Biosimilars: Realizing the potential in the US

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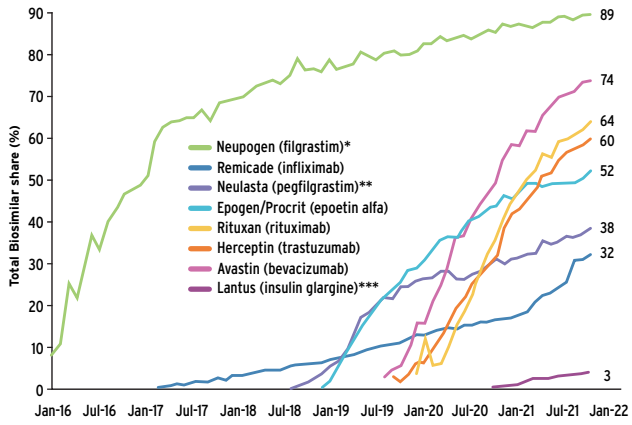
After a slow, unsteady start, biosimilars are beginning to deliver on their initial promise

Since the first biosimilar was introduced to the US market with the launch of Zarxio® (filgrastim-sndz) in 2015, biosimilars have been shown to provide effective treatment at a lower cost compared to branded biologics.[1-3] Their introduction created expectations for healthy competition within the biologic category, opening up greater opportunities for better contracting and manufacturer discounts – and, ultimately, invaluable cost reductions for providers, payors and patients alike.

In these early years, adoption of biosimilars proved to be slow – a consequence of several factors that remain in play today (see sidebar on page 2). Most notably, biologic spending increased while biosimilar uptake remained low. Specifically, between 2010 and 2015, 70% of drug-spending growth in the United States came from biologics.[3] By 2019, biologics accounted for 43% of pharmaceutical spending for a total of $211 billion that year – even though only an estimated 2% of Americans used biologics.[2,3]

However, since biosimilars have become more established in the market, improvement in some of these barriers – such as coverage – has enabled an increase in adoption compared to previous years (Figure 1).[4]

Figure 1: **Use of biosimilars has grown significantly since 2015[4]**

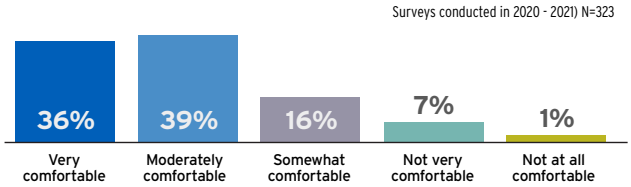


Source: IQVIA Accessed via IQVIA National Sales Perspective (NSP) SMART Data. (October 2021).

*Filgrastim excludes Granix®.
***Insulin glargine excludes Basaglar®.
****Neulasta Syr. only biosimilars market share is 75%

"Provider perceptions of biosimilars over this time period have evolved from a 22% acceptance of [switching to a biosimilar] in 2017 to a near 100% for some indications in 2021."[4]

Figure 2: **What is your comfort level with automatic substitution of a biosimilar for its reference product by a pharmacy or an insurance company?[4]**



To date, the oncology market has been most receptive with more than 7 in 10 oncologists being very comfortable or comfortable with automatic substitution of a biosimilar.[4]

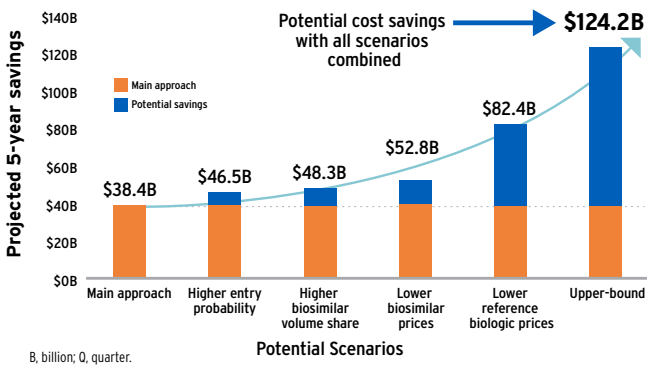
Notably, Oncology has seen the fastest uptake in biosimilars, as evidenced by the difference between filgrastim and bevacizumab biosimilar product volume attainment after launch.[2] Two years after their introduction to the market, filgrastim biosimilars, launched in 2015, achieved a 39% volume, while bevacizumab, launched in 2019, attained a 42% volume after just 12 months.[1,2] This rapid rate of adoption has been attributed to changes in physician attitudes to biosimilars, education of healthcare providers and patients, and financial incentives.

