Granulocyte-Colony Stimulating Factor (G-CSF) Biosimilars

Frequently Asked Questions

What is a biologic drug?

Biologic drugs are made from living cells using biotechnology. They treat diseases and medical conditions including diabetes, inflammatory bowel disease, and some forms of cancer. Unlike chemically produced pharmaceutical drugs where manufacturers can make identical copies, it is impossible to make identical copies of biologic drugs due to the unique way they are made.

What is a biosimilar?

A biosimilar is a biologic drug manufactured to be very much like the reference or originator biologic drug. Biosimilars are demonstrated to have no meaningful therapeutic differences in safety, purity, or efficacy (effectiveness) when compared to the FDA-approved biologic drug. A biosimilar is not expected, nor required, to be identical to the reference biologic drug.

What is a reference or originator product?

A reference (or originator) product is the single biologic product, already approved by FDA, against which a proposed biosimilar product is compared. FDA approves a reference product based on, among other things, a full complement of safety and effectiveness data. Manufacturers must ensure that a proposed biosimilar product is highly similar (very much alike) to the reference product and has no clinically meaningful differences.

Are biosimilars the same as generics?

No, biosimilars are not the same as generic drugs. Generic drugs are small molecules that are chemically synthesized (made) and contain identical medicinal ingredients to their brand name reference drug. Generic drugs must be bioequivalent and contain the same active ingredients as the brand name drug. In contrast, biosimilars are large and complex molecules that are developed in living organisms, making it impossible to be identical.

Why use biosimilars?

Reference biologic drugs are very expensive. Biosimilars cost about 20% to 30% less than their reference products. Biosimilars enhance market competition and increase cost savings without compromising health outcomes. In addition, biosimilars may improve access to care. Some insurance companies may also prefer or require biosimilar use.

Will the biosimilar product work as well as the original biologic therapy?

Biosimilars are strictly regulated. FDA approval of biosimilars depends upon review of rigorous studies that confirm they are very much like the original product in terms of molecular characteristics. They must also be equally safe and effective to the reference biologic product.

What is a G-CSF biosimilar?

The body produces a natural substance called granulocyte-colony stimulating factor (G-CSF). G-CSF promotes stimulation of granulocytes (a type of white blood cell), which are necessary to fight infection. A biosimilar G-CSF is the man-made version of the substance naturally produced by the body.

Before a patient receives a biosimilar G-CSF product, what should they share with their health care provider?

Patients should tell their healthcare provider if they have sickle cell disease, kidney disease, or are pregnant or breastfeeding. Patients should also disclose to their healthcare provider all medications they are taking, including prescription and over-the-counter drugs and all vitamins and supplements. Finally, patients should report any history of serious allergic reaction to pegfilgrastim or filgrastim.

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References:

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2. Guthrie G. Biosimilars and cancer care: an expert opinion. Cancer.Net. February 14, 2018. Accessed at https://www.cancer.net/blog/2018-02/biosimilars-and-cancer-care-expert-opinion, January 25, 2021.

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