Biosimilars FORUM

Humira® Biosimilars: Reaching the Market's Cost-Savings Potential

In 2023, a wave of biosimilars for Humira® (adalimumab) are set to hit the market. The next 18 months will be consequential in determining the future success of the biosimilars market in the U.S.

Humira® (adalimumab) biosimilars have the potential to save billions in U.S. health care spending, but if - and only if - they have fair and timely access to formularies and are accessible to patients and providers.

The Biden Administration, Congress and federal regulators can promote biosimilar access on formularies and help achieve the cost-savings promised to Medicare. Similarly, PBMs can also promote the use of biosimilars and prioritize patients by making adalimumab biosimilars available on their formularies when the biosimilars become available on the U.S. market.

Biosimilars Provide Potential Cost-Savings for Medicare

Humira® and Enbrel® (etanercept) accounted[1] in 2019 for more than $5.7 billion in Part D spending—more than 14 times the $405 million that Part D spent that year for reference products with available biosimilars.

Humira® currently faces no U.S. competition amidst a 470% price increase[2] since first introduced.

Medicare could have saved[3] an estimated $2.19 billion on Humira® over four years had biosimilar competition been available.

Part D spending on biologics with available biosimilars could have decreased[4] by $84 million, or 18 percent, if all biosimilars had been used as frequently as the most used biosimilars.

Biosimilars Provide Cost-Effective Treatment Options

Expanding access to cost-effective treatment options through the use of FDA-approved, confirmed safe and effective biosimilars is the best way to build a competitive, robust marketplace.

Biosimilars Create a Competitive Market that Lowers Prices for All Patients that Need Them

Humira® can cost patients upwards of $84,000[5] per year and currently faces no U.S. competition amidst a 470% price increase[6] since first introduced on the market. Therefore, it is crucial to provide patients with safe and effective lower-cost treatment options to Humira®.

Biosimilars are critical to lowering prescription drug prices in the U.S. Not only are FDA-approved biosimilars just as safe and effective as and lower-cost than their reference biologics, but they also lower the price of biologics through increased competition.[7]

The Time to Act Is Now

- Much of the **future of the biosimilars industry depends on whether Humira® biosimilars will be placed on formularies** as they become available in the U.S. market.
- This requires that the Administration and PBMs consider placement of biosimilars when they become available in the U.S. as a routine maintenance change to formularies.
- With the upcoming launch of the Humira® biosimilars, **actions must be taken to accelerate biosimilar placement on formularies immediately** when they become available.

If these biosimilars are not made available, patients will not have immediate access to lower-cost treatment choices, and the industry's promise of strong competition and healthcare savings could be lost forever.

Support is needed

Policymakers and Regulators Must Take Action

The Biden Administration, Congress, and federal regulators need to ensure all biosimilars are available to Medicare patients.

- **CMS and policymakers must implement a clear and expedited pathway** to add all biosimilars to Medicare Part D formularies when they become available.
- **CMS and policymakers must classify all biosimilar additions to formularies as maintenance changes**, in which plans may notify beneficiaries at the same time as these changes are submitted to CMS.

PBMs Must Support Patients That Need Biosimilars

- **Patients should have timely access to biosimilars and their cost-savings** once they hit the market, especially Humira biosimilars.
- **Midyear formulary changes should be allowed for all biosimilars** and encouraged by PBMs and CMS, especially Humira biosimilars.
- **PBMs must prioritize patients over profits** and provide patients with timely options for lower-cost, safe, effective biosimilars.

The Biosimilars Forum

The Biosimilars Forum is a nonprofit organization working to advance biosimilars in the United States with the goals of expanding access and availability and improving healthcare outcomes. Since its inception, the Forum has worked to expand the uptake of biosimilars throughout the healthcare system through policies that will increase access for patients and lower costs through increased competition. Forum members represent companies with the most significant U.S. biosimilars development portfolios.

For more information on the Biosimilars Forum's work to increase access to lower-cost biosimilars, visit **www.biosimilarsforum.org**.

Sources

[1] Medicare Part D and Beneficiaries Could Realize Significant Spending Reductions With Increased Biosimilar Use. U.S. Department of Health and Human Services Office of Inspector General. Published March 29, 2022. Accessed July 2022. https://oig.hhs.gov/oei/reports/OEI-05-20-00480.pdf.

[2] House committee uncovers how Humira's price spiked by 470% as AbbVie execs cashed bonuses tied to the hikes. Endpoint News. Published May 18, 2021. Accessed July 2022. https://endpts.com/house-committee-uncovers-how-humiras-price-spiked-by-470-as-abbvie-execs-cashed-bonuses-tied-to-the-hikes.

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[4] Medicare Part D and Beneficiaries Could Realize Significant Spending Reductions With Increased Biosimilar Use. U.S. Department of Health and Human Services Office of Inspector General. Published March 29, 2022. Accessed July 2022. https://oig.hhs.gov/oei/reports/OEI-05-20-00480.pdf.

[5] How much does Humira cost? See prices and ways to save. SingleCare. Published January 6, 2021. Accessed July 2022. https://www.singlecare.com/blog/humira-cost.

[6] House committee uncovers how Humira's price spiked by 470% as AbbVie execs cashed bonuses tied to the hikes. Endpoints News. Published May 18, 2021. Accessed July 2022. https://endpts.com/house-committee-uncovers-how-humiras-price-spiked-by-470-as-abbvie-execs-cashed-bonuses-tied-to-the-hikes.

[7] Biosimilars in the United States 2020–2024: Competition, Savings, and Sustainability. IQVIA. Published September 29, 2020. Accessed July 2022. https://www.iqvia.com/insights/the-iqvia-institute/reports/biosimilars-in-the-united-states-2020-2024.