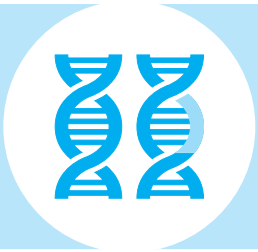
How a Biosimilar Reaches a Patient

Biosimilars are safe, effective, and competitive alternatives to expensive original brand medicines. 15+ biosimilars have undergone rigorous FDA review and are approved. Here's the path biosimilars travel to get to a patient:

1 FDA Approval

A biosimilar developer uses state-of-the-art technologies to study the reference product (original brand) and recreate its physical structure.



The new biosimilar candidate undergoes extensive testing for "biosimilarity." Once FDA approves as clinically equivalent, the biosimilar can become available for patient use.

2 Patient Diagnosis and Treatment Plan

After a doctor's diagnosis, you and your healthcare provider set a treatment plan to help manage your condition.

Treatment plans for some conditions may include a prescription for an FDA-approved biosimilar medicine.

Only your doctor can prescribe a biosimilar medicine, and therefore, to switch from one biosimilar or original brand to another, your doctor must write a new prescription. If you are currently on a brand product, the decision to change to a biosimilar, which may be more affordable, is between you and your doctor.

3 Receiving Your Medicine

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At a hospital or doctor's office, the biosimilar will be administered to you by a healthcare professional. Since most biologics are used to treat chronic conditions, you will have to make return visits for your treatment.

TWO OPTIONS

2

If the biosimilar can be self-administered, you may pick up your treatment at the pharmacy like any other medication.

Some biosimilars may apply for FDA designation as interchangeable biologics. Interchangeable biologics can be automatically substituted for an original brand biologic at the pharmacy counter and will only impact self-administered biosimilars dispensed at the pharmacy. Like generic drugs, these medicines are FDA-approved as therapeutically equivalent to the original brand medicine.

Biosimilars Council
A Division of AAM

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