the relatively higher cost of biologics, biosimilar competition is likely to produce greater total savings per drug than generic competition.<sup>57</sup>



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# HEALTHCARE PROFESSIONALS



Healthcare professionals, including physicians, physician assistants, nurse practitioners, and pharmacists, are central to the adoption of biosimilars. It is important that healthcare professionals:



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# PRESCRIBERS

Science-based education campaigns about biosimilars may provide stakeholders with greater confidence in their use

Educational campaigns by the FDA and organizations such as the Biologics Prescribers Collaborative (BPC), American Society of Clinical Oncology (ASCO), Community Oncology Alliance (COA), Pharmaceutical Research and Manufacturers of America (PhRMA), and Biotechnology Innovation Organization (BIO) include:



Scientific information about the complexity of manufacturing biologics, including biosimilars



The concept of extrapolation



How biosimilars are approved by regulators

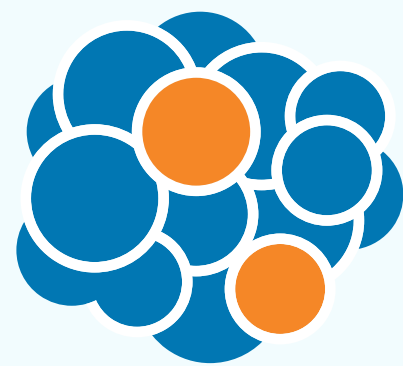


Clinical considerations for use



In December 2021, the FDA's Center for Drug Evaluation and Research released a biosimilar teaching guide to help faculty educate students in healthcare professional degree programs on biosimilars as they transition into professional practice.<sup>58</sup> **The curriculum discusses the foundational concepts of biosimilars as well as real-world considerations when prescribing or dispensing biosimilars and interchangeable biosimilars.**

**Specialty societies of physicians, nurse practitioners, and others are recognizing the promise of biosimilars for providers and patients. These groups continue to educate their members about biosimilars.**<sup>59</sup>



## CANCER

A new report from an ASCO expert panel found that biosimilars may represent an affordable and effective alternative for cancer care. The report supports the inclusion of biosimilars in clinical practice guidelines, which could help expand their use with patients.<sup>60</sup> Additionally, in 2019, COA released a position statement saying it will work with stakeholders to support the acceptance of biosimilars by educating oncologists.<sup>61</sup>



## AUTOIMMUNE DISEASES

The American College of Rheumatology provided a comprehensive overview of the scientific, clinical, economic, and prescribing issues pertaining to biosimilar use, including efficacy, competition, and drug pricing. The paper encourages providers to incorporate these drugs into the treatment plans of patients with rheumatic diseases where appropriate.<sup>62</sup>

The International Psoriasis Council endorsed evidence from clinical trials and increasing experience from daily clinical practice, which show that biosimilars are equivalent to reference products in terms of quality, efficacy, and safety profiles.<sup>63</sup>



## HEALTH-SYSTEM PHARMACIES

To enhance the adoption of biosimilars in a range of therapeutic areas, the American Society of Health-System Pharmacists (ASHP) engaged a group of stakeholders to develop a deeper understanding of current trends, understand health-system challenges and opportunities, and identify best practices learned from early adopters of biosimilars. The project generated an Accelerating the Adoption of Biosimilars report, webinar, and an August 2022 podcast.<sup>64</sup>



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# PRESCRIBERS

Providers are increasingly familiar and comfortable with prescribing biosimilars; however, there remains work to be done

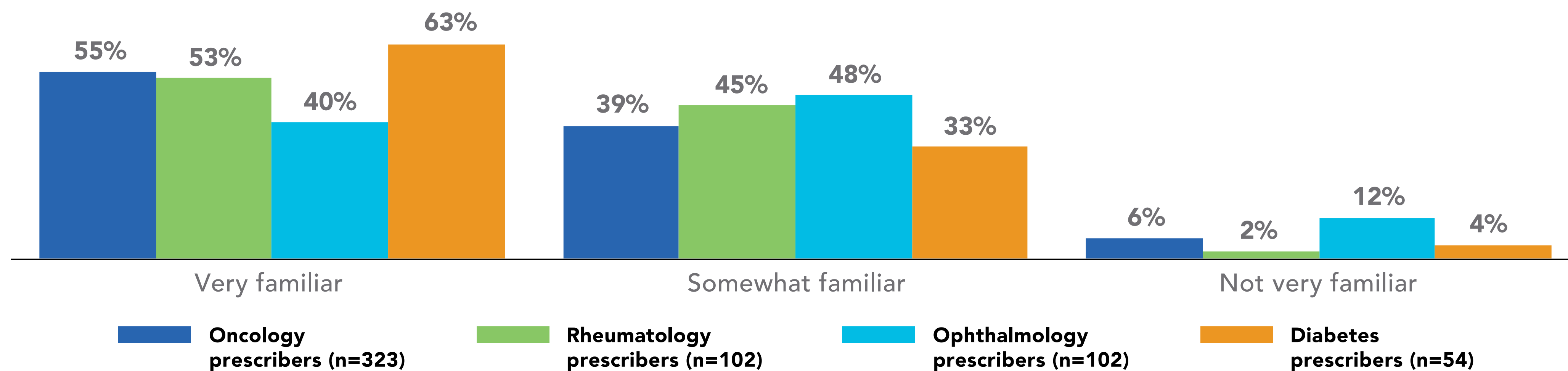
Eight years after the first biosimilar launched in the US, physician knowledge of biosimilars in each specialty where they are available continues to grow. Providers are increasingly familiar with prescribing biosimilars; however, there are still knowledge gaps to be filled. Prescribers may be hesitant to convert patients to biosimilars due to concerns of efficacy and cost to patients, and often find inconsistent payer policies a barrier to prescribing.<sup>64</sup>

Cardinal Health recently surveyed specialists who prescribe biosimilars regarding their comfort level with the products.<sup>65</sup> **Figure 37** shows that 98% of rheumatologists, 96% of providers treating diabetic patients, 94% of oncologists, and 88% of ophthalmologists were either “very” or “somewhat” familiar with biosimilars.

*“It is about becoming comfortable with the concept that [biosimilars] are therapeutically equivalent [to the originator].”<sup>66</sup>*

– Angus Worthing, MD,  
Georgetown University Medical Center

**Figure 37. Prescriber Familiarity With Biosimilars<sup>65</sup>**



Key: US – United States.  
Surveys conducted 2020–2021.



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# PRESCRIBERS

The next few years will see biosimilars expand into new specialty areas, with a range of awareness levels that could impact adoption rates in those specialty areas

The same 2022 survey from the previous page found that approximately 40% of retina specialists would be uncomfortable prescribing biosimilars from a clinical standpoint.<sup>65</sup>

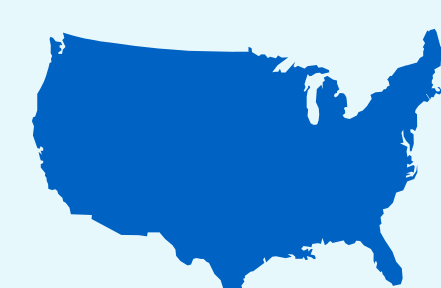
A potential challenge to the broader adoption of biosimilars may be the large variation in biosimilar prescribing experience among specialties. In 2021, a survey was administered to 507 US healthcare professionals practicing dermatology, gastroenterology, nephrology, oncology, hematology, or rheumatology.<sup>67</sup> The percentage of respondents who said they had previous experience with biosimilars varied widely—from 81% for hematologists/oncologists to only 13.5% of dermatologists in **Table 3**. Although all respondents practiced in a specialty in which biosimilars have been approved and marketed, about half of all respondents had not previously prescribed a biosimilar.

**Table 3.** Previous Experience Prescribing Biosimilars, by Specialty

Specialty	Previous prescribing experience
Dermatology	13.5%
Gastroenterology	51.5%
Nephrology	53.0%
Oncology/hematology	81.0%
Rheumatology	65.3%
<b>AVERAGE ACROSS ALL SPECIALTIES LISTED ABOVE</b>	<b>49.5%</b>

For the almost half of physicians who did not want to prescribe a biosimilar, 48.5% said their reason was because “they were waiting until biosimilar products have been on the market longer before prescribing them.”

The study identified financial savings to the patient as the most influential factor in a prescriber’s decision of whether to prescribe a biosimilar product.



**In this relatively early phase of biosimilar use in the US, increasing uptake faces a circular conundrum: Lack of experience with biosimilars causes hesitancy, but hesitancy limits experience. More education can help prescribers feel more comfortable with biosimilars.**



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# PRESCRIBERS

## Preparing for biosimilars

Savings expected from biosimilars are particularly important when considering that hospital systems and provider groups are focused on providing quality care while being mindful of costs and savings opportunities.

Health systems and providers will need to prepare for the growing availability of biosimilars by <sup>68</sup>:



**Being familiar with major payers' coverage and reimbursement policies for biosimilars**



**Anticipating potential differences in delivery device between a reference product and a biosimilar**



**Understanding the different patient support services provided by biosimilar manufacturers**



**Understanding how to differentiate the electronic health records when stocking the reference product and biosimilar to minimize the risk of errors**

**“The surge in biosimilars is exciting from a customer perspective. Patients and physicians are looking for more affordable options. We expect that trend to continue in cancer care and in other disease areas, and that will allow for more choice and savings in the marketplace. In our view, that’s a win-win.”**

– Jan Burkett, President,  
Strategic Global Sourcing at AmerisourceBergen



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# PRESCRIBERS

## High-quality, reliable supply

The FDA holds all biologics – both reference products and biosimilars – to the same Good Manufacturing Practice standards.<sup>69</sup> Biosimilar manufacturers must have a long-term commitment to quality for biosimilars to succeed. When choosing a biosimilar, providers may want to consider manufacturers' overall experience manufacturing biologics.

Providers should consider a manufacturer's history of shortages and recalls and evaluate its capability to maintain adequate production and stock to support demand when deciding to use any product. Providers should also consider the robustness of the manufacturer's supply chain when evaluating product use.<sup>70</sup>

### Potential effects of drug shortages may include:

 **Drug rationing and need to prioritize patients**

 **Time burden involved in managing shortages**

 **Errors due to inexperience with alternatives**

 **Increased costs across the system**

 **Compromised patient care**



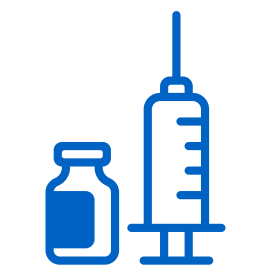
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# PHARMACISTS

## Retail pharmacist spotlight



Due to current biosimilars being overwhelmingly processed through the medical benefit, retail pharmacists have had very little exposure to biosimilars to date.



The only current biosimilar that retail pharmacists may have encountered is the insulin interchangeable Semglee, biosimilar to reference insulin Lantus. However, Semglee was launched in November 2021, so retail pharmacists have not even had a year's experience working with a completely new category of drugs.<sup>71</sup>



Retail pharmacist exposure to biosimilars is about to change. Up to 7 biosimilars to HUMIRA – the world's second-highest-selling drug, with \$20.7 billion in sales in 2021<sup>72</sup> – are scheduled to be launched throughout 2023, with at least one having an interchangeable designation.

HUMIRA and STELARA are pharmacy-benefit drugs that can be dispensed at retail pharmacies, so pharmacists are likely to see many prescriptions for one or more HUMIRA and STELARA biosimilars.



