



Amgen Releases 8th Edition of Biosimilar Trends Report

September 22, 2021

Report Finds That Competition Created by Biosimilars Delivered \$9.8 Billion in Savings Over the Past Five Years to the U.S. Healthcare System, Generating Savings for Patients, Payers and Employers
With Both a Strong Innovator Portfolio and a Deep Investment in Biosimilar Products, Amgen has Been a Pioneer in Biotechnology for ~40 Years and Invested Close to \$2 Billion Across a Portfolio of 10 Biosimilar Medicines

THOUSAND OAKS, Calif., Sept. 22, 2021 /PRNewswire/ -- Amgen (NASDAQ: AMGN) today released the 8th edition of the Biosimilar Trends Report, which examines the current state of the U.S. biosimilars marketplace across inflammation, oncology and nephrology categories, while a new feature considers how advancements in biosimilars can support the long-term success and sustainability of the U.S. healthcare system. To access the full report, visit: www.amgenbiosimilars.com/commitment/trends-report.

To view the multimedia assets associated with this release, please click: <https://www.multivu.com/players/English/8812854-amgen-8th-edition-biosimilar-trends-report/>



Since the first biosimilars entered the U.S. marketplace in 2015, **30 products** have been approved and **21 products** have been launched, giving patients and the health system more treatment options. This growth is expected to continue in the coming years, with competition estimated to triple by 2023¹, as the U.S. marketplace sees biosimilars introduced for multiple new therapeutic areas, including the potential approval of more interchangeable biosimilars.

Increased Payer Biosimilar Adoption

Increasingly, payers are adopting biosimilars, including or replacing originator products with biosimilars on their formularies, or designating biosimilars as preferred products, which helps promote competition and has the potential to lower costs. In fact, biosimilars are expected to save the U.S. healthcare system \$100B over the next 5 years.²

How Biosimilars May Generate Savings for Payers

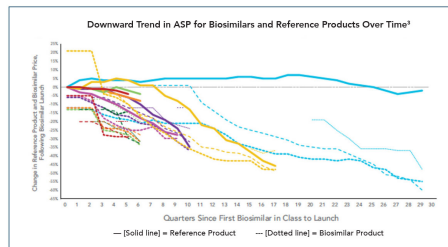
Biosimilars may lead to potential cost savings for payers across both reference products and other biosimilars in the same therapeutic category.

Biosimilars Usually Launch with Significant Discounts to WAC and ASP: Biosimilars generally launch at a Wholesale Acquisition Cost (WAC) **15% to 37%** lower than the reference product WAC. Almost all biosimilars have launched at a WAC **3% to 24%** below the reference product Average Sales Price (ASP).³

Competition Usually Drives Down ASP Across Therapeutic Category: As shown in the graph below, in most cases, the prices of biosimilars decline once ASP is established. This steady downward trend over time drives down reference product ASP, leading to potential additional system savings.

The availability of biosimilars in key therapeutic categories that currently have only 1 or a few originator biologics available helps promote competition and is a tool payers can use to help lower costs.

For more information on the role biosimilars play in helping reduce health system costs, you can view Amgen's Biosimilar Trends Report here: <https://www.amgenbiosimilars.com/commitment/trends-report>



¹ IQVIA Institute for Human Data Science. The Global Use of Medicine in 2019 and Outlook to 2023. January 29, 2019. URL: <https://www.iqvia.com/institute/reports/the-global-use-of-medicine-in-2019-and-outlook-to-2023>. Accessed June 2020.
² IQVIA. A positive road ahead for biosimilars? January 2021. <https://www.iqvia.com/insights/the-iqvia-institute/reports/a-positive-road-ahead-for-biosimilars>.
³ Data on file, Amgen, Product and Biosimilars - WAC and ASP Price; July 2021.

The Report shows that competition created by biosimilars has saved the U.S. healthcare system \$9.8 billion over the past five years,ⁱ and has the potential to reduce out-of-pocket spending by \$238 million for patients in the nine biologic drug classes where biosimilars have been approved. According to the Report:

- Biosimilars contribute to competition that drives down healthcare costs by providing significant wholesale acquisition cost (WAC) and average sales price (ASP) discounts at launch, resulting in additional savings over time.
- Biosimilars are launching at a price that is generally 15% to 37% lower than the reference product.ⁱⁱ Furthermore, the ASP is declining for both reference products and biosimilars over time, while the rate of biosimilar uptake is generally increasing over time.^{iii,iv}
- Biosimilars have gained substantial share in the majority of therapeutic areas where they have been introduced.^v For

therapeutic areas with biosimilars launched in the last two years, the average share was 65%.^{vi}

This year's Report features a new section, Future State of the Marketplace, which outlines how biosimilars can continue to offer more affordable treatment options, drive cost savings through increased competition between biosimilars and with reference biologics, and promote a more resilient U.S. healthcare marketplace. The U.S. marketplace is poised to see further growth in biosimilars approved to date and welcome many new biosimilars in the years to come.

"As part of Amgen's commitment to staying at the forefront of biosimilar education, Amgen is pleased to announce the launch of the 2021 Biosimilar Trends Report," said Jennifer Norton, vice president, Head of U.S. Value and Access at Amgen. "The increasing availability and adoption of biosimilars means these treatments are delivering on the fundamental promise of reducing healthcare costs for payers, employers, and patients in the United States."

