Welcome to the

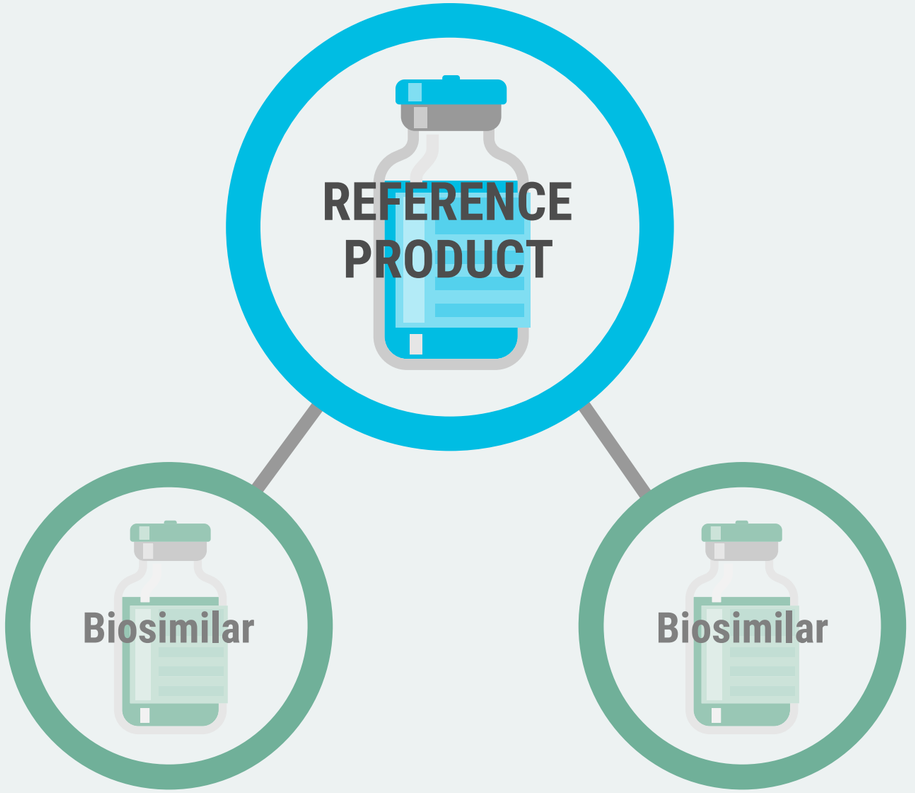
BIOSIMILARS LEARNING CENTER

For Patients and Caregivers

Biosimilars are biologic medicines that may provide more treatment options for people with serious or chronic illnesses.[1]

If you are considering treatment with a biosimilar, or if you are already taking a biosimilar, you may have questions about these therapies.

This resource provides answers to many of the most commonly asked questions about biosimilars. You can choose a topic or explore the full list of questions to learn more about what biosimilars are, how they are made, and more.



1. U.S. Food and Drug Administration. Consumer updates: Biosimilar and interchangeable biologics. October 12, 2021. https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices. Accessed November 2, 2021.

WHAT ARE BIOSIMILARS?

Biosimilars are safe and effective biologic medicines for treating many conditions such as arthritis, cancer, diabetes, kidney disease, and inflammatory bowel diseases, such as Crohn's disease and ulcerative colitis.[1]

As a biologic medicine, biosimilars are made from living organisms, such as bacteria or yeast, or plant or animal cells. They are developed to be highly similar to, and have no clinically meaningful differences from, an original biologic medicine that is approved to treat a disease or medical condition. When comparing biosimilars to an original biologic, your health care team may describe the original biologic as the "reference product."[2]

A biosimilar is[3]