Whether or not pharmacists are prepared for biosimilars is not yet clear, with surveys of the profession showing mixed results. Cardinal Health reported in early 2022 that pharmacists were generally acquainted with biosimilars, with two-thirds of respondents (68%) saying they are “somewhat familiar,” while one-quarter (24%) said they were “very familiar.”<sup>73</sup>



Half of pharmacists (51%) in the Cardinal Health study said they are “very comfortable” substituting a biosimilar for a reference product if the biosimilar would deliver a lower out-of-pocket cost for the patient.<sup>65</sup>



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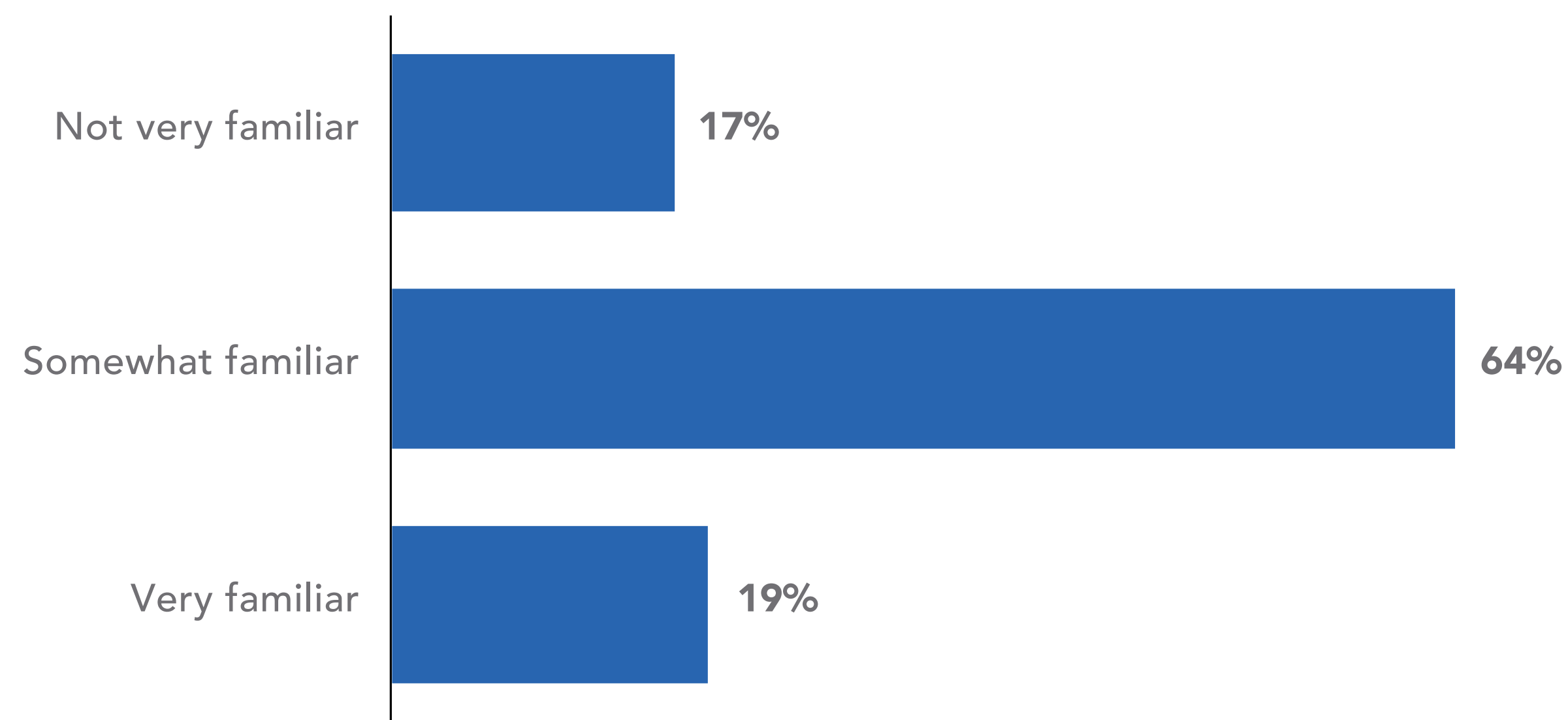
# PHARMACISTS

## Recent surveys found that pharmacists' awareness of the interchangeability designation appears somewhat lower than their knowledge of biosimilars

The 2022 Cardinal Health survey also found awareness and understanding of the FDA's interchangeability designation were low among pharmacists, as shown in **Figure 38**. Most were somewhat familiar, but less than a quarter were very familiar, with FDA's interchangeability designation. <sup>65</sup>

In addition, a March 2021 survey found pharmacists had limited awareness of concepts underlying FDA approval of the interchangeable designation for biosimilars, though this survey was conducted before the first interchangeable biosimilar was approved (July 2021). <sup>74</sup> The survey also showed that just 20% of pharmacists knew that interchangeable status means pharmacists can make substitutions without consulting the physician who prescribed the medicine. <sup>74</sup>

**Figure 38.** Pharmacists' Familiarity With the Interchangeability Designation for Biosimilars (N=115) <sup>65</sup>



The variability of the survey results is not surprising, considering the newness of the category. This presents an opportunity to educate pharmacists regarding the relationships among reference products, their biosimilars, and biosimilars with an interchangeable designation.



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# PAYERS AND INTEGRATED DELIVERY NETWORKS (IDNs)

Payers are looking to biosimilars as an opportunity to help manage costs and offer more treatment choices <sup>75</sup>

The availability of biosimilars in key therapeutic categories that currently have only 1 or a few reference products available promotes competition and is a tool payers and employers may use to help lower costs.

**Payers should evaluate several clinical, economic, and manufacturer partner factors when considering adding biosimilars to the formulary, including <sup>75</sup>:**

Robust regulatory standards to demonstrate biosimilarity	How biosimilars will be covered and placed on formularies and any utilization management mechanisms	Whether providers will be willing to prescribe biosimilars
Whether, how, and when to switch patients to biosimilars	The potential of biosimilars to contribute to lower costs while maintaining patient access to necessary treatments	Cost-effectiveness
Manufacturer experience with biologics in the therapeutic area	Manufacturer ability to supply reliably	Manufacturer past performance with biosimilars and future commitment to biosimilars
Patient support services	Ease of device use without a steep learning curve for patients	Available RWE from other markets or early adopters

**Biosimilars offer the potential of cost savings to payers for both the reference product and the biosimilar.**

Increasingly, payers are showing a desire to embrace biosimilars, which could help promote competition and potentially lower costs for the US healthcare system.

One study estimated that gradually shifting patients to a bevacizumab biosimilar would provide **substantial cost savings** for US payers. <sup>76</sup>

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# PAYERS AND IDNs



The 3 largest PBMs have taken different paths to covering reference products and biosimilars<sup>77-79</sup>

Below, we compare the varying formulary management for 2 product categories in **Table 4** and **Table 5**. PBMs appear to be taking different strategies to adding reference products or biosimilars to their formularies. Manufacturers may not be able to rely on simply offering the lowest price.

**Table 4.** CVS Caremark, Express Scripts, and OptumRx’s Formulary Management for **Infliximab** Reference Products and Biosimilars, as of September 2022

	Infliximab			
	REMICADE	INFLECTRA	RENFLEXIS	AVSOLA
CVS Caremark	✓	✗	✗	✗
Express Scripts	✗	✓	✗	✗
OptumRx	✗	✓	✗	✓

Key: ✓ - covered/preferred product. ✗ - excluded from coverage.

**Table 5.** CVS Caremark, Express Scripts, and OptumRx’s Formulary Management for **Rituximab** Reference Products and Biosimilars, as of September 2022

	Rituximab			
	RITUXAN	TRUXIMA	RUXIENCE	RIABNI
CVS Caremark	✗	✗	✓	✗
Express Scripts	✗	✗	✓	✗
OptumRx	✗	✗	✓	✗

Key: ✓ - covered/preferred product. ✗ - excluded from coverage.

## PBM’s varying coverage of reference products and biosimilars incorporates clinical and non-clinical factors<sup>80</sup>

The PBMs are inconsistent in their formulary management with the infliximab class.

- CVS Caremark includes the reference product REMICADE and no biosimilars.
- Express Scripts only includes the biosimilar INFLECTRA, leaving out the reference product and the other biosimilars.
- OptumRx includes 2 biosimilars, leaving out the reference product and 1 biosimilar.

By contrast, the PBMs have identical formulary policies for the rituximab class. All 3 only cover the biosimilar RUXIENCE and exclude the reference product RITUXAN and the other 2 biosimilars (TRUXIMA and RIABNI).

One PBM observed that the pharmacy-benefit biosimilars give payers more control over their distribution, because “most of these products are being dispensed out of a specialty pharmacy that is vertically integrated with the payers, [thus giving them] more control.”<sup>81</sup>

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# EMPLOYERS

Employers have a vested interest in controlling and containing healthcare costs<sup>82</sup>

Health benefit costs jumped 6.3% in 2021, and although employers expect a more typical increase of 4.4% in 2022, several factors – higher utilization due to “catch-up” care, claims for long COVID, new extremely high-cost cellular drug therapies, and inflation in healthcare prices – could result in ongoing acceleration of costs.<sup>83,84</sup>

The employee trade group ERISA Industry Committee (ERIC) launched an initiative to better understand biosimilars’ role in reducing healthcare costs.<sup>85</sup>

ERIC commissioned the Bloomberg School of Public Health at Johns Hopkins University to track spending by 13 large employers on 2 biosimilars: infliximab and filgrastim. **The Johns Hopkins school found the infliximab biosimilar was 32% less expensive than its reference product and the filgrastim biosimilar was 26% less expensive than its reference product.**

The study showed that biosimilars created significant savings for employees and their families. **Patients who took the biosimilar paid on average 12% (~\$300) less out-of-pocket for infliximab and 45% (~\$600) less out-of-pocket for filgrastim than those who took the reference product.**

## Case Study: Ford Company Utilization of Biosimilars

In 2019, Ford started requiring new and current utilizers of reference product REMICADE to convert to biosimilar INFLECTRA.<sup>86</sup> The company saw **transition rates of 100% within its HMO medical plan** and **88.1% in its PPO**, with no disruption to patients and no negative feedback from its members.

This transition, since expanded to 4 other biosimilar drugs, has **saved Ford nearly \$5 million as of June 2021.**

The case study recommends actions that companies and organizations can make for successful adoption of biosimilars, including:

- Ask for data from medical carriers and for information about existing biosimilar programs.
- Consider hiring a pharmacy specialist.
- Be aggressive when negotiating benefit contracts. Ask for a utilization review.
- Educate the provider community and employees/members early on about biosimilars.
- Offer site-of-care program for employees and members.

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# EMPLOYERS

## Biosimilar adoption and impact for employers

Escalating specialty drug costs present a challenge for many employers trying to control their healthcare spend while maintaining a profitable business. Continued biosimilar penetration could help increase competition and lower costs without compromising quality, efficacy, or patient safety.

### Case Study: Biosimilar Specialty Tiers

In 2021, Wellmark Blue Cross and Blue Shield added a new specialty biosimilar tier to provide employers an opportunity to lower the costs of preferred and non-preferred specialty drugs for their employees. The biosimilar tier enables an employer to structure its pharmacy benefits to encourage employees to use biosimilars by setting lower out-of-pocket costs for these products.<sup>87</sup>

### Biosimilars offer employers an opportunity to mitigate their growing health costs

The National Alliance of Healthcare Purchaser Coalitions, trying to understand how employers could improve the utilization of biosimilars to lower healthcare costs, convened a series of roundtable discussions with 7 regional business coalitions from across the country to discuss with employer members the current biosimilar landscape, current challenges to implementing biosimilars, and best practice strategies for making formulary and benefit design decisions.<sup>88</sup>

The National Alliance found 5 key themes for action:

- 1 Revamping health plan designs to prioritize biosimilars, minimize disruption to members, and limit changes to members' treatment cycles.
- 2 Taking on a bigger role in ensuring biosimilar formulary placements and targeted utilization management.
- 3 Increasing focus on low-net-cost options and understanding how rebates impact overall drug pricing.
- 4 Ensuring coverage of biosimilars at an appropriate tier level and implementing incentives to encourage adoption.
- 5 Focusing on impact of the site of care on drug-delivery costs.



