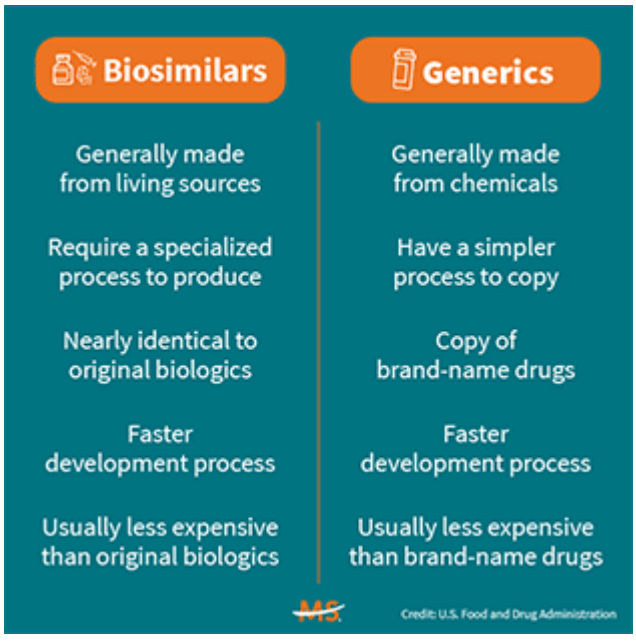
5 Things to Know About Biosimilars

Disease-modifying therapies, or DMTs, are a type of treatment for multiple sclerosis that can reduce the number of relapses, delay progression of disability and limit new disease activity.

The first biosimilar DMT used to treat MS is expected to be approved in 2023 and you might be wondering . . . what is a biosimilar?



1. Biosimilars are not the same as generic medications due to how they are produced.

Biosimilars are made from living sources whereas generics are made from chemicals. Biosimilars and generics are both versions of medications already approved by the FDA and both may offer more affordable treatment options. Generics are follow-on medications to brand name medications while biosimilars are follow-on medications to biologic medications.

Biosimilars and generics have the same mechanism of action as their respective reference medication equivalent (they work the same way in the body as the reference medication equivalent), provide the same clinical benefits and are given at the same strength, dose and form as the reference medication.

2. A biosimilar is a follow-on medication to its reference (original) biologic medication.

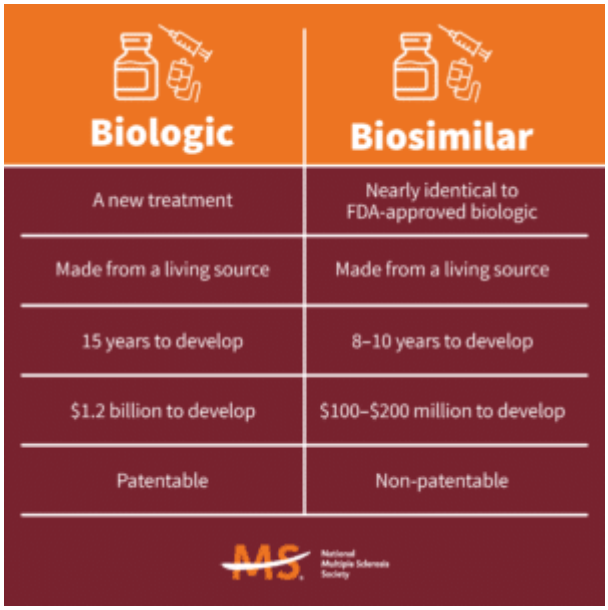
Biologics and biosimilars are made from living sources such as microorganisms (bacteria or yeast), plant cells or animal cells. They are usually administered via injection or infusion and require a specialized process to produce. Biosimilars are created to increase access to medications, increase competition in the market, decrease costs to the healthcare system and, ultimately, drive down costs realized by individuals.

3. A biosimilar is nearly identical to its reference biologic medication.

A biosimilar is produced to be nearly identical to a previously FDA-approved biologic, known as the reference or originator medication. Since biologics and biosimilars are made from living sources, they will have natural variations even from batch to batch of the same medication. Slight variations are expected and clinically acceptable as the FDA requires that these variations be carefully controlled, monitored and kept within acceptable limits. A biosimilar is as similar to its biologic as the biologic is to itself. The FDA provides more information in this **downloadable PDF**.

4. Biosimilars are safe and effective.

In 2010, the FDA was given the authority to approve versions of biologic products with the goal of providing lower cost alternatives to reference biologics. The FDA takes the same precautions when approving biosimilar products as it does with all other medications. The FDA requires biologic and biosimilar manufacturers to carefully control and monitor differences to ensure no clinically meaningful differences exist. This means that a person living with MS should have the same clinical response to the biosimilar as they would to the reference product.



Additionally, biosimilars have a long record of clinical effectiveness and safety around the world. Over 40 biosimilars have been approved and used in the United States to treat conditions such as arthritis, cancer and gastrointestinal disorders.

5. Biosimilars will likely be less expensive over time.

As more biosimilars for any given reference biologic become available, this will lead to increased competition in the market, will decrease the cost to the healthcare system and will likely decrease costs realized by the individual. A person might start treatment with a biosimilar or switch to a biosimilar based on insurance coverage or to save money. It is important to note that the lower cost is not a reflection of the effectiveness or safety of the product.

Since 1993, the landscape of disease-modifying therapies has evolved from one treatment available to 20+ medications available in 2023. From injectable medications to oral medications to infusible medications, from only branded medications available to generic and now a biosimilar medication on the cusp of launching . . . we have come a long way in treating MS in the past three decades. With time, experience and additional competition, we expect biosimilars to offer people living with MS additional treatment options and savings.