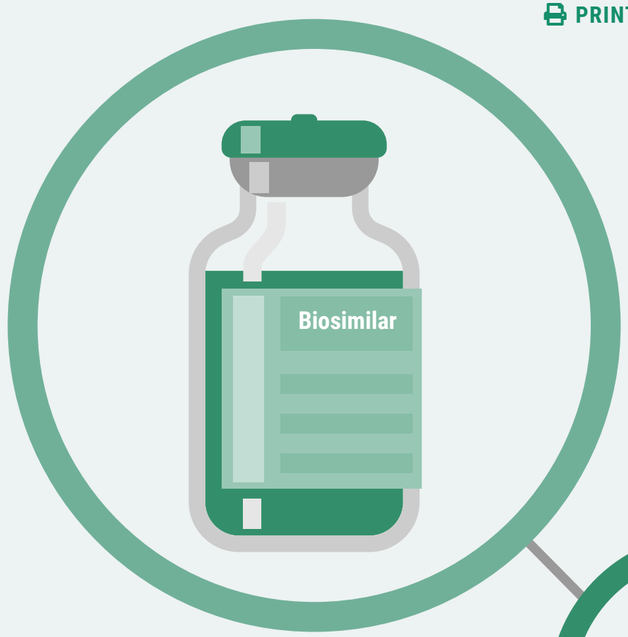
- ✔ Made to work in the same way as the original biologic
- ✔ Given the same way and at the same dose
- ✔ As safe and effective as the original biologic

RELATED QUESTIONS

WHAT ARE BIOLOGICS?

WHAT HEALTH CONDITIONS CAN BE TREATED WITH BIOSIMILARS?

ARE BIOSIMILARS THE SAME AS GENERIC DRUGS?



ABOUT BIOSIMILARS

BIOSIMILARS VS ORIGINAL BIOLOGICS

HOW BIOSIMILARS ARE GIVEN

WHY BIOSIMILARS

HOW BIOSIMILARS ARE MADE

APPROVAL PROCESS

WHEN BIOSIMILARS ARE PRESCRIBED

TALKING WITH YOUR DOCTOR

INSURANCE ISSUES

1. U.S. Food and Drug Administration. Overview of Biosimilar Products. Updated July 2021. https://www.fda.gov/media/151058/download. Accessed November 10, 2021. **2.** U.S. Food and Drug Administration. Biosimilar basics for patients. October 7, 2020. https://www.fda.gov/drugs/biosimilars/patient-materials. Accessed November 2, 2021. **3.** U.S. Food and Drug Administration. Consumer updates: Biosimilar and interchangeable biologics. October 12, 2021. https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices. Accessed November 2, 2021.

WHAT ARE BIOLOGICS?

Biologics are medicines made from living organisms, such as bacteria or yeast, or plant or animal cells.[1] They are produced through a complex process that uses advanced technology to make proteins that help prevent, treat, and cure diseases.[2]

Biologic medicines have greatly improved the treatment of many diseases, including rheumatoid arthritis, cancer, diabetes, blood disorders, and inflammatory bowel disease (IBD).[3]

Biologic medicines have been used for 40 years. The first biologic was approved by the FDA in 1982.[4]

RELATED QUESTIONS

WHAT ARE BIOSIMILARS?

WHAT HEALTH CONDITIONS CAN BE TREATED WITH BIOSIMILARS?

ARE BIOSIMILARS THE SAME AS GENERIC DRUGS?

ABOUT BIOSIMILARS

BIOSIMILARS VS ORIGINAL BIOLOGICS

HOW BIOSIMILARS ARE GIVEN

WHY BIOSIMILARS

HOW BIOSIMILARS ARE MADE

APPROVAL PROCESS

WHEN BIOSIMILARS ARE PRESCRIBED

TALKING WITH YOUR DOCTOR

INSURANCE ISSUES

1. U.S. Food and Drug Administration. Biosimilar basics for patients. October 7, 2020. https://www.fda.gov/drugs/biosimilars/patient-materials. Accessed November 2, 2021. **2.** U.S. Food and Drug Administration. Biological Product Definitions. October 2017. https://www.fda.gov/media/108557/download. Accessed November 2, 2021. **3.** U.S. Food and Drug Administration. Overview of Biosimilar Products. Updated July 2021. https://www.fda.gov/media/151058/download. Accessed November 10, 2021. **4.** Kinch MS. *Drug Discov Today.* 2015;20:393-398.