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# PATIENTS

Patient understanding of biosimilar products, including their safety and efficacy, will be key to the utilization of these drugs. Education on what biosimilars are and the potential for cost savings will be of paramount importance to encourage their utilization<sup>89</sup>

Patients want to hear first from their healthcare providers when it comes to biosimilars, as their doctors are the primary sources of information. Having the provider introduce the subject of biosimilars is a key part of the conversation with patients.<sup>90</sup> It is important for patients to understand the following:

 **What is a biosimilar? Is it safe and effective?<sup>91</sup> Is it as safe and effective as the reference biologic?**

 **How many other patients like me have been treated with a biosimilar of the product I'm currently taking?<sup>92</sup>**


 **Do biosimilars undergo the same development process as other FDA-approved products?<sup>91</sup>**

 **Does my doctor support the use of a biosimilar?<sup>90</sup>**

 **How much will a biosimilar cost me?<sup>93</sup> Are there patient assistance programs for biosimilars to help me with these costs?**

 **Will I be able to stay on this drug long-term or will I have to make another change next year?<sup>90</sup>**

 **Is there an FDA-approved biosimilar for the biologic I'm taking?<sup>93</sup> Is it appropriate for me to switch to it?**

 **Can my pharmacist substitute a biosimilar for my biologic, like a generic drug may be substituted for a brand drug?<sup>91</sup>**



[Click here](#) to see the patient resources available on the FDA's website.



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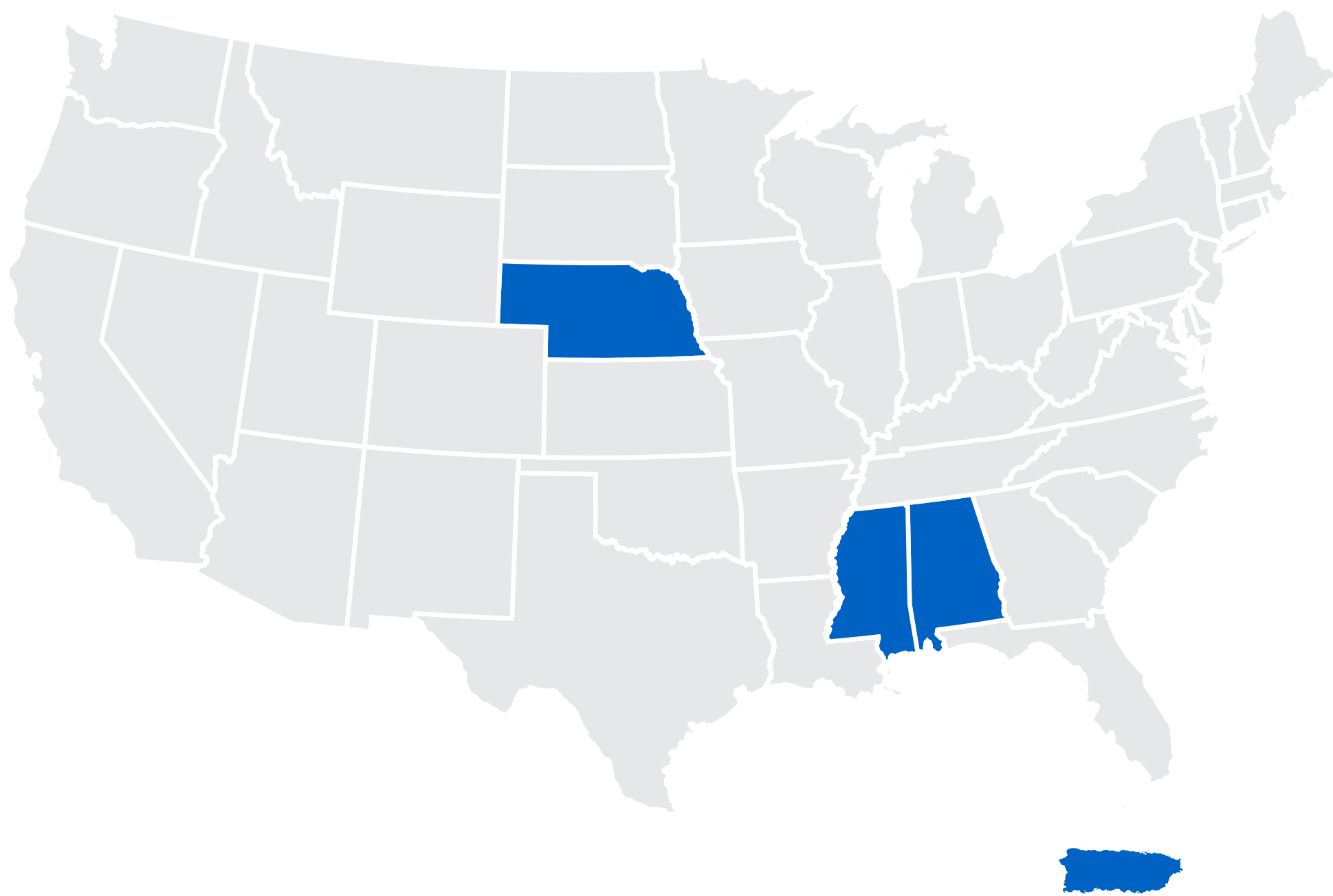


# PATIENTS

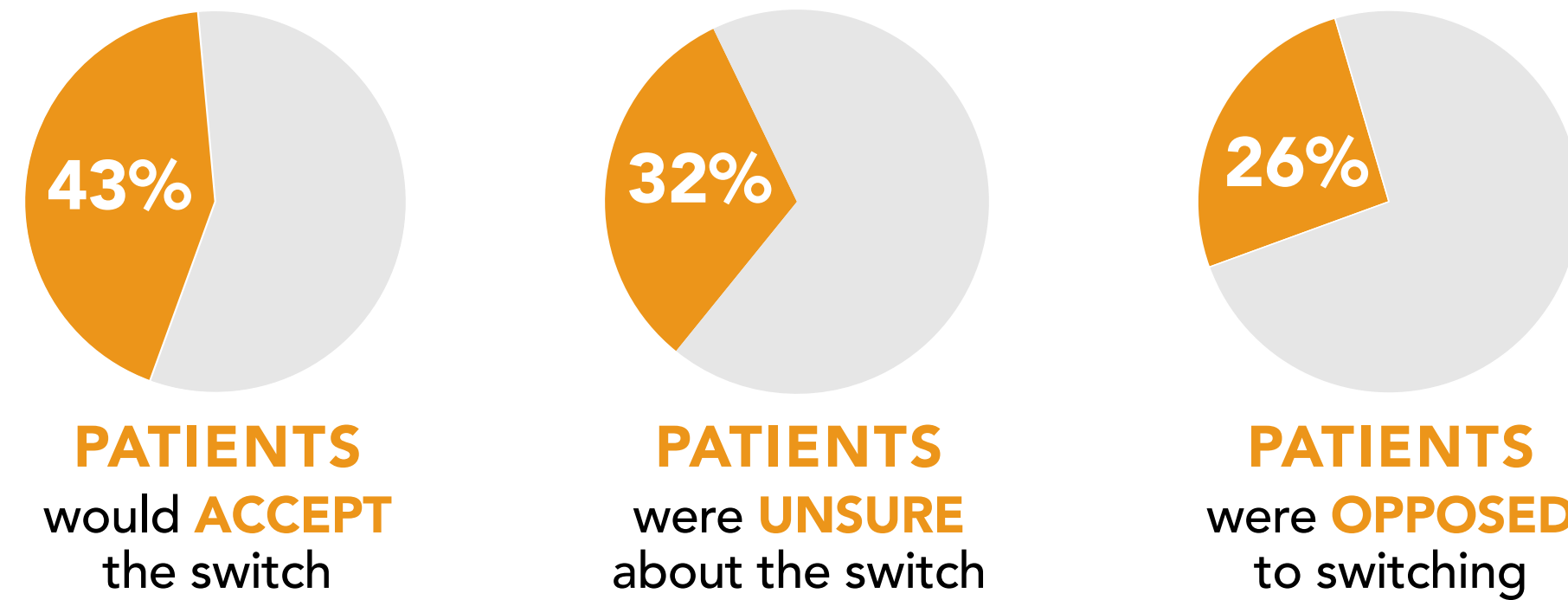


## Despite biosimilars being available in the US since 2015, educating patients is still necessary

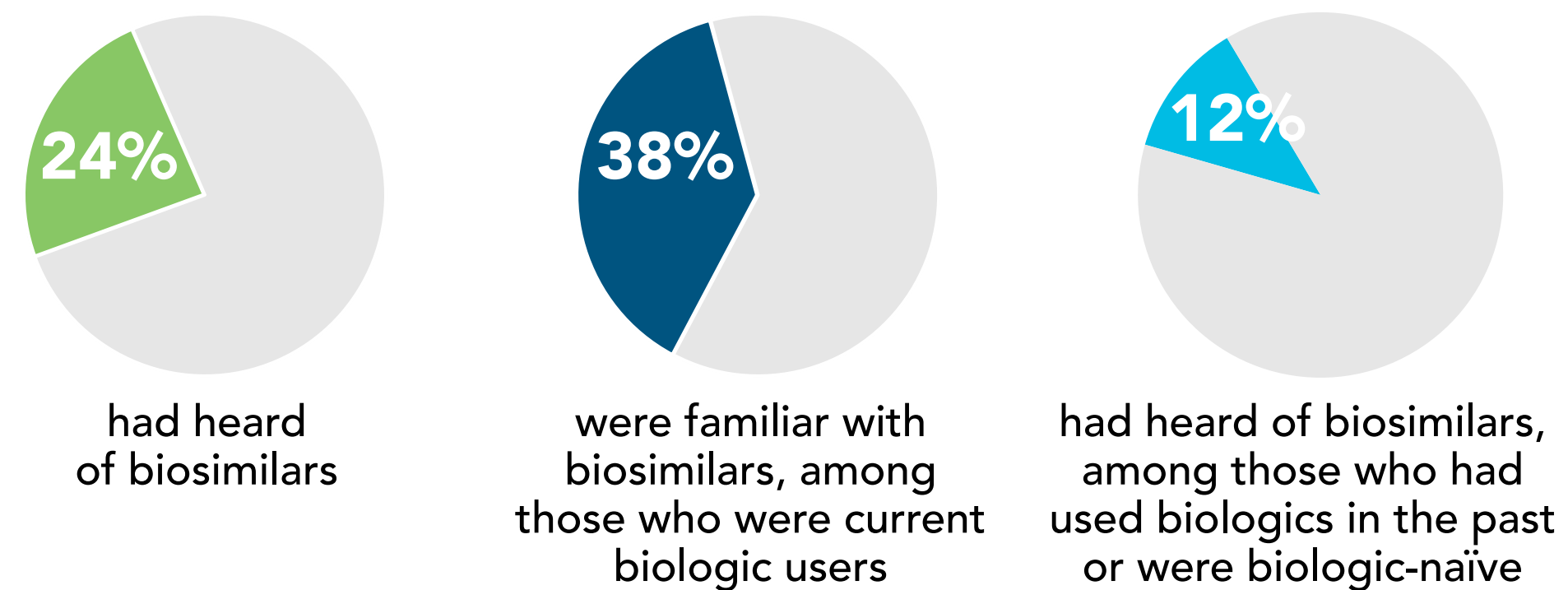
A survey from December 2020 to January 2021 found that patients with immune-mediated conditions from **Alabama, Mississippi, Nebraska, and Puerto Rico** (N=500) were only moderately inclined to accept anti-tumor necrosis factor biosimilars.<sup>94</sup>



Patients under treatment with an originator biologic at the time of the survey were asked whether they would switch to biosimilar treatment if proposed by their provider\*:



The findings suggested patient knowledge and experience with biosimilars were low among biologic users and non-users:



**Additional hesitancy was reported by patients expressing concern about adverse events that might arise during biosimilar use and how well biosimilars would treat their disease.**

### Patient Education in Action

The International Foundation for Autoimmune & Autoinflammatory Arthritis (AiArthritis) launched an educational series “Biosimilars for Rheumatoid Arthritis: What Do I Need to Know?,” which not only informs participants of the key differences between reference biologics and biosimilars, but it also provides helpful tips for patients preparing to have an open and educated conversation with their healthcare provider.<sup>95</sup>

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# MEDICARE UPDATES

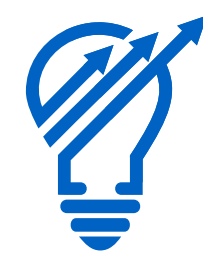
## Biosimilars may be covered under the medical benefit or the pharmacy benefit

Self-administered medicines (often delivered by a specialty pharmacy) are typically covered under the pharmacy benefit, while those injected or infused under the supervision of a physician are typically paid for under the medical benefit. Most biosimilars marketed in the US are covered under the medical benefit by payers, though they may also be covered under the pharmacy benefit, especially when managed through specialty pharmacies.

