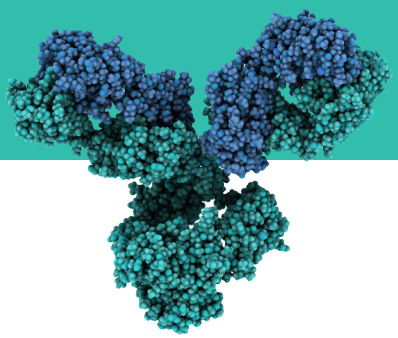
UNDERSTANDING BIOSIMILARS:
What They Are and Why Use Them



Advances in medicine have changed the way many diseases are treated. Increasingly, diseases such as cancer, rheumatoid arthritis and even asthma are being treated with biologic medications known as biosimilars.

WHAT IS A BIOSIMILAR?

A biosimilar is a new type of medicine grown in a lab from living cells used to prevent, treat or cure a variety of diseases including cancer.

Biosimilars are FDA-approved medications that are compared to the original biologic, also known as the reference product, and are highly similar in structure and function.

Because biologics are large and complex, it is not possible to create identical versions. The process used to develop biosimilars is therefore different from that used to develop generic drugs.

FDA APPROVAL PATHWAY

The regulatory pathway for biosimilars is designed to ensure the development and approval of high-quality drugs. Biosimilar medicines are approved only after FDA review of thorough research and testing to evaluate efficacy and safety.

Biosimilars are FDA approved having met rigorous standards and are manufactured at FDA-licensed facilities.

EFFICACY & SAFETY

- Biosimilars are highly similar to the reference product having been made with the same types of living sources but are not the same.
- There are no clinically meaningful differences between a biosimilar and the reference product in terms of safety, purity and effectiveness.
- The FDA monitors the safety and effectiveness of all medications after their approval to ensure continued safety.
- The FDA has approved 34 biosimilars in the U.S., with 97 more in development.

BENEFITS OF BIOSIMILARS

Biosimilars expand the choices patients have in treating various conditions, offering new options to target the immune system.

Biosimilars offer patients more treatment options at a lower cost. Experts estimate that biosimilars will be priced 10-35% less than their brand-name drug competitors. This means patients could save as much as $54 billion in the next decade.

Lower cost biosimilars can allow for the reallocation of resources to other areas of patient care which may not be funded by Medicare or commercial payers.

Speak to your physician if you have any questions regarding biosimilars.

[1] FDA Biosimilar Product Information. Available at: https://www.fda.gov/drugs/biosimilars/biosimilar-product-information
[2] FDA-TRACK: Center for Drug Evaluation & Research Pre-Approval Safety Review Biosimilars Dashboard. Available at: https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-center-drug-evaluation-research-pre-approval-safety-review-biosimilars-dashboard
[3] Biosimilar Drugs May Reduce U.S. Health Spending by $54 Billion. Available at: https://bit.ly/2EsWDOr
[4] The $250 Billion Potential of Biosimilars, Express Scripts Int'l (April 23, 2013). Available at: http://bit.ly/2qYlu4Z

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