WHAT HEALTH CONDITIONS CAN BE TREATED WITH BIOSIMILARS?

Biosimilars have been approved to treat many serious diseases and chronic illnesses. These include cancer, diabetes, Crohn's disease, ulcerative colitis, rheumatoid arthritis, psoriasis, chronic kidney disease, and macular degeneration and other eye conditions.[1,2]

RELATED QUESTIONS

WHAT ARE BIOLOGICS?

WHAT ARE BIOSIMILARS?

ARE BIOSIMILARS THE SAME AS GENERIC DRUGS?

ABOUT BIOSIMILARS

BIOSIMILARS VS ORIGINAL BIOLOGICS

HOW BIOSIMILARS ARE GIVEN

WHY BIOSIMILARS

HOW BIOSIMILARS ARE MADE

APPROVAL PROCESS

WHEN BIOSIMILARS ARE PRESCRIBED

TALKING WITH YOUR DOCTOR

INSURANCE ISSUES

1. U.S. Food and Drug Administration. Overview of Biosimilar Products. Updated July 2021. https://www.fda.gov/media/151058/download. Accessed November 10, 2021. **2.** U.S. Food and Drug Administration. FDA approves first biosimilar to treat macular degeneration disease and other eye conditions. News release. September 17, 2021. https://www.fda.gov/news-events/press-announcements/fda-aproves-first-biosimilar-treat-macular-degeneration-disease-and-other-eye- conditions. Accessed November 10, 2021.

ARE BIOSIMILARS THE SAME AS GENERIC DRUGS?

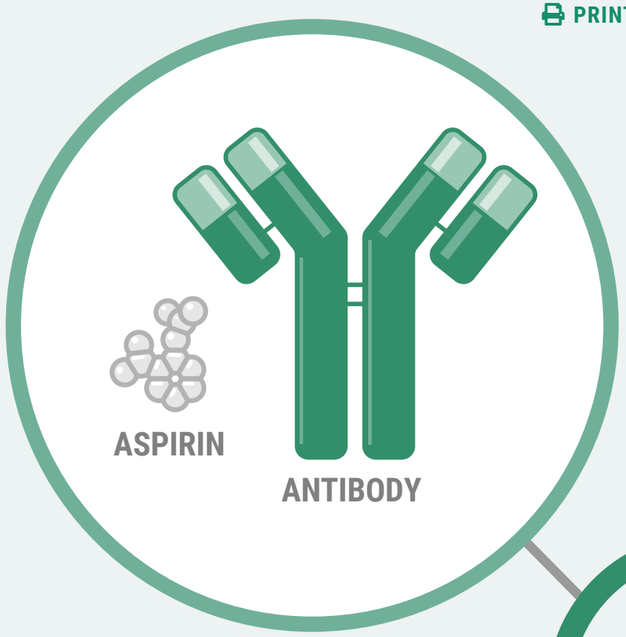
No, generic drugs are exact copies of medicines generally made from chemicals. Because a biosimilar, like other biologic medicines, is a protein made in living cells, it cannot be an exact copy, but is highly similar to the original biologic drug it is based on. An approved biosimilar has been thoroughly tested to show that it is as safe and effective as the original biologic and is given in the same way.[1,2]

RELATED QUESTIONS

WHAT ARE BIOLOGICS?

WHAT HEALTH CONDITIONS CAN BE TREATED WITH BIOSIMILARS?

WHAT ARE BIOSIMILARS?



ABOUT BIOSIMILARS

BIOSIMILARS VS ORIGINAL BIOLOGICS

HOW BIOSIMILARS ARE GIVEN

WHY BIOSIMILARS

HOW BIOSIMILARS ARE MADE

APPROVAL PROCESS

WHEN BIOSIMILARS ARE PRESCRIBED

TALKING WITH YOUR DOCTOR

INSURANCE ISSUES

1. U.S. Food and Drug Administration. Biosimilar basics for patients. October 7, 2020. https://www.fda.gov/drugs/biosimilars/patient-materials. Accessed November 2, 2021. **2.** American Cancer Society Cancer Action Network. Understanding biologic and biosimilar drugs. July 27, 2018. https://www.fightcancer.org/policy-resources/understanding-biologic-and-biosimilar-drugs. Accessed November 1, 2021.