### Medical benefit

As of January 2018, CMS assigns each biosimilar a unique payment code (known as a HCPCS code), and its ASP is not combined with other biosimilars of the same reference product.<sup>9</sup>

Assigning a unique HCPCS code to each biosimilar can help promote a robust, competitive landscape by:



Increasing the potential for innovation



Allowing each product to be treated on its own for reimbursement purposes. Distinct HCPCS codes additionally reduce potential for confusion with traceability that would be created by shared codes



Lowering risks associated with developing and marketing these complex products



Helping physicians have certainty around their reimbursement rate if they choose a different biosimilar of the same reference product

Please refer to the [Biosimilar FAQs](#) section at the end of the report for coding, coverage, and payment characteristics of biosimilars among various payers.



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Key: ASP – average sales price; CMS – Centers for Medicare & Medicaid Services; HCPCS – Healthcare Common Procedure Coding System.

\*Sequestration is a statutory 2% payment reduction across all Medicare spending, established under the Balanced Budget and Emergency Deficit Control Act of 1985.<sup>96</sup> Sequestration was suspended through July 1, 2022.<sup>97</sup> When it resumes, the ASP add-on amount will be 4.3% (not 6%).



# MEDICARE UPDATES

## Medicare Part B reimburses at ASP + 6% of the reference biologic's ASP

The Affordable Care Act (ACA) included language to promote a level playing field between reference products and biosimilars. Medicare Part B reimburses providers for biosimilars at the biosimilar's ASP plus a 6% add-on of the reference biologic's ASP.<sup>\*,9</sup> In other words, Congress kept the field level by providing physicians the same add-on amount regardless of whether they prescribe a reference product or a biosimilar. This helps all manufacturers compete on equal terms.

Because there is often a lag time of 2 calendar quarters from the time when a product launches until its ASP is published, Medicare reimburses Part B drugs – including biosimilars – based on their WAC plus a 3% add-on until the ASP becomes available.

Hypothetical examples of physician office or community clinic and outpatient payments for a biosimilar under Medicare Part B can be found in **Table 6** below.

**Table 6.** Payment Methodology for Biosimilars Under Medicare Part B

Biologic product	Reference product	Biosimilar A	Biosimilar B
WAC (list price)	\$1,000.00	\$800.00	\$700.00
ASP*	\$800.00	\$640.00	\$560.00
6% of reference product's ASP		\$48.00	
Payment rate (ASP + 6%)	\$848.00	\$688.00	\$608.00
Patient cost-share (20%)	\$169.60	\$137.60	\$121.60

Note: Payment rate does not reflect sequester reductions.



**The 2% mandatory payment reduction for the Medicare program, known as sequestration, returned July 1, 2022.<sup>97</sup>**

Since the price for biosimilars is almost always less than their reference products, **Medicare beneficiaries will often have lower out-of-pocket costs when they use biosimilars.**

Part B payment for biosimilars = Biosimilar ASP + 6% of reference biologic's ASP

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# MEDICARE UPDATES

Medicare Part D and the pharmacy benefit will play a much larger role in upcoming years, as 2023 will be a landmark year due to the biosimilars expected to launch against reference product HUMIRA

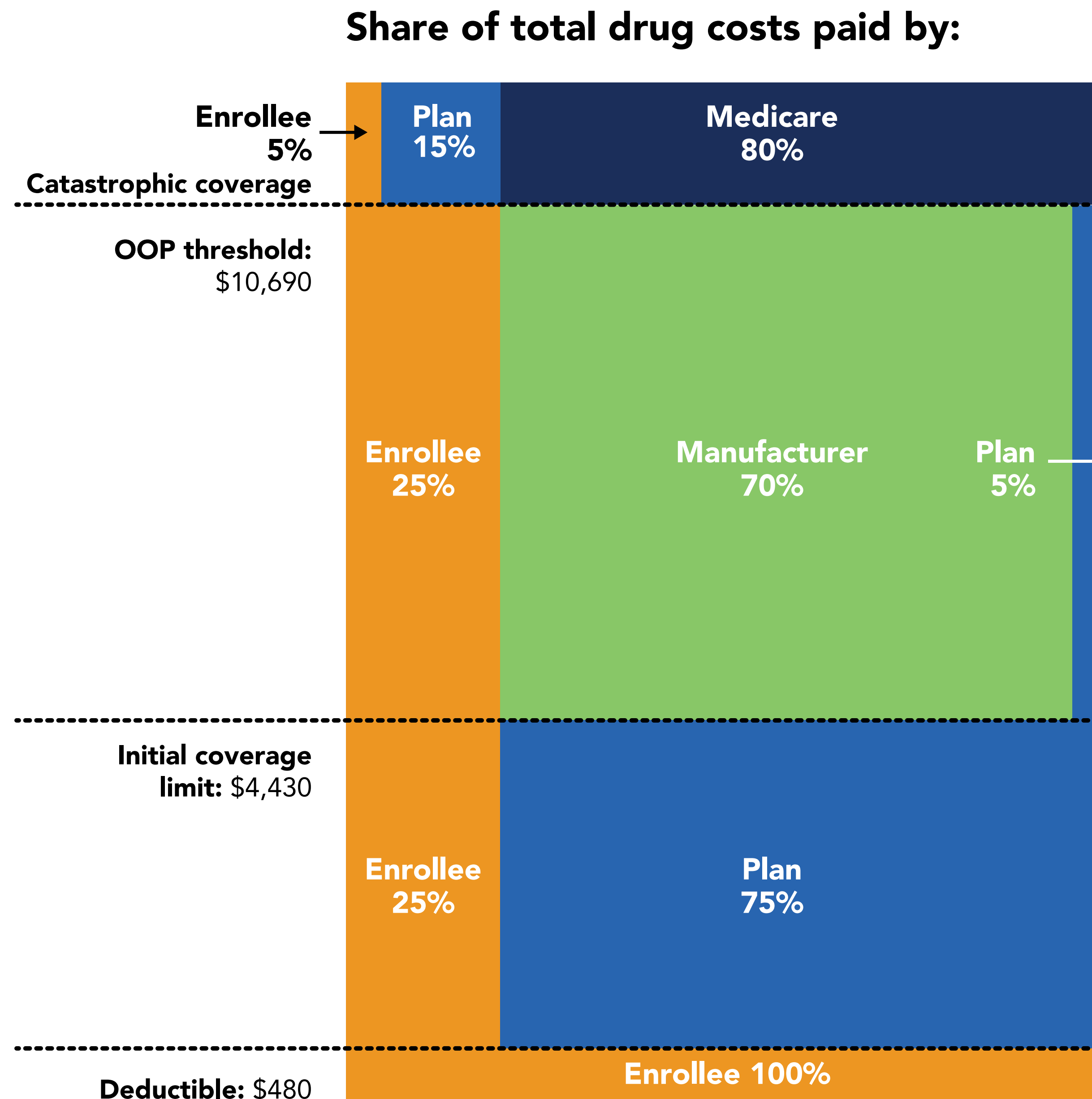
As shown in **Figure 39**, the Medicare Part D standard benefit is divided into 4 phases of coverage: deductible, initial coverage, coverage gap (“donut hole”), and catastrophic coverage, although it does not have a hard cap on out-of-pocket spending.

All stakeholders – patients, health plans, Medicare, and manufacturers – contribute financially under the Part D program (**Figure 39**).

## Drilling down on patient out-of-pocket costs

In 2022, after paying a \$480 deductible, beneficiaries have a 25% copayment for brand name drugs and biologics (including biosimilars) until they reach catastrophic coverage. After the deductible, beneficiaries spend another \$2,552.55 out of pocket to reach catastrophic coverage, where they have a 5% copayment with no spending ceiling. Including the deductible, beneficiaries will have spent \$3,032.55 out of pocket to reach catastrophic coverage in 2022.

