

Patient Resources

Biologic and Biosimilar Medicine FAQs

Biologic medicines are medicines produced by living organisms to include human, animal and microorganism cells. Biosimilar medicines, just as its name lends, is highly alike its biologic medicine, or its “reference biologic”.

How do biologic & biosimilar medicines work?

Biologics (and biosimilars) typically work by supplementing or interrupting natural processes and signals to treat specific conditions.

What is the difference between a biologic & a biosimilar?

A biosimilar is a highly similar replica of the reference biologic. The Food and Drug Administration (FDA) only approves the use of biosimilars that have demonstrated an ability to treat the disease, its safety profile and overall quality of the biosimilar.



If biologics & biosimilars are so alike, then what is the purpose of biosimilars?

Biologics are highly complex medicines and are often very costly- many individuals that would benefit from treatment with a biologic are unable to afford it. There are many financial assistance programs offered by pharmaceutical companies, however, it can still be a significant expense for individuals. As biosimilars are approved for use in treatment, it is expected that the cost of biologics will decrease and the access to biologics will increase.

Do biosimilars work the same way as their biologic reference?

Yes; biosimilars are required to have demonstrated the ability to treat the disease, have a safety profile like that of the biologic reference, and have highly similar overall quality to the reference biologic to be FDA-approved for use.

Are biosimilars safe?

Yes; to become FDA-approved for use in treatment the biosimilar is required to have a safety profile that is highly alike the biologic reference, in addition to a highly similar overall quality and ability to treat the disease.