ARE BIOSIMILARS AS SAFE AND EFFECTIVE AS ORIGINAL BIOLOGICS?

Yes, biosimilars are as safe and effective as the original biologics for the medical conditions they have been approved to treat. This means approved biosimilars will have the same treatment benefits and possible side effects as the original biologic medicines approved to treat the same conditions.[1] Biosimilars may be approved for some or all of the same conditions as the original biologic medicines.[2]

Because biologic medicines are made from living cells, there may be slight differences between an original biologic and a biosimilar. To be approved, a biosimilar must show that these small differences do not affect how well the biosimilar works in the body or how safe it is to take.[3]

RELATED QUESTIONS

WILL A BIOSIMILAR HAVE THE SAME SIDE EFFECTS AS THE ORIGINAL BIOLOGIC DRUG?

WILL A BIOSIMILAR WORK THE SAME WAY AS THE ORIGINAL BIOLOGIC DRUG?

WHAT IS A REFERENCE PRODUCT?

ABOUT BIOSIMILARS

BIOSIMILARS VS ORIGINAL BIOLOGICS

HOW BIOSIMILARS ARE GIVEN

WHY BIOSIMILARS

HOW BIOSIMILARS ARE MADE

APPROVAL PROCESS

WHEN BIOSIMILARS ARE PRESCRIBED

TALKING WITH YOUR DOCTOR

INSURANCE ISSUES

1. U.S. Food and Drug Administration. Consumer updates: Biosimilar and interchangeable biologics. October 12, 2021. https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices. Accessed November 2, 2021. **2.** U.S. Food and Drug Administration. Prescribing Biosimilar Products. October 2021. https://cacmap.fda.gov/media/108103/download. Accessed November 22, 2021.
3. U.S. Food and Drug Administration. Overview of Biosimilar Products. Updated July 2021. https://www.fda.gov/media/151058/download. Accessed November 10, 2021.

WILL A BIOSIMILAR HAVE THE SAME SIDE EFFECTS AS THE ORIGINAL BIOLOGIC DRUG?

Yes, a biosimilar may have the same possible side effects as the original biologic.[1]

Before you start taking a biosimilar, your doctor will explain the possible side effects to watch for and what to report to your health care team. Your doctor or nurse can also give you tips on how to manage the possible side effects of your biosimilar treatment.

RELATED QUESTIONS

ARE BIOSIMILARS AS SAFE AND EFFECTIVE AS ORIGINAL BIOLOGICS?

WILL A BIOSIMILAR WORK THE SAME WAY AS THE ORIGINAL BIOLOGIC DRUG?

WHAT IS A REFERENCE PRODUCT?

ABOUT BIOSIMILARS

BIOSIMILARS VS ORIGINAL BIOLOGICS

HOW BIOSIMILARS ARE GIVEN

WHY BIOSIMILARS

HOW BIOSIMILARS ARE MADE

APPROVAL PROCESS

WHEN BIOSIMILARS ARE PRESCRIBED

TALKING WITH YOUR DOCTOR

INSURANCE ISSUES

1. U.S. Food and Drug Administration. Consumer updates: Biosimilar and interchangeable biologics. October 12, 2021. https://www.fda.gov/consumers/consumer-updates/biosimilar-and- interchangeable-biologics-more-treatment-choices. Accessed November 2, 2021.

WILL A BIOSIMILAR WORK THE SAME WAY AS THE ORIGINAL BIOLOGIC DRUG?

You can expect that a biosimilar will work the same way as the original biologic medicine. Any possible side effects would be similar to what you experienced with the original biologic.[1]

RELATED QUESTIONS

WILL A BIOSIMILAR HAVE THE SAME SIDE EFFECTS AS THE ORIGINAL BIOLOGIC DRUG?