**Figure 39.** 2022 Part D Standard Benefit Design<sup>98</sup>



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# MEDICARE UPDATES

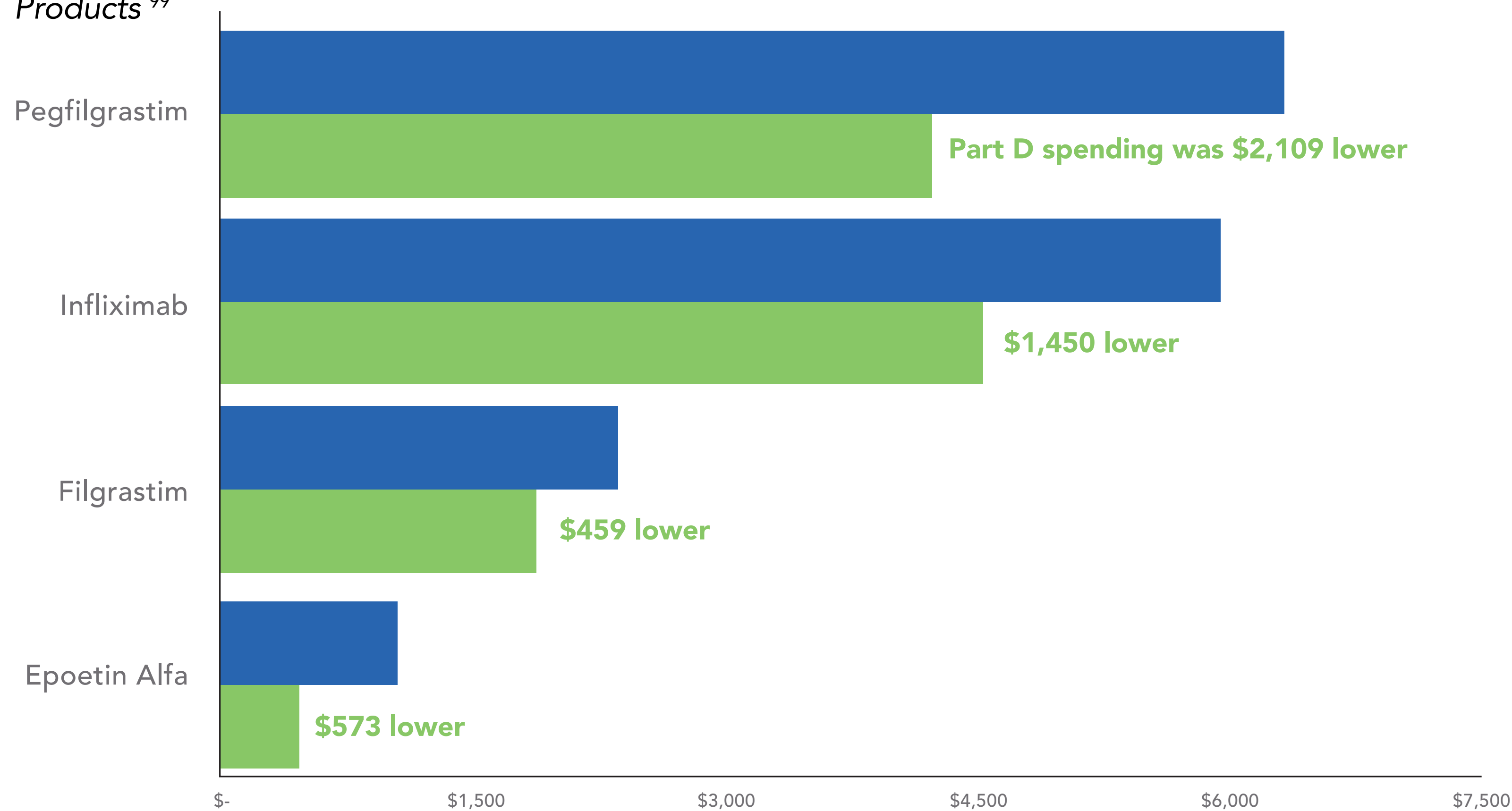


## Increasing the use of biosimilars in Medicare Part D could reduce spending for CMS

In Medicare Part D, biosimilar reimbursement is set through negotiation between plans and pharmaceutical manufacturers. According to a 2022 report from the Department of Health and Human Services Office of Inspector General (HHS OIG), Part D spending could have been reduced between 18% and 31% if biosimilars were used at a higher rate.<sup>99</sup> However, a number of factors limit the use of biosimilars in Part D, such as formulary exclusion, unfavorable formulary tier placement, and rebates for preferential formulary treatment of reference products.<sup>99</sup> In addition, CMS may not interfere with the price negotiations, which does help keep a level playing field between reference products and biosimilars.<sup>99</sup>

There are 8 biosimilars available and approved as alternatives to 4 reference products for beneficiaries in Part D.<sup>99</sup> So far, HUMIRA® and ENBREL® are covered only under Part D, with their biosimilars not yet available to US consumers.<sup>99</sup>

**Figure 40.** Medicare Part D Spending for Typical Prescriptions was Lower for Biosimilars than for the Biosimilars' Reference Products<sup>99</sup>



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# 340B PROGRAM



The 340B Drug Pricing Program requires pharmaceutical manufacturers participating in Medicaid to sell outpatient drugs at discounted prices to nonprofit healthcare organizations that provide care for many uninsured and low-income patients. Sites within a healthcare system that qualify as 340B entities can obtain federally mandated “ceiling price” discounts for covered outpatient drugs.<sup>100</sup>

Before January 1, 2018, Medicare paid both 340B and non-340B hospitals at the same rate for certain 340B treatments, such as biologics (including biosimilars), even though 340B hospitals can obtain those treatments at a discount.<sup>101</sup> Effective January 1, 2018, however, Medicare paid for non-pass-through drugs and biologics (other than vaccines) purchased through the 340B program at ASP minus 22.5%.<sup>9</sup>

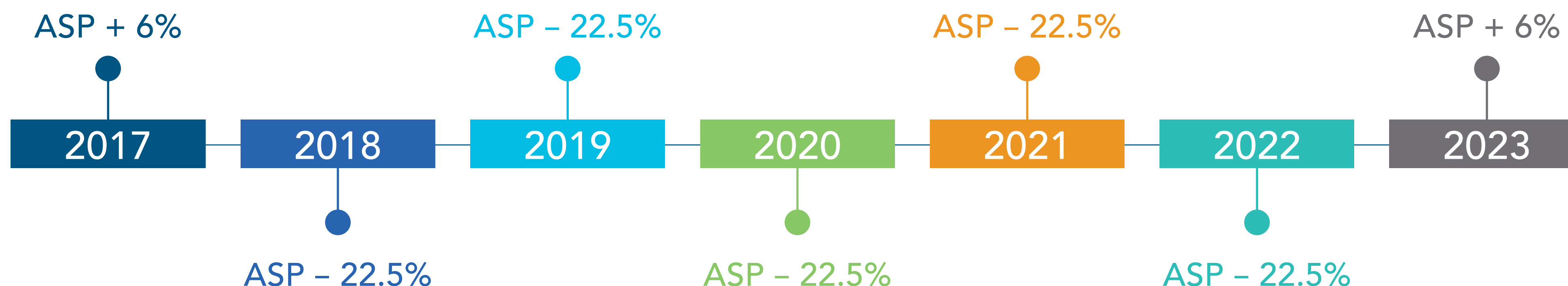
However, in June 2022, the US Supreme Court held that CMS may not vary the reimbursement rates only for 340B hospitals. The Court found that the Medicare statute lays out the formula HHS must employ to set the reimbursement rate for covered outpatient prescription drugs.<sup>102</sup>

In its calendar year 2023 proposed rule for the Outpatient Prospective Payment System, CMS stated it “fully anticipates” applying a rate of ASP + 6% to 340B-acquired drugs and biologics in the final rule for calendar year 2023, in light of the Supreme Court’s decision.<sup>103</sup>

**340B healthcare organizations include nonprofit community health centers, children’s hospitals, hemophilia treatment centers, critical access hospitals, sole community hospitals, rural referral centers, and public and nonprofit disproportionate-share hospitals that serve low-income and indigent populations.**<sup>104</sup>

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**Figure 41.** Timeline of 340B Reimbursement Rates





# US POLICY UPDATE

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# BIOSIMILARS POLICY OVERVIEW

Spending on medicines in the US reached over \$400 billion in 2021, up 12% year over year.<sup>34</sup> While spending related to COVID medicines drove much of the growth, spending on non-COVID medicines grew as well. During this time, biosimilars have continued to gain share, potentially helping to offset additional growth in spending in the marketplace.<sup>34</sup> With policymakers focused on alleviating cost pressures, particularly patient out-of-pocket costs, biosimilars may play an important role in achieving that goal.

Competition created by reliably supplied, high-quality biosimilars has the potential to alleviate some of the financial burden for governments, hospitals, and patients, while delivering the clinical benefits of reference biologic medicines. Biosimilars have placed downward pressure on product prices through competition.

With this in mind, certain US federal policy changes have been enacted to promote a level playing field between reference products and biosimilars, which will allow physicians to choose which product is best for their patients, based on a number of attributes.



***As we look ahead, biosimilars may continue to offer more affordable biologic treatment options, drive cost savings through increased competition between biosimilars and reference biologics and promote a more resilient healthcare marketplace. Policy and regulatory actions continue to impact the adoption of biosimilars and will continue to do so over the next few years.***



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# BIOSIMILAR REIMBURSEMENT POLICIES



Policymakers continue to play an important role in helping to set the reimbursement framework for medicines, including biosimilars.

Importantly, Medicare Part B currently reimburses for reference products and biosimilars with separate payment codes which has paved the way for the success of the current competitive landscapes whereby we see multiple biosimilars per reference product. Congress has also lessened the impact of financial considerations on clinical decision making by providing that the add-on payment in Medicare Part B is based on the reference product's ASP regardless of whether the provider prescribes a reference product or biosimilar.<sup>105</sup> This has bolstered the success of the rapidly growing marketplace, allowing manufacturers to compete on a level playing field, as well as to invest in delivery devices, patient support, provider education, and commitment to reliable supply.<sup>106</sup> These are examples of productive policy that promotes competition and supports long-term marketplace sustainability.



**Competition has resulted in potential cost savings for both reference products and biosimilars, while providing additional treatment options for patients.**



## Global Policy Perspectives

### Considerations regarding a single-tender winner structure

The single-tender winner structure is not used in the US. The US healthcare system is based on price competition among manufacturers operating on a level playing field, which has shown the potential to drive down prices for both reference products and biosimilars. Tendering is a formal procedure in which multiple suppliers bid to supply a medicine, with providers aiming to select the supplier that offers the best value.

In the EU, public and nonpublic hospitals and clinics are encouraged to organize tenders to obtain lowest-cost biologics. Tendering is a formal procedure in which multiple suppliers bid to supply a medicine, with providers aiming to select the supplier that offers the best value. Twelve European countries have single-winner tenders awarded to the manufacturer with the lowest bid and proven capacity to supply.

However, the tender structure can have unintended consequences. In France, the single-tender winner structure has led to shortages and product withdrawals from the market. In some drug classes, there was only one alternative available. To maintain competition and avoid shortages, France now implements a "two-winners" approach for certain products in national tenders.<sup>107</sup>

The single-tender winner structure is not used in the US. The US healthcare system is based on the market providing price competition and supporting patient access.

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# POLICY LANDSCAPE



## Inflation Reduction Act

On August 16, 2022, the Inflation Reduction Act was signed into law by President Biden. The Act includes several healthcare elements that impact the biopharmaceutical industry, including biosimilar manufacturers. Outlined below are key provisions that will have potential impact on the marketplace with biosimilars:

- The law temporarily increases the Medicare Part B add-on payment for certain biosimilars from 6% to 8% of the reference product's ASP from October 1, 2022, through the end of 2027.
- The law gives the Secretary of Health and Human Services (HHS) the authority to establish a Maximum Fair Price (MFP) for certain high-spend Medicare drugs.
- A reference product is excluded from the MFP process if there is already a marketed biosimilar. The law also empowers the Secretary of HHS to delay implementation of an MFP if there is a "high likelihood" that a biosimilar will be approved within 2 years.

The implementation of the law is underway. Analysis of the potential impact of the Inflation Reduction Act on the marketplace with biosimilars is ongoing.



[Click here](#) for more details regarding the bipartisan Advancing Education on Biosimilars Act of 2021.

## Access to biosimilars

In September of 2022, Congress reauthorized the Biosimilar User Fee Act (BsUFA) for fiscal years 2023-2027, known as BsUFA III. This reauthorization allows the FDA to continue to collect fees from pharmaceutical manufacturers that submit marketing applications for biosimilars.<sup>108</sup> The fees support FDA review of new biosimilar products and enhance the biosimilar product development process. The legislation also promotes the development and availability of interchangeable biosimilars.<sup>108</sup> More generally, BsUFA III supports patient access to biosimilars, focusing on best practices in communication between FDA and sponsors, regulatory science, finance, hiring and retention at FDA, and supplemental applications.<sup>108</sup>



[Click here](#) for the FDA provider education toolkit.

## Education policies

Separately, policies focused on educating healthcare providers, patients, payers, employers, and the organizations that represent them about biosimilars will be a key part to supporting biosimilar acceptance and use.

**The bipartisan Advancing Education on Biosimilars Act, signed into law in April 2021, requires the FDA to provide educational materials and programs to patients and providers that describe the safety and effectiveness of approved biosimilars, enhancing confidence in these medicines, with the potential to support uptake and drive healthcare savings.<sup>109</sup> This new educational material will supplement the already expansive [educational content made available by FDA](#).**

**In February 2022, the FDA hosted a webinar titled, FDA Drug Topics: Biosimilar and Interchangeable Biosimilars: Review of Scientific Concepts, Case Studies, and Resources. This webinar provided an intermediate overview of the scientific and regulatory basis for the biosimilar and interchangeable biosimilar approval pathway. After successful completion of the webinar's post-test, physicians, physician assistants, and nurses can receive continuing education credits.<sup>110</sup>**

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# 4 KEY ELEMENTS TO A SUCCESSFUL MARKETPLACE WITH BIOSIMILARS

In order to continue to realize the promise of biosimilars – including meaningful cost savings and strengthened healthcare system resilience – over the long term, Amgen believes that the following elements are critical:



**Implementing scientifically appropriate regulatory standards to demonstrate biosimilarity and interchangeability, and to facilitate product identification.**

This supports confidence among prescribers and patients. Current standards outlined in FDA guidance for demonstrating biosimilarity and interchangeability are scientifically appropriate and will serve to promote patient safety and build physician confidence when biosimilars are prescribed or substituted appropriately at the pharmacy level.



