Myths vs. Facts About Biosimilars
For Payers

WHAT ARE BIOSIMILARS?

A biosimilar is a medicine that is highly similar to a brand biologic medicine. As of September 2021, there are 30+ FDA-approved biosimilars[1] helping patients with common but difficult-to-treat diseases including cancer, arthritis and other inflammatory diseases. Ninety more biosimilars are in development.[2]

Biosimilars are safe, effective alternative versions of existing brand biologic medicines (known as "reference products") with scientifically comparable quality, safety and effectiveness. Biologic medicines are expensive for patients, taxpayers and insurers. Biosimilars provide more prescribing options, which can help lower costs and increase patient access to lifesaving medications.

MYTHS	FACTS
"Biosimilars are less safe for patients than brand biologics."	Biosimilars undergo **rigorous FDA testing, review and safety monitoring**. The biosimilar development process is complex and biosimilar manufacturers are committed to providing safe, effective products to patients. To obtain FDA approval, the route of administration, dosage form and strength of the biosimilar and biologic medication must be the same.
"Biosimilars aren't as effective as brand biologics."	A biosimilar drug will work as safely and as effectively as a biologic drug. Biosimilars have been used in more than 121 million days of patient therapy and have resulted in almost 10 million additional days of therapy.[3]
"Biosimilars won't save the health care system that much money."	Biosimilars are, on average, priced 30% lower than their brand counterparts and have the potential to save more than $130 billion through 2025.[4]
"Biosimilars that are interchangeable are better than non-interchangeable biosimilars"	An interchangeable biosimilar has simply met additional FDA standards requirements. These additional standards do not mean that the interchangeable product is better or of a higher quality than an FDA-approved biosimilar.[5]

References

1 FDA. Biosimilar Product Information: Approved Biosimilar Products. Available at: http://bit.ly/2BQwQig. Accessed September 22, 2021.
2 FDA-TRACK: Center for Drug Evaluation & Research - Pre-Approval Safety Review - Biosimilars Dashboard. Available at: https://bit.ly/3zbmwuw. Accessed September 22, 2021.
3 Biosimilar Medicines Equal More Accessible Care for America's Patients. Available at: https://bit.ly/2Z0mTM3. Accessed September 22, 2021.
4 The Use of Medicines in the U.S.: Spending and Usage Trends and Outlook to 2025. Available at: https://bit.ly/3A9zR7M. Accessed September 22, 2021.
5 FDA. Biosimilar Product Information: What Is An Interchangeable Product? Available at: https://bit.ly/2Kx2Tot. Accessed September 22, 2021.

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