

THE U.S. MARKET FOR BIOSIMILARS AND BIOLOGICS MEDICINES

Since Congress enacted the Biologics Price Competition and Innovation Act (BPCIA) in 2010, biosimilars have become an important way to bolster competition and increase options for patients. The BPCIA created an abbreviated approval pathway for biosimilars while providing 12 years of data protection following the first licensure of innovative biologics, balancing the goal of reducing costs with the need to maintain incentives for the development of new innovative biologics. Since enactment of the BPCIA, a robust biosimilars market has emerged in the U.S., yielding increased competition and substantial savings for patients and the government. Here's what you should know about the biosimilar market today:

While the BPCIA is just over a decade old, it's clear the legislation has been a success in spurring competition in the biologics marketplace.

Owing to the ongoing implementation of the BPCIA framework, the number of biosimilar approvals in the U.S. biosimilar market has grown faster than the EU biosimilar market over a comparable period of time. In the six years following the EU's first biosimilar approval, there were a total of 11 approved biosimilars.^{1,2} By contrast, the U.S. Food and Drug Administration (FDA) has approved 31 biosimilars in the six years following the first biosimilar approval including the first interchangeable biosimilar.³ As of September 2021, there are 21 biosimilars on the market in the U.S. competing against 8 brand biologics. And there are 9 additional FDA approved biosimilars due to come to market over the next several years.⁴

The Biosimilar User Fee Act (BsUFA) has been vital to the regulatory review of biosimilar and interchangeable biosimilar products in the U.S. As a result of BsUFA, there is tremendous potential for biosimilars to continue to drive competition and savings in the years ahead with nearly 100 biosimilars in development for which sponsors are paying BsUFA fees as of June 2021.⁵

Owing to this successful framework, analysts have noted that we have truly reached "an inflection point," as competition is becoming increasingly robust and initial barriers to adoption and uptake are subsiding.⁶

Biosimilars are reducing prices, achieving market uptake, and are increasingly producing cost savings.

The biosimilars marketplace has become increasingly competitive with annualized savings from biosimilars reaching \$6.5B in 2020.⁷ Many biologics are physician-administered medicines reimbursed under Medicare's Average Sales Price (ASP) formula in Part B. In 2021, biosimilar ASPs were as much as 45% less than brand biologic product ASPs were at the time biosimilars were originally launched. And ASP prices for available biosimilars have been decreasing annually at a rate between 9% and 19%.⁸ One study highlights the savings brought on by growing biosimilar competition, finding in the absence of biosimilars, by April 2021 every brand name brand biologic would have had a much higher ASP, on average 56% higher.⁹ Importantly, increasing biosimilar competition has also resulted in out-of-pocket savings for patients, estimated at \$238 million per year.¹⁰

Additionally, this year marked a significant milestone for the millions of Americans who require insulin with the introduction of the first interchangeable biosimilar—an insulin—which is expected to further fuel competition in the biosimilar marketplace in the years ahead. Like many generics today, in most states interchangeable biosimilars may be substituted automatically at the pharmacy counter without intervention from the prescriber. Likewise, the savings that are anticipated to result from interchangeable biosimilar insulins are substantial.¹¹

More recently launched biosimilars are also reaching much greater market uptake than earlier launched biosimilars, which analysts see as a reflection of the maturing biosimilar market in which we continue to see positive shifts in physicians’ attitudes around prescribing biosimilars as well as increased provider and patient awareness of biosimilars.^{12, 13, 14} In fact, biosimilars of a supportive oncology therapy, which first launched in 2013, were only able to achieve a market share of 39% after 2 years on the market. In contrast, biosimilars first launched in 2019 of a commonly used breast cancer therapy reached 42% market share after just 1 year on the market, and analysts project these biosimilars will reach 60% in just 2 years’ time, with greater savings expected as a result.¹⁵

“This is a momentous day for people who rely daily on insulin for treatment of diabetes, as biosimilar and interchangeable biosimilar products have the potential to greatly reduce health care costs.”

Acting FDA Commissioner Janet Woodcock, MD

Importantly, evidence also suggests the increasingly competitive environment is leading to price reductions from both biosimilars and branded biologics, leading to lower costs for patients and Medicare. The Medicare Advisory Commission (MedPAC) found substantial drops in ASP for brand biologics facing biosimilar competition.¹⁶ For example, one brand biologic that dropped its ASP by 46% was able to stave off significant penetration from biosimilars; whereas another brand biologic that dropped its ASP by 6% lost significant market share to biosimilars which garnered 77% of the market by late 2020 (see chart below).

