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Biosimilars are lowering costs in Medicare Part B and across the healthcare system overall

Introduction

Recently, stakeholders have expressed concern about the lack of use of biosimilars—which are often covered by Medicare Part B—for complex specialty medicines in the United States (US). Over the past several years, a number of academic researchers and stakeholders have questioned the strength of the US biosimilars market and its potential to deliver savings.[1]

Much of this criticism has focused on Medicare spending on physician-administered drugs under Part B, with the Department of Health and Human Services Office of Inspector General announcing their intent to further study the issue.[2] However, as more data have emerged over the past several years, they point to an increasingly strong biosimilars market in the US with the potential to yield significant savings in Medicare over the next 10 years.

Despite claims of limited prescribing of biosimilars in Part B, according to MedPAC, the biosimilar market share ranged as high as 77% in 2020.[3] There are signs that biosimilar competition is driving down costs and yielding significant savings in the program and across the healthcare system.

In addition to the increasing market share of biosimilars, there are more coming to market. Twenty-two biosimilars are now available, and 1 cancer biologic has 5 competing biosimilars—4 of which have prices more than 50% lower than when they launched. In fact, there is only 1 reference product (a supportive-care agent) facing competition from 1 biosimilar, and both prices are almost 40% lower since the biosimilar launch.

The pace of biosimilars reaching the market was accelerating until the COVID-19 outbreak caused the Food and Drug Administration (FDA) to shift resources toward the pandemic.[4] There is every reason to believe, however, that the introduction of biosimilars will resume its previous stride, as the FDA returns its attention to those products.

Many biologics are physician-administered medicines reimbursed under Medicare's average sales price (ASP) formula in Part B (**Figure 1**).

Figure 1. ASP calculation

$$\text{ASP} = \frac{\text{Manufacturer's sales of drug to all purchasers in the US in a calendar quarter}}{\text{Total number of units of drug sold by manufacturers in the same quarter}}$$

Medicare reimburses for a biosimilar based on its ASP plus an add-on payment that is 6% of the reference product's ASP.

Data presented here show significant ASP declines following biosimilar introduction, thus producing substantial savings for Medicare. As ASP is a measure of what commercial payers pay for drugs, it also reflects savings occurring in the healthcare market more broadly. In this brief, we detail the state of the biosimilar marketplace for physician-administered drugs, ASP trends, and the range of projected savings estimates for the healthcare system to date.

Current landscape and pipeline

As might be expected, the early years of the biosimilar market in the US saw only a handful of products introduced: in the first 4 years, 6 biosimilars became available. However, the pace has accelerated considerably since then—in 2019, 6 more biosimilars became available, followed by another 7 in 2020. However, there were only 2 biosimilar launches in 2021, but this was likely caused by stalled on-site inspections due to the COVID-19 pandemic.[4]

As of June 2022, 22 biosimilars have been launched against 7 reference products in the US. These biosimilars are currently available in 3 therapeutic categories: oncology, supportive care, and immunology.

Interest in biosimilars is certainly not waning: FDA's Biosimilar Biological Product Development Program shows 97 biosimilar development programs enrolled as of Q1 of fiscal year 2022.[5]

Biopharmaceutical companies are developing additional biosimilars in the 3 categories listed previously and in new categories and therapeutic areas that represent significant segments of drug spending in Medicare Part B, such as autoinflammatory conditions, multiple sclerosis, ophthalmology, and osteoporosis.

Biosimilars are driving down ASPs for other biosimilars and reference products

The introduction of competition into the biologics market has led to dramatically lower prices not only for biosimilars, but also for reference products.

Table 1 shows how biosimilars lead to significant cost savings to patients and the healthcare system.

Average ASPs of biosimilars are less expensive than 4 of the reference products (A, B, C, and F)—ranging from 38% to 64% cheaper—so patients using those products benefit from lower costs.

Conversely, 3 reference products (D, E, and G) are **less** expensive than their respective biosimilars. While many business factors contribute to lowering drug prices, competitors flowing into the market undoubtedly play a key role as reference-product manufacturers fight to maintain market share. Considering that biosimilars enter the market discounted to their reference products, the fact that 3 reference products are less expensive than their biosimilars indicates significant reference-product price erosion.

Biosimilars drive down costs for the class in 2 ways: Either by offering a treatment alternative at a substantial discount to the reference biologic, or by forcing the manufacturer of the reference biologic to reduce the price to match (or be lower than) the biosimilar.