ARE BIOSIMILARS AS SAFE AND EFFECTIVE AS ORIGINAL BIOLOGICS?

WHAT IS A REFERENCE PRODUCT?

ABOUT BIOSIMILARS

BIOSIMILARS VS ORIGINAL BIOLOGICS

HOW BIOSIMILARS ARE GIVEN

WHY BIOSIMILARS

HOW BIOSIMILARS ARE MADE

APPROVAL PROCESS

WHEN BIOSIMILARS ARE PRESCRIBED

TALKING WITH YOUR DOCTOR

INSURANCE ISSUES

1. U.S. Food and Drug Administration. Consumer updates: Biosimilar and interchangeable biologics. October 12, 2021. https://www.fda.gov/consumers/consumer-updates/biosimilar-and- interchangeable-biologics-more-treatment-choices. Accessed November 2, 2021.

WHAT IS A REFERENCE PRODUCT?

A reference product is an approved biologic medicine to which a biosimilar is being compared. In order to be approved for use, a biosimilar must be shown to be highly similar to the reference product and have no clinically meaningful differences in terms of how safe or effective it is.[1]

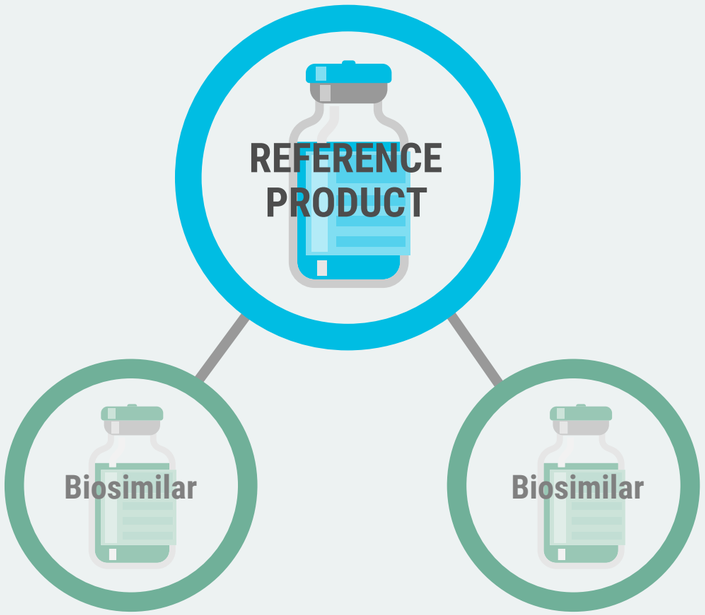
A reference product may also be called the original biologic or originator biologic.

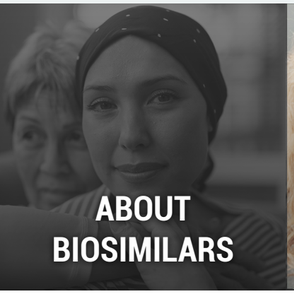
RELATED QUESTIONS

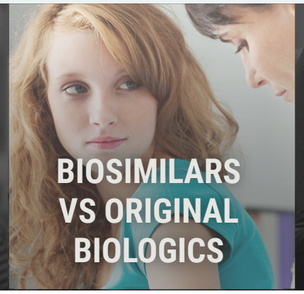
WILL A BIOSIMILAR HAVE THE SAME SIDE EFFECTS AS THE ORIGINAL BIOLOGIC DRUG?

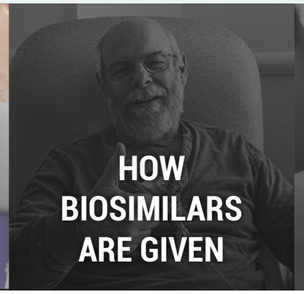
WILL A BIOSIMILAR WORK THE SAME WAY AS THE ORIGINAL BIOLOGIC DRUG?