Cost savings are on the rise

More importantly, biosimilars are beginning to demonstrate notable increases in cost savings. In 2020, when three new biosimilars were approved and seven others were launched, biosimilars comprised less than 30% of the biologic market volume.[1,5,6] However, their use resulted in cost savings of $7.9 billion, more than three times the cost savings realized by biosimilars in 2019.[6]

Forecasts of potential cost savings from biologic use between 2021 and 2025 vary, but suggest that these savings have potential to exceed $100 billion.[7] One projected estimate suggests that the amount of realized savings should reach $38.4 billion, or 5.9% of projected total spending on biologics, between 2021 to 2025 (see Figure 3).[7] Different scenarios that include more biosimilar product market entries, higher biosimilar volume share, lower biosimilar and reference biologic prices could create higher savings, respectively. (Notably, the largest cost savings estimate in this projection came with the assumption that competition in the market could reduce reference biologic prices down by another 25%.) However, when combining these potential savings – based on all these scenarios occurring simultaneously – those realized savings could be as high as $124.2 billion.[7]

Figure 3: **Five-year Projected Savings, Main Approach vs Upper-Bound Scenario[7,a]**



B, billion; Q, quarter.

[a]Savings are calculated as the difference in spending under the main approach vs baseline scenario. MIDAS data reflect estimates of marketplace activity obtained under licence from IQVIA.

Source: Author analysis of Q1 2014-Q4 2020 IQVIA MIDAS data (extract date March 2, 2021). CMS average sales price data, and other sources.

Roadblocks to biosimilar adoption

Since the introduction of biosimilars to the US market in 2015, uptake has been slow compared to what has been observed in the European Union. As of January 2022, only 33 biosimilars have been approved in the United States; in contrast, as of July 2022, 73 biosimilars have been approved for use in the European Union.[1,2,8]

While the field is opening up to higher uptake of biosimilars in the United States, a range of issues – such as payer coverage – surround their usage (see Figure 4).[4]

Complex stakeholder relationships[9-13]

- Each biosimilar undergoes complicated contracting, reimbursement, and policy decision-making processes
- Biosimilar preference often differs for prescribers and payors; consistency is lacking

Negative perceptions of biosimilars[3]

- Prescribers and patients may perceive biosimilars as inferior to the reference product

Operational issues for formularies and pharmacies[9,12,13]

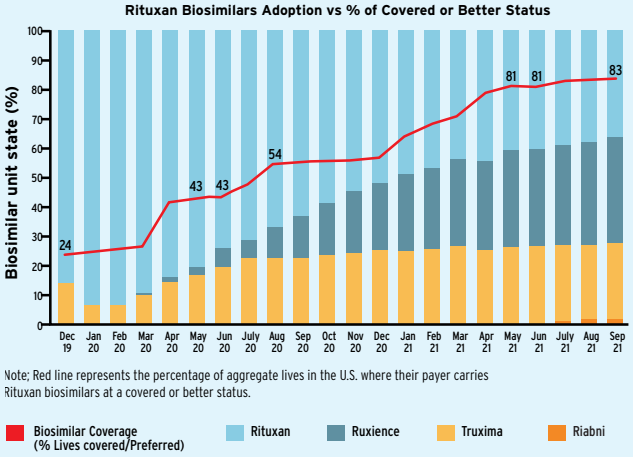
- Need to evolve inventory management for each biosimilar including stocking, storage, creating new orders, and safety alerts
- Additional time and resources needed to match patients to approved product
- Higher risk of medication errors and delays

Coverage complexities[9,10,14]

- Delivery and form factor
- EHR tracking/substitution status
- Major payors' coverage and reimbursement policies
- Patient programs and support from different manufacturers

Figure 4: **A strong correlation is shown between biosimilar adoption and increases in payer coverage[4]**

As an example, there is a 97% correlation between Rituxan biosimilars adoption and the percentage of plans covering Rituxan biosimilars at parity or in preferred positions.