Trends in Medicare Part B Payment Rates for Brand Biologics and their Biosimilar Products (Adapted from MedPAC)

	First Biosimilar Entry	Percent Change in Brand Biologics’ ASP Since Biosimilar Entry (through 2021 Q1)	Biosimilars’ Payment Rate as a Percent of Brand Biologic’s Payment Rate (2021 Q1)	Biosimilar Market Share (2020 Q3)
Brand Biologic A and Biosimilars	2015 Q3	-6%	44%–56%	77%
Brand Biologic B and Biosimilars	2016 Q4	-46%	94%–115%	16%
Brand Biologic C and Biosimilars	2018 Q3	-35%	97%–116%	27%
Brand Biologic D and Biosimilars	2018 Q4	-28%	97%	47%
Brand Biologic E and Biosimilars	2019 Q3	-8%	75%–79%	41%
Brand Biologic F and Biosimilars	2019 Q3	-8%	74%–90%	40%
Brand Biologic G and Biosimilars	2019 Q4	-4%	74%–75%	24%



While evidence clearly demonstrates a well-functioning and robustly competitive biosimilar marketplace is increasingly at work today, uptake of biosimilars may vary significantly by setting, particularly for physician administered oncology medicines.^{17, 18, 19, 20} As awareness and comfortability with biosimilars has grown tremendously among both physicians and patients, this variability indicates that other factors may be influencing hospital-based purchasing decisions beyond obtaining the lowest-priced option for delivering appropriate care to patients.²¹

Market distortions may impede more expedient uptake of biosimilars.

Unfortunately, for many hospitals, there are market incentives to use a more costly brand biologic over a lower cost biosimilar due to the significantly higher reimbursements that hospitals obtain from marking up the cost of physician-administered drugs. On average, the reimbursements hospitals receive from commercial insurers are nearly 2.5 times larger than what they paid to acquire the medicines.²² Additionally, hospitals participating in the 340B program receive an average of 3-4 times what they paid to acquire the medicine.^{23,24} That is due, in part, because participation in the 340B program enables hospitals to access deeply discounted drugs which can generate significant profits from high reimbursement rates. Hospitals are not required under the 340B program to reinvest such profit margins in providing care to 340B vulnerable

or uninsured patients. Experts agree the greater profit potential (or “spread”) on 340B discounted drugs creates market distortions that increase costs across the health care system.²⁵ In fact, the GAO has found hospitals participating in the 340B program prescribe not only more drugs but more expensive drugs.²⁶ This is because the 340B spread is typically larger for more expensive medicines.²⁷

Slower uptake of certain biosimilars at 340B hospitals—with many not even carrying biosimilars at all—calls into question whether 340B-driven market distortions encourage the prescribing of more expensive medicines and discourage uptake of biosimilars in those settings.^{28,29,30,31} Ultimately, greater profit margins offered on brand biologics relative to biosimilars, which compete on reduced pricing relative to the brand biologic, may be too attractive for a hospital to pass up.

Looking forward, biosimilars are projected to drive an almost 5-fold increase in savings as new biosimilars launch and existing biosimilars see continued uptake and price declines. These savings are expected to exceed \$100 billion in aggregate between 2020 and 2024.³² However, there is a wide range of possible savings—from \$69 to \$140 billion—depending on a variety of factors that may influence the evolving landscape.³³ In order to harness the full potential of the biosimilars marketplace and realize the savings they offer to our health care system and patients, we need a balanced approach that reduces barriers to uptake of biosimilars and fosters competition.



Further focus and attention in the following areas is needed to continue to foster a robust biosimilar market:

1. **We need to reduce perverse incentives driven by the 340B program.** Policymakers should reform the 340B program to ensure patients benefit more directly from the discounts provided by manufacturers and that hospitals participating in the program are held accountable for how they use 340B discounts to benefit patients. This will not only help patients as intended but can also help reduce the financial incentives which may discourage use of biosimilars.
2. **Meaningful reforms to the rebate system may also reduce barriers to biosimilar uptake and promote access and competition.** Reforming the existing rebate system is expected to redefine the competitive landscape for payers and reshape the contracting relationships between stakeholders.^{34,35} As a result, as Milliman has noted, some of these reforms may promote increased uptake of generics and biosimilars which in turn could encourage more biosimilar launches.³⁶
3. Additionally, though increasing uptake of biosimilars indicates a positive shift in physician and patient attitudes towards the use of biosimilars, **we need to encourage continued focus on increasing provider and patient education to maximize the benefits of that shift**—this effort should include the development and dissemination of evidence-based materials on the full range of treatment options, including biosimilars, to further support appropriate biosimilar adoption
4. Now and into the future, **ensuring the long-term stability of the BsUFA program through financial transparency, efficiency, and accountability will be critical to further ensuring robust competition in the biosimilar marketplace.**
5. Lastly, to continue to foster the rapid emergence of the robust market for biosimilars we are seeing today, we need to maintain a balanced approach to **reimbursement policy to ensure there are adequate incentives for continued innovation and facilitating patient choice.**

In enacting the BPCIA over a decade ago, U.S. policymakers rightly sought to balance increased competition with policies that support the United States' leading role in finding new treatments for patients. By allowing the market to continue to evolve and enacting policies that support this evolution, we'll continue to see biosimilars' benefits for patients and society.

Endnotes

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