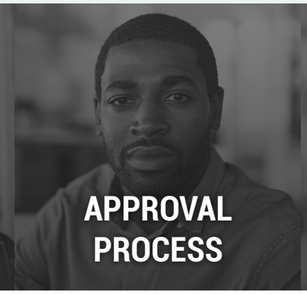
ARE BIOSIMILARS AS SAFE AND EFFECTIVE AS ORIGINAL BIOLOGICS?

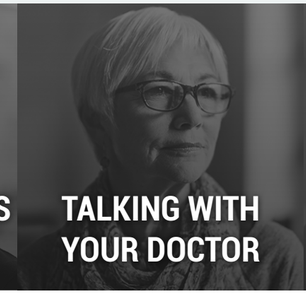












1. U.S. Food and Drug Administration. Biological Product Definitions. October 2021. https://www.fda.gov/media/108557/download. Accessed November 2, 2021.

IS A BIOSIMILAR GIVEN THE SAME WAY AS THE ORIGINAL BIOLOGIC?

Yes. All biologic treatments are given as an injection or as an infusion into a vein.[1]

- If your biologic treatment is given through an intravenous (IV) infusion at a doctor's office, hospital, or infusion center, you will receive your biosimilar the same way[2]
- If you self-inject your biologic treatment at home, you will still give yourself an injection, but you may be switched to a different type of injector device[2]

A biosimilar will also follow the same treatment schedule as the original biologic.[2] If you have questions about how often your biosimilar medicine will be given or how many treatments you will have, talk to your doctor.

RELATED QUESTIONS

HOW ARE BIOSIMILARS USUALLY GIVEN?

WILL THE DOSE OF A BIOSIMILAR BE THE SAME AS THE DOSE OF THE ORIGINAL BIOLOGIC DRUG?

WILL MY TREATMENT SCHEDULE CHANGE IF I AM SWITCHED FROM THE ORIGINAL BIOLOGIC TO A BIOSIMILAR?

ABOUT BIOSIMILARS

BIOSIMILARS VS ORIGINAL BIOLOGICS

HOW BIOSIMILARS ARE GIVEN

WHY BIOSIMILARS

HOW BIOSIMILARS ARE MADE

APPROVAL PROCESS

WHEN BIOSIMILARS ARE PRESCRIBED

TALKING WITH YOUR DOCTOR

INSURANCE ISSUES

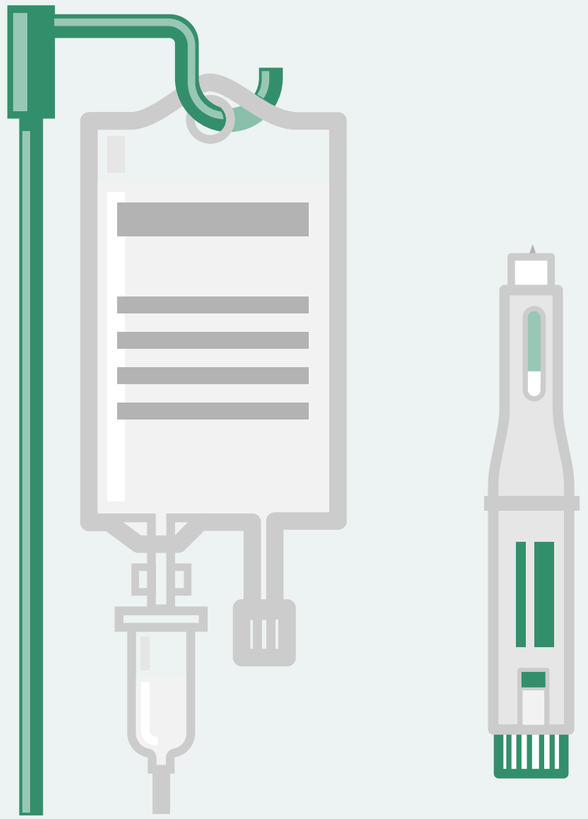
1. American College of Rheumatology. