

# TAKE A CLOSER LOOK

Learn more about biologics and biosimilars.

Your healthcare provider has recommended a biologic medicine because it has been approved by the FDA to treat your condition. You may have been recommended to receive a type of biologic known as a “biosimilar.” Here are some key facts about what **biologics and biosimilars** are, how they work, and what they could mean for your treatment.

## FAST FACTS ABOUT BIOLOGIC MEDICINES

Biologics are made by a modern manufacturing process that uses **living cells** to produce a medication that is typically administered as an injection or an infusion<sup>1</sup>.



Biologics mimic proteins found **naturally** in our bodies<sup>2</sup> and are effective at treating a variety of conditions including:<sup>3,4</sup>

- Some types of cancer
- Crohn's disease
- Diabetes
- Multiple sclerosis
- Psoriasis
- Rheumatoid arthritis

Biosimilars are biologic medicines that are made by a different manufacturer, and are designed to match the structure of a reference biologic. To be approved by the FDA, biosimilars are required to **clinically match** the reference biologic. This means they have to<sup>5</sup>:



Work the same way



Have the same route of administration, dosage form (how you receive the medicine), and strength (how much medicine you need to receive)



Produce the same result



Be as safe and have the same overall quality

A biosimilar medicine approved by the FDA is considered just as safe and effective as the reference biologic.<sup>4</sup>



# TESTING

## & APPROVAL PROCESS

Biosimilars are biologic medicines created to match an existing reference medicine. Biosimilars must undergo a testing and approval process to ensure that the **safety** and ability to treat your condition are the same as the reference biologic.<sup>5</sup>

# ADVICE



As with all medicines, you should **talk** with your doctor (and healthcare team) about all available treatment options and associated safety, health benefits and risks before deciding what treatment is best for you.



For more information on biosimilar medicines, visit the biosimilars section of the a FDA web site, which can be found at <https://www.fda.gov/> (once you are in the site, simply enter the word biosimilars in the search bar to find what you need).



## REFERENCES

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3. Guilford-Blake R, Strickland D, et al. Guide to Biotechnology. Washington, DC: Biotechnology Industry Organization; 2008.
4. HYRIMOZ Injection [package insert]. Princeton, NJ: Sandoz Inc.; 2018.
5. U.S. Food and Drug Administration (FDA). Information for Consumers (Biosimilars). <https://www.fda.gov/downloads/Drugs/DevelopmentApprovalProcess/HowDrugsareDevelopedandApproved/ApprovalApplications/TherapeuticBiologicApplications/Biosimilars/UCM581282.pdf>

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