**Providing scientifically accurate educational outreach that helps give all stakeholders confidence and helps support biosimilar acceptance and use.**

It's important to help physicians and other healthcare professionals understand the scientific data needed to attain regulatory approval for biosimilars, as well as help build trust that an approved biosimilar will be as safe and effective as its reference product. This allows prescribers and patients to make confident treatment decisions.



**Maintaining an environment that encourages head-to-head competition between biosimilars and their reference products on a level playing field and supports long-term resiliency of the marketplace with biosimilars.**

This means that in addition to cost savings, manufacturers can compete with important product attributes such as delivery devices, patient support services, provider education, and commitment to reliable supply.



**Ensuring a foundation of strong intellectual property protections.**

Intellectual property is essential to promoting research and development that delivers cutting-edge medicines and addresses unmet medical needs. A strong intellectual property environment also promotes competition among reference products and biosimilars. Providing strong and predictable incentives for innovation will lead to the next cutting-edge product, which in turn can lead to a biosimilar of that product and promote competition.



## Global Policy Perspectives

### Impact of limiting supplemental protections

Supplementary protection certificates (SPCs) are an intellectual property right that function as a patent extension for the originator product. The rationale for this common practice is to make up for exclusivity time lost between patent registration and marketing authorization.

In response, certain global markets have introduced an SPC waiver. In the EU, SPC waivers allow biosimilar developers to manufacture biosimilars of products covered by the SPC for the purposes of exporting them outside the Union or for storing them during the final stages of the SPC. This helps ensure timely market entry of biosimilars and puts biosimilar manufacturers on a level playing field with their competitors.

While the US does not provide SPCs, it uses other non-patent exclusivity provisions such as clinical investigation exclusivity, orphan drug exclusivity, and pediatric exclusivity.<sup>111</sup>

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# THE BOTTOM LINE



US policymakers can best nurture a long-term, sustainable marketplace with biosimilars by maintaining effective policies that allow head-to-head competition on a level playing field among reference products and between biosimilars.



If the right balance is achieved, biosimilar competition has the potential to produce meaningful savings that will endure well into the future. This will allow for a resilient system that supports both biosimilars and new reference products – providing patients, physicians, and payers with a range of treatment options and a degree of flexibility of choice.



Meanwhile, policymakers continue to assess the impact of biosimilars on healthcare spending. In February 2022, the HHS OIG announced it will study biosimilar use and spending across the Medicare Part B program to understand how the increased use of biosimilars across Part B may save the program money and to examine barriers to biosimilar utilization. The study is set to begin in 2023.<sup>112</sup>



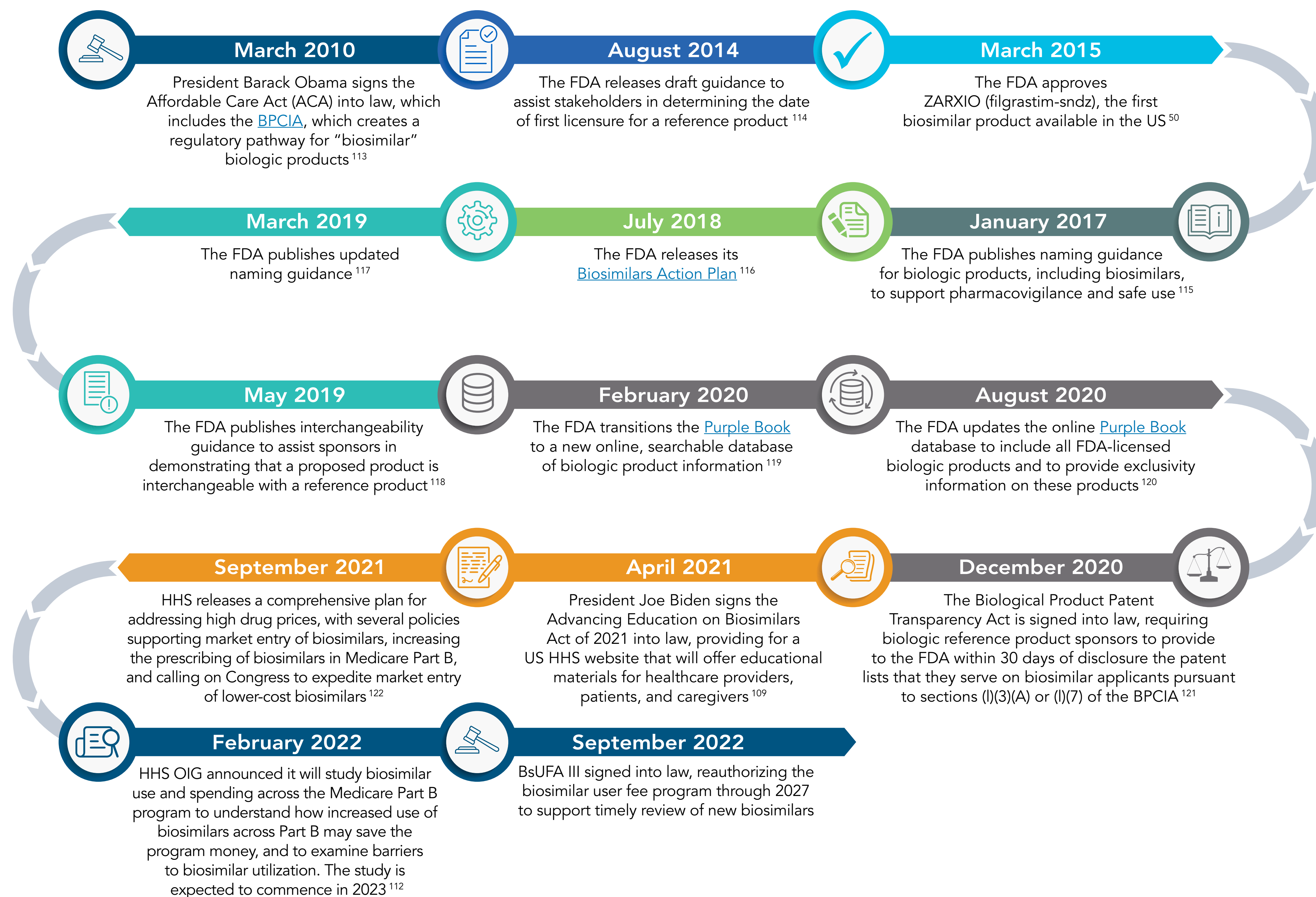
Separately, the HHS OIG published an analysis in March 2022 that found that Medicare Part D spending on biologic medicines in 2019 could have been reduced by \$84 million, or 18%, if biosimilars had been used more frequently – and beneficiaries themselves could have saved \$1.8 million. The report recommends that CMS encourage plans to increase access to and use biosimilars in Part D. Although a limited number of biosimilars are currently available for Part D–covered reference products, multiple biosimilars for HUMIRA are expected to be available in 2023.<sup>99</sup>

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# A GLANCE AT THE PAST DECADE

## Biosimilar milestones



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# BIOSIMILAR FAQs

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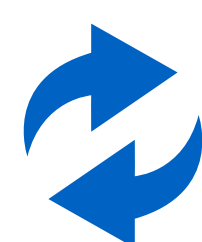
# WHAT ARE THE CHARACTERISTICS THAT DEFINE BIOSIMILARS?

A biosimilar is a biologic that is highly similar to, and has no clinically meaningful differences from, another biologic that is already approved by the FDA (known as the originator biologic or reference product).<sup>123</sup>

For additional information regarding the fundamental differences between biologics (including biosimilars) and small-molecule drugs (including branded drugs and generics), please refer to Amgen’s BioEngage Inside Biosimilars website:



[What Are Biosimilars?](#)



[Biosimilars vs. Reference Biologics](#)



[Biologics vs. Small-Molecule Drugs](#)

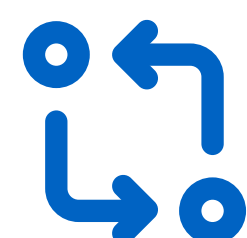
# WHAT IS THE FDA APPROVAL PATHWAY FOR BIOSIMILARS?

The BPCIA, signed into law as part of the ACA in 2010, established the **abbreviated approval pathway** for biosimilars in the US.<sup>124</sup>

Because biologics contain active substances derived from living cells or organisms, the development of a biosimilar is much more complex than the process for developing a small-molecule generic drug. A biosimilar requires the creation of a new manufacturing process and a custom cell line, since the reference product’s manufacturing process is proprietary and not publicly available.<sup>125</sup>

Due to the complex nature and production methods of biologics, relatively minor changes in manufacturing processes may significantly affect product quality, safety, and efficacy.<sup>126</sup>

Based on the provisions in the BPCIA, the FDA recommends a step-by-step biosimilar development approach. At each step in development, an applicant should do the following<sup>127</sup>:



Identify any differences between the reference and biosimilar products



Determine what residual uncertainty about biosimilarity remains based on the potential impact of the observed difference



Design subsequent studies to address the remaining residual uncertainty



[Click here](#) for downloadable resources.

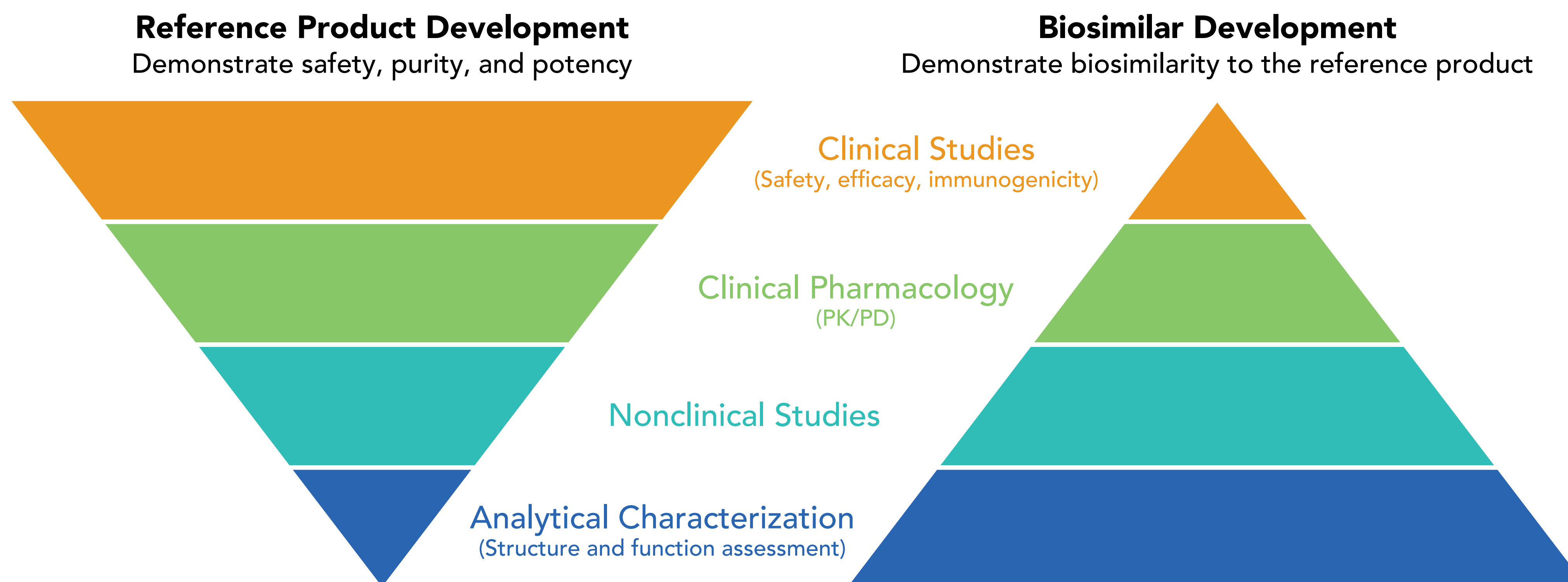
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# WHAT ELSE IS UNIQUE ABOUT THE FDA'S APPROVAL PATHWAY FOR BIOSIMILARS?