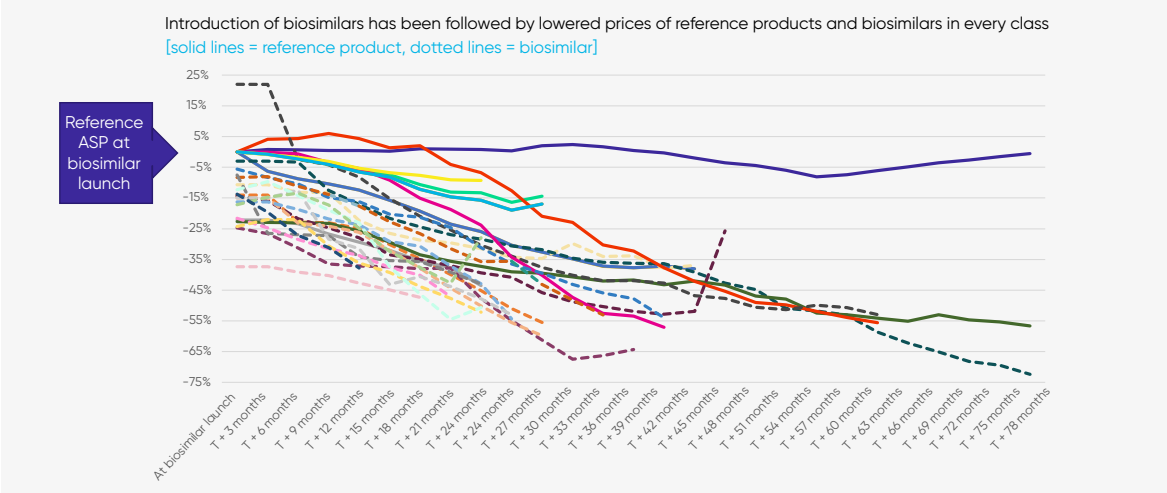
Figure 2 shows that, with very few exceptions, the ASPs for both biosimilars and reference products have plummeted since biosimilars entered the market.

Table 1. Current ASP differences between reference product and biosimilars

Therapeutic category	Reference product	ASP of reference product (as of April 2022)	Average ASP of biosimilars to reference product (as of April 2022)	Difference between ASP of reference product and average ASP of biosimilars	Difference between ASPs of biosimilars and reference products by category
Oncology	A	$69.49	$41.00[a]	41%	48%
	B	$85.44	$53.37[a]	38%	
	C	$88.60	$54.70[a]	38%	
Supportive care	D	$8.11	$8.26	−2%	37%
	E	$167.68	$196.21[a]	−17%	
	F	$0.99	$0.36[a]	64%	
Immunology	G	$36.51	$47.69[a]	−31%	31%

[a] Reference product has multiple biosimilars; ASPs of the biosimilars were averaged.

Figure 2. ASP changes over time for all reference products and biosimilars



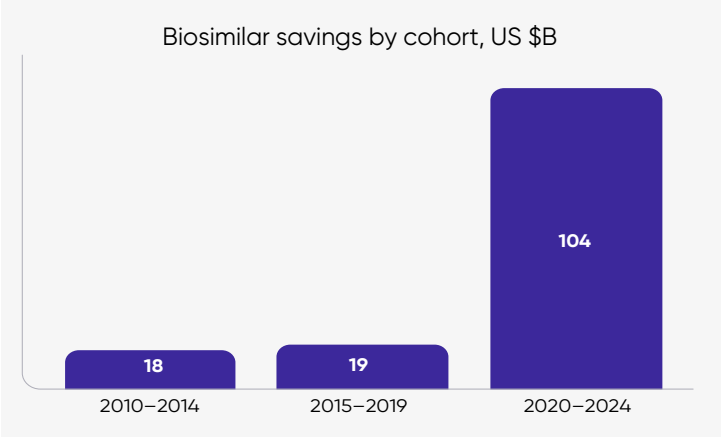
Source: Xcenda data on file.

The ASPs of many reference products and biosimilars have decreased more than 45% since biosimilars have launched.

Biosimilars are generating savings across the healthcare system

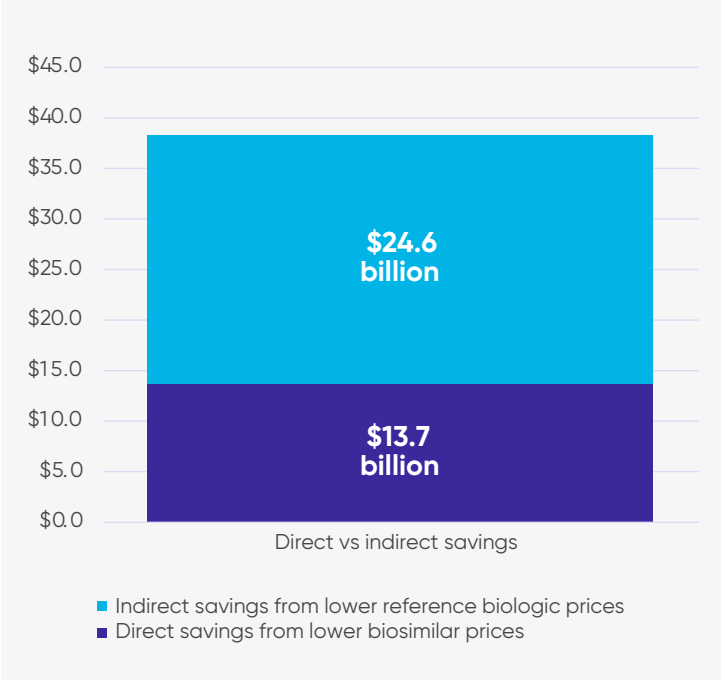
Several studies have quantified how growing biosimilar sales have led to material savings from their introduction into the markets. For example, **Figure 3** shows IQVIA's estimates of biosimilar savings in the US market, which are projected to increase markedly after 2020.[6] This period will see the entrance of biosimilars referencing adalimumab, the world's second highest-selling biopharmaceutical. IQVIA's model shows savings enabled by biosimilars to exceed $100 billion in the aggregate from 2020 to 2024, though the authors acknowledge volume and price dynamics remain volatile and significant uncertainty remains.

Figure 3. IQVIA's estimated savings from biosimilars, US, 2020



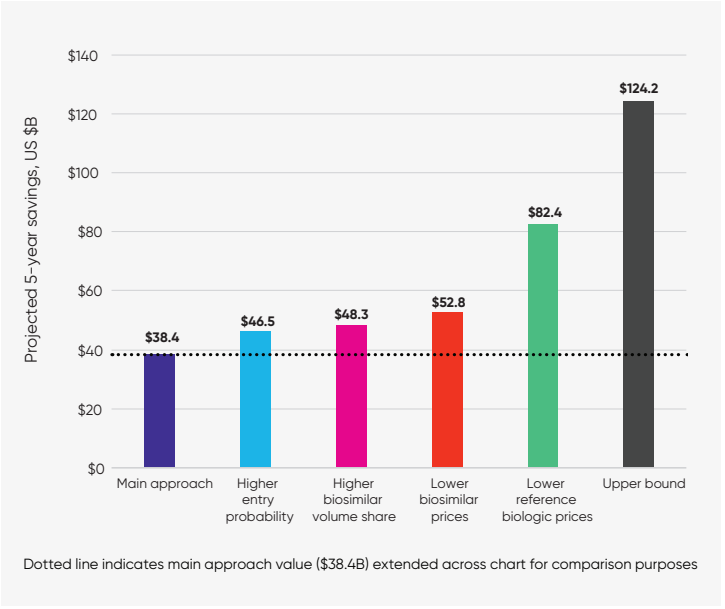
In 2022, an article published in the *American Journal of Managed Care (AJMC)* by Mulcahy et al estimated that biosimilar savings from 2021 to 2025 would yield $38.4 billion, or 5.9% of projected spending on biologics over the same period, as depicted in **Figure 4**.[7] Of that amount, $13.7 billion comprised direct savings from lower biosimilar prices, and $24.6 billion represented indirect savings from lower reference product prices.

Figure 4. Estimated savings from biosimilars, 2021-2025



As shown in **Figure 5**, Mulcahy et al estimated substantially higher savings ($124.5 billion) under a more aggressive (upper-bound) scenario that assumed quicker biosimilar entry, greater biosimilar volume share, and more robust price competition.[7]

Figure 5. Five-year projected savings, main approach vs upper-bound scenario



Conclusion

As seen in **Figure 2**, biosimilars have had a dramatic impact on drug prices and show the ability of competition to lower costs and drive savings across the healthcare system.

Stakeholders have argued that the biosimilars market would not be up to the task of lowering drug costs due to "onerous testing requirements" and biologics only facing "2 or 3 competitors over many years."[8]

At the time of those critiques, the US biosimilars market was only 4 years old, with 9 biosimilars available. Barely 3 years later, there are 22 biosimilars on the market, and 1 cancer biologic has 5 competing biosimilars—4 of which have prices more than 50% lower than when they launched. In fact, there is only 1 reference product (a supportive-care agent) facing competition from 1 biosimilar, and both prices are almost 40% lower since the biosimilar launch.

As a result of this growing competition, the savings to the healthcare system generated from the biosimilar marketplace increased markedly following 2020. And as **Figures 3, 4,** and **5** all demonstrate, the market is projected to drive even greater savings over the next several years. However, these estimates vary widely and depend on a range of factors. Importantly, these lower and upper bounds underscore not only the tremendous potential of the biosimilars marketplace but the harm that may come from policies that limit the market in the years ahead.

A chief concern with prematurely declaring the biosimilar market dead is that policymakers and regulators may resort to more draconian efforts to lower drug costs, such as price controls. As the Mulcahy et al study stated[7]:

> **"Broader US policies aiming to reduce reference biologic prices could leave less headroom for biosimilar savings to accrue. Depending on their design, these policies may affect incentives for industry to invest in biosimilar development."**

The data show biosimilars are succeeding in what they were designed to do: lower prescription drugs costs to patients and drive savings in the system. With more biosimilars in development, their adoption and associated savings should accelerate—provided the market is permitted to operate as it is currently designed.

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