Note; Red line represents the percentage of aggregate lives in the U.S. where their payer carries Rituxan biosimilars at a covered or better status.

Sources: Managed Markets Insight & Technology, LLC (MMIT) Analytics Accessed November 2021 and IQVIA: Accessed via IQVIA National Sales Perspective (NSP) SMART Data. (October 2021).

The core benefits of competition: Even greater cost savings and patient access to care

As we begin 2023, lawmakers and regulators are increasingly acknowledging the importance of having robust biosimilar competition. While the recently enacted Inflation Reduction Act created a new incentive – increasing Medicare Part B reimbursement from average sale price (ASP)+6% to ASP+8%[15] – more must be done to tackle the barriers to market entry and formulary placement. Fortunately, bipartisan support in Congress for patent reform and formulary coverage initiatives are gaining momentum. Combined, these initiatives are poised to unlock the incredible potential of biosimilars in the US.

In a poster presented at the American Society of Health-System Pharmacists 2022 Midyear Meeting, researchers presented the results of a pharmacist-driven biosimilar substitution program. Part of the study was assessing biosimilar utilization and uptake and financial impacts. Of note, preferred pegfilgrastim use increased from less than 20% to over 60% during the study period. It was estimated that payors saved approximately $29 million over the six-month period prior to implementation and $47 million after the implementation.[16]

Nonetheless, this expanding roster of biosimilar molecules promises to usher in far greater price competition in their respective therapeutic categories (see Figure 6).[5] As more competition enters the market, prices for biosimilars and reference products are driven down, sometimes as much as 50%.[5]

Likewise, the presence of biosimilars within a category has reduced the related reference product's average cost by about 25%.[5]

With the addition of more biosimilars to the market, patient access to care has also benefited.[5] The use of biosimilars has supported 150 million more days of patient therapy than would have been possible otherwise.[5]

Figure 6: **Brand and biosimilar average sales price, 2016-2022[5]**

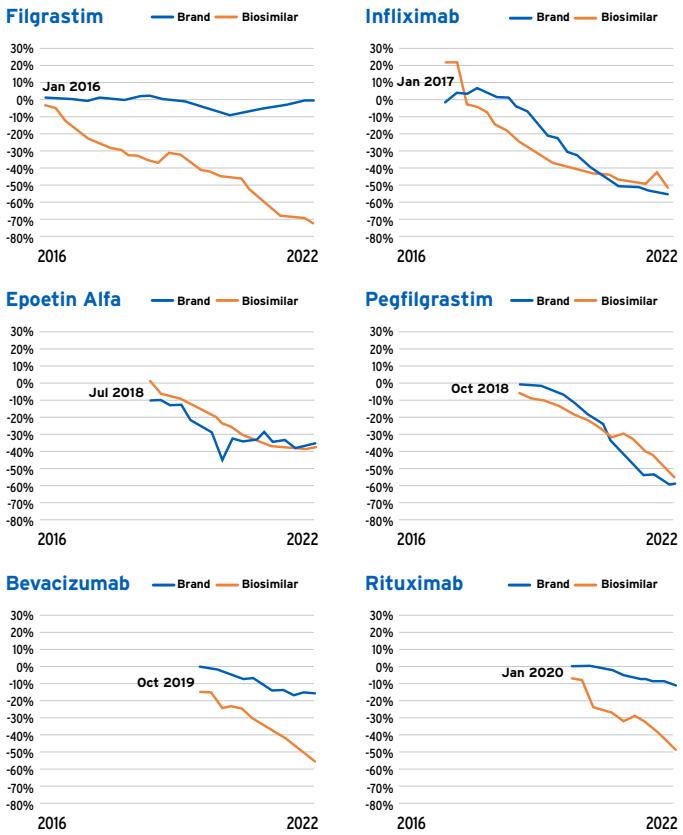
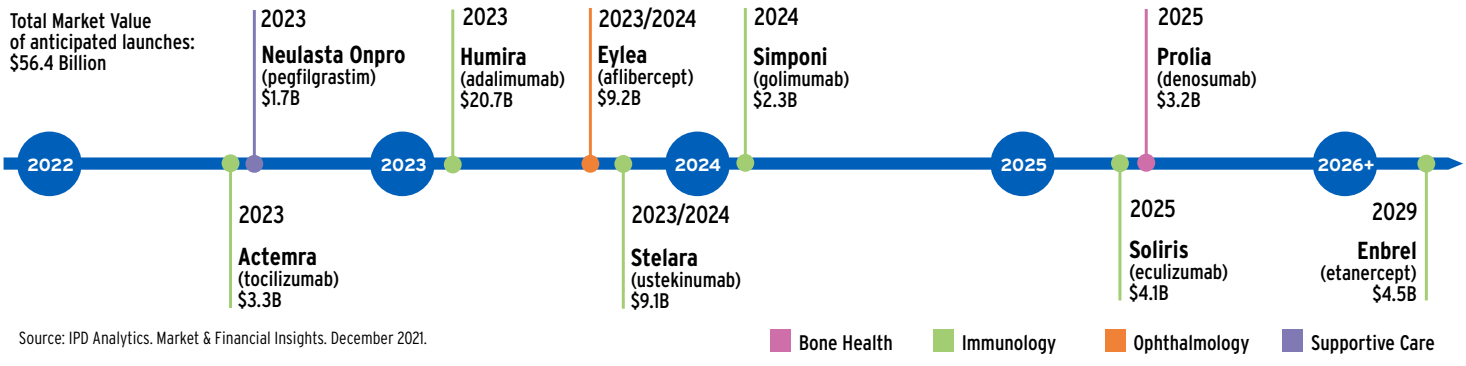