The 2021 Biosimilar Trends Report also outlines the four key elements that Amgen believes are necessary for sustaining biosimilars' growth:

- Implementing scientifically appropriate regulatory standards for the approval, manufacture, and uninterrupted availability of safe and effective biological products, including biosimilars;
- Maintaining a marketplace that encourages competition on a level playing field to achieve meaningful savings and long-term stability;
- Providing scientifically accurate educational outreach to drive confidence with healthcare providers, patients, payers, and employers; and
- Ensuring a foundation of strong intellectual property to encourage innovation and investment.

"The U.S. marketplace with biosimilars is well established and accelerating across key therapeutic areas, creating cost savings, and additional treatment options for physicians and patients," said Chad Pettit, executive director, Marketing, Global Biosimilars Commercial Lead at Amgen, adding, "By continuing to advance science-based policies that support competition and enhance confidence from patients, physicians, and other stakeholders, the U.S. can help promote a robust and resilient healthcare system needed for the long term."

About Amgen Biosimilars

Amgen is committed to building upon Amgen's experience in the development and manufacturing of innovative human therapeutics to expand Amgen's reach to patients with serious illnesses. Biosimilars help to maintain Amgen's commitment to connect patients with vital medicines, and Amgen is well positioned to leverage its nearly four decades of experience in biotechnology to create high-quality biosimilars and reliably supply them to patients worldwide.

For more information, visit www.amgenbiosimilars.com and follow us on www.twitter.com/amgenbiosim.

About Amgen

Amgen is committed to unlocking the potential of biology for patients suffering from serious illnesses by discovering, developing, manufacturing and delivering innovative human therapeutics. This approach begins by using tools like advanced human genetics to unravel the complexities of disease and understand the fundamentals of human biology.

Amgen focuses on areas of high unmet medical need and leverages its expertise to strive for solutions that improve health outcomes and dramatically improve people's lives. A biotechnology pioneer since 1980, Amgen has grown to be one of the world's leading independent biotechnology companies, has reached millions of patients around the world and is developing a pipeline of medicines with breakaway potential.

For more information, visit www.amgen.com and follow us on www.twitter.com/amgen.

CONTACT: Amgen, Thousand Oaks
Megan Fox, 805-447-1423 (media)
Trish Rowland, 805-447-5631 (media)
Arvind Sood, 805-447-1060 (investors)

ⁱ Data on file, Amgen; Biosimilars Spend Analysis; July 2021.

ⁱⁱ Data on file, Amgen; Product and Biosimilars - WAC and ASP Price; July 2021.

ⁱⁱⁱ Data on file, Amgen; Product and Biosimilars - WAC and ASP Price; July 2021

^{iv} Data on file, Amgen; Biosimilars Market Share Trends; July 2021

^v Data on file, Amgen; Biosimilars Market Share Trends; July 2021

^{vi} Data on file, Amgen; Biosimilars Market Share Trends; July 2021

THE PROMISE OF BIOSIMILARS



As more biosimilars reach the marketplace, Amgen expects to see significant savings driven by competition with originator products and between biosimilars.¹ At a time when healthcare costs are rising, potential cost savings from switching from originator biologics to biosimilars is projected to be between \$40-250 billion by 2025 in the U.S., and in Europe, cost savings are already estimated to be more than €10 billion.^{2,3}

WHAT ARE BIOLOGICS?

Biologics are produced in genetically engineered living cells.⁴

Biologic medicines include therapeutic proteins, which replace or augment beneficial human proteins, and monoclonal antibodies.⁴

WHAT ARE BIOSIMILARS?

Biosimilars are biologic medicines that are highly similar to existing licensed biologic products (reference products or originator biologics) with no clinically meaningful differences in terms of safety and efficacy.⁴

Reference product or originator biologic refers to the original biologic medicine, approved based on a full dossier of product-specific preclinical and clinical data, against which a biosimilar is evaluated.⁴

WHY BIOSIMILARS?



Biosimilars may provide patients, physicians, and payers a range of treatment options and a degree of flexibility of choice in therapies that they may not otherwise have.⁴



Over time, meaningful savings can be derived from head-to-head competition – with originator products and between biosimilar products.⁵



Savings could be used to improve the broader healthcare system by allowing more funds to support system-wide improvements in key areas, such as:

- Supporting the adoption of new innovative medicines and technologies;⁶
- Diagnosis and prevention;⁶ and
- Maintaining appropriate healthcare staffing levels.⁶

BIOSIMILARS ARE NOT GENERICS

Generics are small molecule drugs and exact copies of their originator products. They are manufactured using a wholly reproducible process.⁷

Biologics, including biosimilars, are more structurally complex than generics and can be up to 1,000 times their size.⁸

A biologic molecule is grown in living cells which leads to inherent variability; therefore, a biosimilar is highly similar, though not structurally identical, to an originator product.⁸

Because of these distinct properties, biologics are more complicated to develop than small molecule drugs, and the regulatory pathway for biosimilar approval contains additional scientifically appropriate steps compared with the pathway for generic drugs.⁸

DEMONSTRATING BIOSIMILARITY

For biosimilars, the totality of evidence to demonstrate biosimilarity is necessary to support licensure. No single study or endpoint should be considered "pivotal" in a biosimilar marketing application.⁹

TOTALITY OF EVIDENCE¹⁰ =

Analytical Characterization

Nonclinical Studies

Clinical Pharmacology

Comparative Clinical Studies

A BIOSIMILAR DEVELOPMENT PROGRAM MUST...

...demonstrate that the biosimilar candidate is highly similar to and has no clinically meaningful differences from its originator product. Physicians and patients can trust that licensed biosimilars have been thoroughly tested and have a similar safety and efficacy profile as the originator product.¹⁰

View original content: <https://www.prnewswire.com/news-releases/amgen-releases-8th-edition-of-biosimilar-trends-report-301382173.html>

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