As shown in **Figure 42**, the types of data that are generated for a biosimilar (e.g., comparative analytical data) are different than for a reference product. How the data are considered is also different: the goal of the biosimilar development program is not to re-establish the safety and efficacy of the product, but rather to demonstrate it is "biosimilar" to the reference product.<sup>127</sup> Due to the ability to rely on the FDA's previous finding of safety and effectiveness for the reference product, a biosimilar may have a shorter and less costly development program.

**The BPCIA's abbreviated licensure pathway allows for reliance on the FDA's previous findings of safety and effectiveness for the reference product, promoting a potentially shorter and less costly development program for biosimilars.**

**Figure 42.** Reference Product Development vs. Biosimilar Development<sup>127</sup>



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# WHAT IS THE ROLE OF COMPARATIVE CLINICAL STUDIES AS PART OF THE BIOSIMILAR DEVELOPMENT PROGRAM?

Comparative clinical testing as part of the biosimilar development program is needed to demonstrate that no clinically meaningful differences exist in terms of safety and efficacy between a biosimilar and its reference product.

The clinical program generally includes a comparative pharmacokinetics study (with a pharmacodynamics comparison where suitable biomarkers exist), which is commonly conducted in healthy volunteers. This is typically followed by a comparative clinical study that is designed to assess comparative efficacy, safety, and immunogenicity in at least one relevant and sensitive patient population.

The aim of the comparative clinical efficacy studies is not to establish de novo safety and efficacy, as this has already been established independently for the reference product. Rather, the aim is to confirm that there are no clinically meaningful differences between the potential biosimilar and the reference product.<sup>128</sup>

# WHAT ROLE DOES EXTRAPOLATION PLAY IN THE DEVELOPMENT OF BIOSIMILARS?

Extrapolation is the approval of a biosimilar for use in an indication held by the reference product not directly studied in a comparative clinical trial with the biosimilar.<sup>129,130</sup> It is an essential regulatory concept for biosimilars that reduces or eliminates the requirement to study a proposed biosimilar with comparative clinical studies for every indication of the reference product.<sup>131</sup> Extrapolation is not automatic and is considered on a case-by-case basis based upon the totality of evidence and scientific justification.<sup>129,130</sup> In some instances, extrapolation will not be granted upon initial approval due to patent or regulatory exclusivity considerations.



For more details regarding indication extrapolation, refer to Amgen's short video "[The Scientific Justification for Extrapolation](#)."

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# CAN A BIOSIMILAR BE APPROVED FOR FEWER INDICATIONS THAN THE REFERENCE PRODUCT?

While less common, biosimilars may be approved for fewer indications than the reference product. This may occur if the reference product has unexpired exclusivity for an indication or is protected by an orphan drug designation or different mechanism of action.<sup>132</sup>

## WHAT IS INTERCHANGEABILITY?

A “biosimilarity” determination by the FDA is a necessary but not sufficient finding to support a demonstration of interchangeability. The FDA designates a biosimilar as “interchangeable” if, in addition to demonstrating biosimilarity, the manufacturer demonstrates<sup>132</sup>:



The product can be expected to produce the same clinical result as the reference product in any given patient



For a product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the product and the reference product is not greater than the risk of using the reference product without such alternation or switch

**To support a demonstration of interchangeability, FDA guidance indicates that it is generally expected for a manufacturer to conduct one or more “switching studies” that will assess the safety or efficacy of alternating between the reference biologic drug product and the biosimilar.<sup>133</sup> The exceptions to this FDA guidance are interchangeable biosimilars with minimal or no risk of clinically impactful immunogenic responses.<sup>133</sup>**

## WHEN CAN AN INTERCHANGEABLE PRODUCT BE SUBSTITUTED FOR THE REFERENCE PRODUCT?

An interchangeable biosimilar product may be substituted for the reference product by a pharmacist without the involvement of the prescriber (pursuant to state pharmacy laws). All 50 states plus DC and Puerto Rico have passed legislation to allow a pharmacist to substitute an interchangeable biosimilar for its reference product at the pharmacy as of July 2021.<sup>46</sup>



### Global Policy Perspectives

#### Pharmacy substitution rules

Despite not having an EU-wide definition of “interchangeability” or a standard for pharmacy-level substitution, some countries have developed specific policies on pharmacy-mediated substitution for biosimilars. Substitution policies allow a pharmacist to dispense one medicine instead of another medicine without the consent of the prescribing physician.

No other country in the world has the US’ “interchangeable” regulatory designation for biosimilars, which is the gold standard for substitution at the pharmacy level.

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# HOW ARE US BIOSIMILARS NAMED?



Pharmacovigilance, the monitoring and tracking of drug safety over time, is important to detect any emerging safety signals of any biologic, including biosimilars.<sup>134</sup> To help facilitate pharmacovigilance, the FDA released final guidance on the nonproprietary naming of biologic products (including biosimilars) in January 2017.<sup>115</sup> The benefits of the naming convention should bolster patient and physician confidence and encourage manufacturer accountability by providing additional ways to help track prescribed products appropriately.<sup>115</sup>

Under the guidance, each new originator biologic, related biologic, and biosimilar will be assigned a nonproprietary name consisting of a core name and a hyphenated distinguishing suffix of 4 lowercase letters.<sup>115</sup>

The example in **Table 7** shows hypothetical nonproprietary names of a reference product and its biosimilar:

**Table 7.** Comparison of Nonproprietary Names of Reference Products and Biosimilars<sup>115</sup>

	Core name	Distinguishing suffix*
Reference product	Same core name	-agdb
Biosimilar	Same core name	-eyfp



For more information regarding the purpose of the FDA’s policy regarding naming, refer to Amgen’s “Prescribing Biosimilars/Naming” article on the [BioEngage website](#).

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Key: FDA – Food and Drug Administration; US – United States.

\*The suffix is an example. Some reference products do not have a suffix, while the biosimilars typically do.

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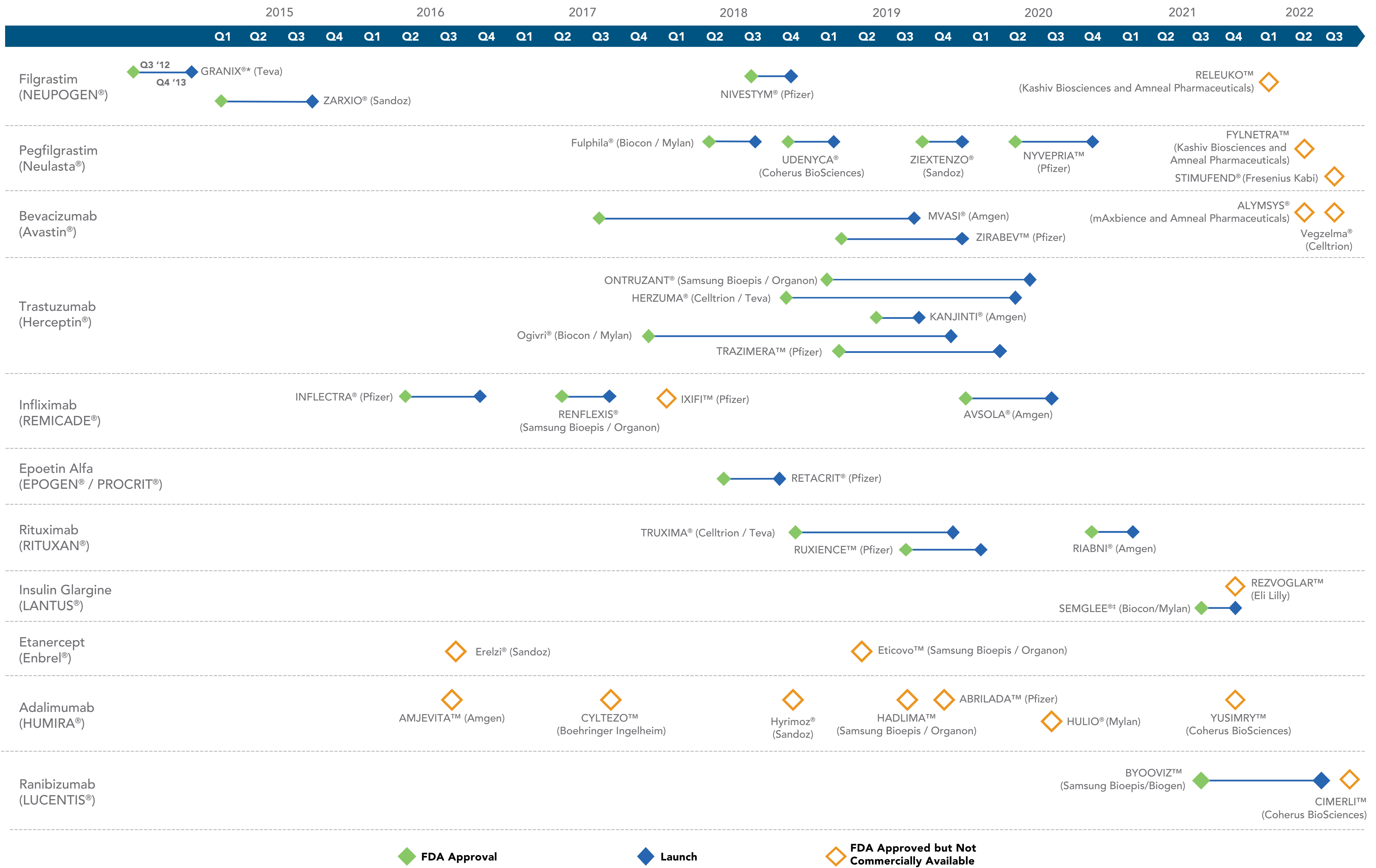
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**Figure 3. Approved and Launched Biosimilars (including GRANIX\*) in the US<sup>2,†</sup>**