Figure 5: **Anticipated biosimilar launches[4,15,17-20]**

Biosimilars either in Phase III trials, pending FDA approval or FDA approved



Source: IPD Analytics. Market & Financial Insights. December 2021.

As expected, competition usually results in lower ASP for both reference products and biosimilars.

Biosimilars launch at a wholesale acquisition cost (WAC) that is generally 10% to 57% lower than the reference product."[21]

The prices of biosimilars are decreasing at negative compound annual growth rate (CAGR) of -9% to -24%.[21]

The prices of most reference products are decreasing at a negative CAGR of -4% to -21%.[21]

The role of manufacturers in the changing landscape

The current expansion of biosimilars in the market promises to continue growing, as manufacturers are developing even more products in a number of therapeutic areas, especially in Immunology and Oncology. Competition between manufacturers is likely to encourage:

- A higher focus on drug formulation practices
- Supply reliability
- Lowered costs
- More focus on patient support and access programs
- Continuing commitment to future biosimilar innovation
- Financial commitment to increased access to care

As more biosilmilars enter the market, manufacturers will be held to higher standards and counted on to help make adoption less difficult. Healthy competition can help drive accountability and new innovations, which could increase the quality of care while simultaneously lowering costs.

Biosimilar manufacturers are also indirectly encouraging healthy competition by focusing on addressing the primary barriers to improved biosimilar competition: the patent landscape, PBM rebating practices, and burdensome regulatory hurdles, actively working to advance policies that will continue to improve the market for biosimilar uptake.

The industry continues to build on valuable learnings that will help systems be better prepared for the influx of biosimilars that are on the precipice of approval. We continue to adapt and learn from best practices that will allow us to accelerate realizing the benefits of biosimilars in the US.

Implementation in your institution: The crucial key to biosimilar success

Effective and efficient implementation is the critical building block that has allowed institutions to start realizing the benefits of biosimilars. In the next issue in this white paper series, we will address how to:

- Build a smarter system that can accommodate efficient adoption of biosimilars
- Design workflows to streamline and overcome operational challenges
- Select biosimilars based on Food and Drug Administration approval, payor preference and cost savings
- Establish best practices in implementation based on research and feedback from interviews with key decision-makers at 33 institutions across the US.

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