CLICK TO CLOSE 



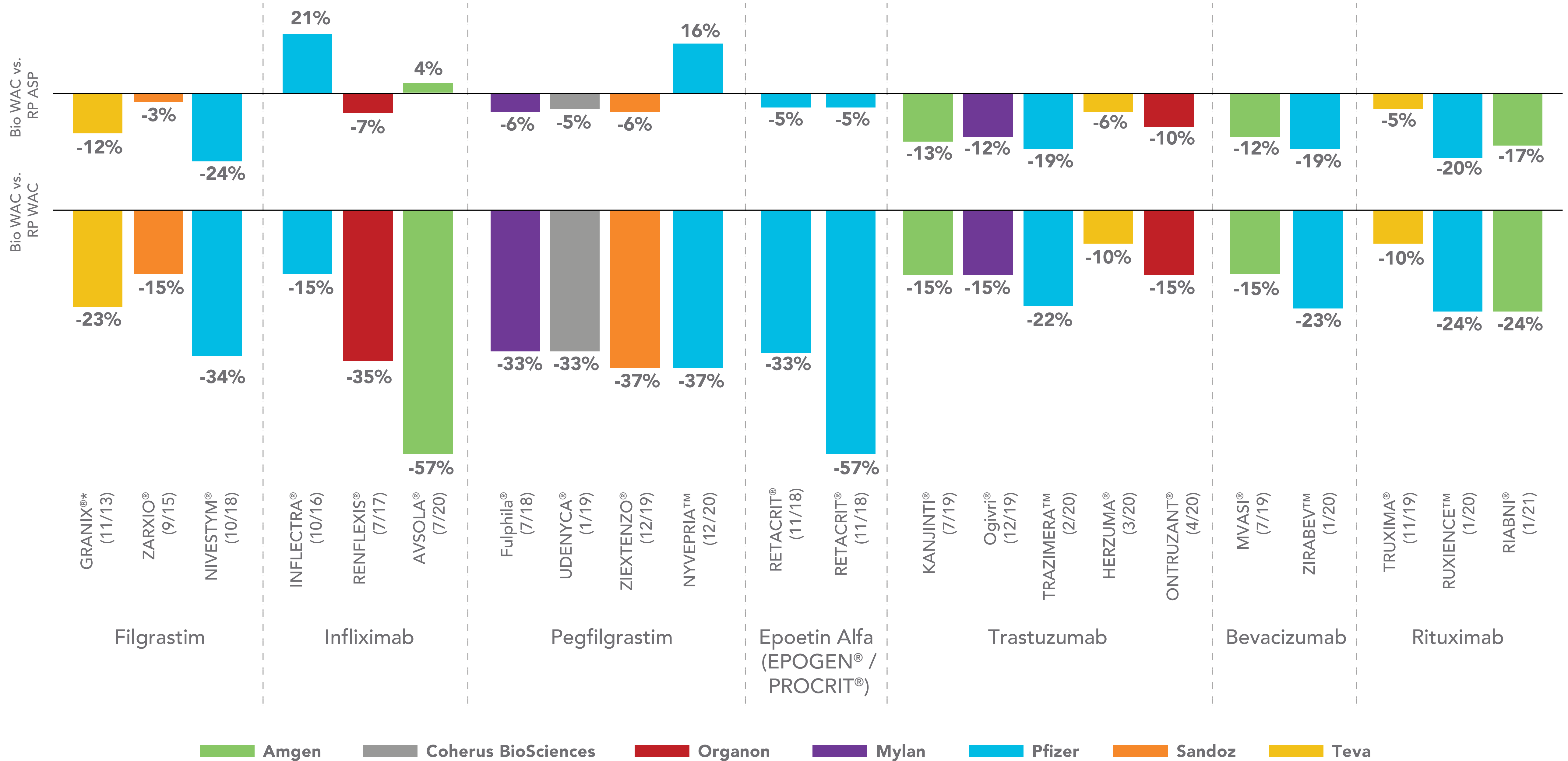
◆ FDA Approval     
 ◆ Launch     
 ◆ FDA Approved but Not Commercially Available

Please [click here](#) for Boxed Warning information for AVSOLA, Enbrel, EPOGEN, KANJINTI, and RIABNI.

Key: BLA – Biologics License Application; FDA – Food and Drug Administration; US – United States.  
 \*GRANIX is not a biosimilar. It was approved under a stand-alone BLA, which was submitted to the FDA before the enactment of the biosimilar approval pathway.  
 †All trademarks appearing herein are the property of their respective owners.  
 ‡SEMGLEE was approved by the FDA in June 2020 with a stand-alone BLA. The FDA subsequently approved SEMGLEE as an interchangeable biosimilar in July 2021.<sup>13,14</sup>

**Figure 4. Price at Launch vs. Reference Product<sup>8</sup>**

CLICK TO CLOSE



Biosimilar WAC vs. Reference Product WAC:

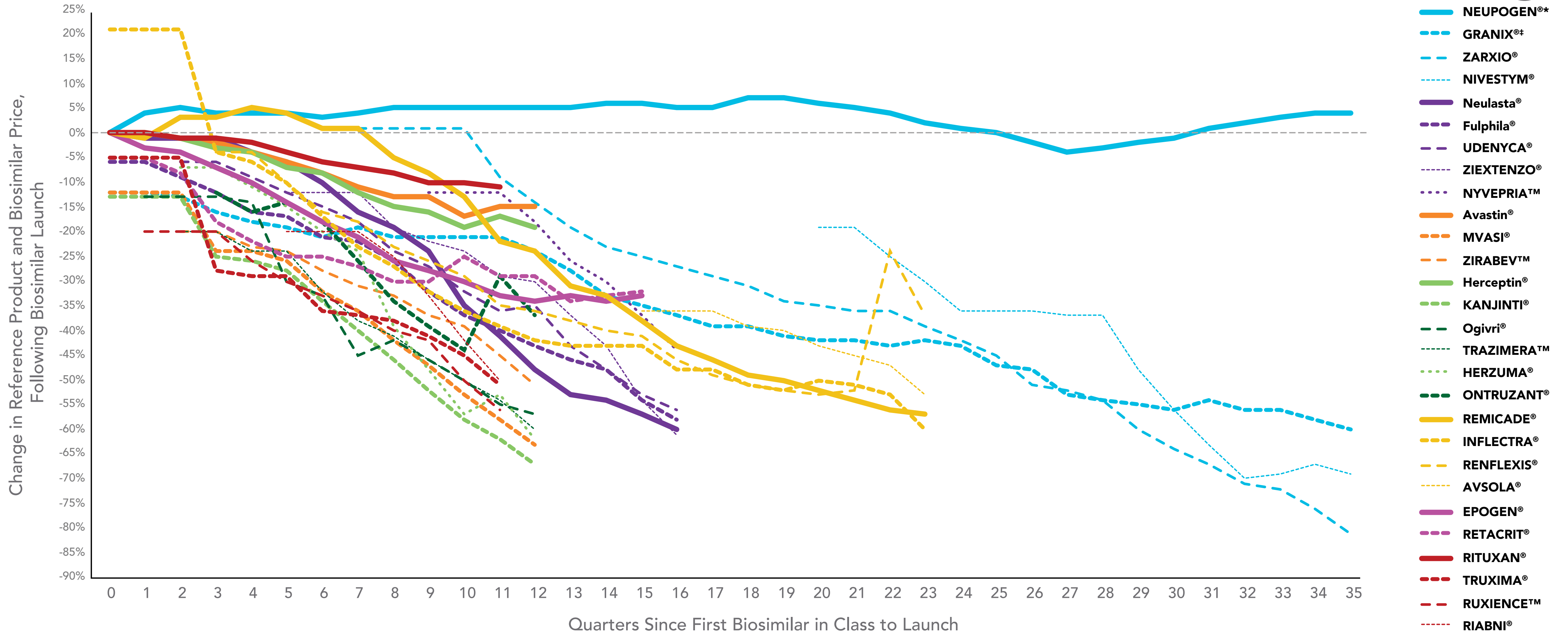
**Biosimilars primarily covered under the medical benefit typically launch at a WAC that is generally 15% to 37% lower than the reference product.**

Please [click here](#) for Boxed Warning information for AVSOLA, Enbrel, EPOGEN, KANJINTI, and RIABNI.

Key: ASP – average sales price; Bio – biosimilar; FDA – Food and Drug Administration; RP – reference product; WAC – wholesale acquisition cost.  
 \*GRANIX is not a biosimilar. It was approved under a stand-alone Biologics License Application, which was submitted to the FDA before the enactment of the biosimilar approval pathway.  
 Source: AnalySource.

**Figure 5. Downward Trend in ASP for Biosimilars and Reference Products Over Time<sup>8</sup>**

CLICK TO CLOSE 



**The prices of biosimilars have decreased at a negative CAGR of -9% to -24%.**

**The prices of most reference products\* have decreased at a negative CAGR of -4% to -21%.**

Please [click here](#) for Boxed Warning information for AVSOLA, Enbrel, EPOGEN, KANJINTI, and RIABNI.

Key: ASP – average sales price; CAGR – compound annual growth rate; FDA – Food and Drug Administration.

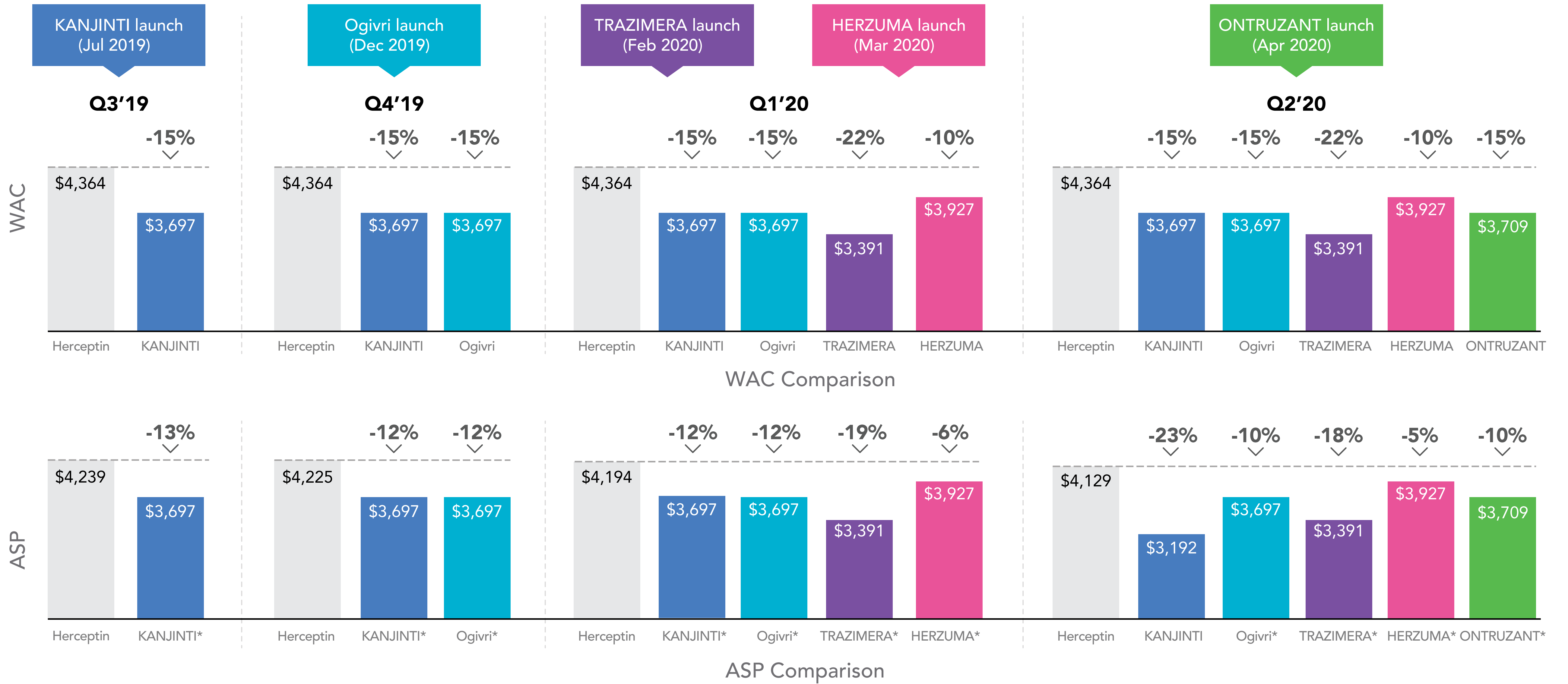
\*NEUPOGEN<sup>®</sup>'s biosimilar price-response strategy focused on account-level provider contracting. This targeted approach modestly increased the ASP-eligible discount rate resulting in a more stable ASP trend.

<sup>†</sup>GRANIX is not a biosimilar. It was approved under a stand-alone Biologics License Application, which was submitted to the FDA before the enactment of the biosimilar approval pathway.

Source: AnalySource.

**Figure 10. WAC and ASP of Trastuzumab Biosimilars Relative to Reference Product at Launch<sup>8</sup>**

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Please [click here](#) for Boxed Warning information for KANJINTI.  
See [Full Prescribing Information](#) for complete risk information.

Key: ASP – average sales price; WAC – wholesale acquisition cost.  
\*ASP was not available for these products at the time of comparison. WAC is used to compare with reference product ASP.  
Source: AnalySource.

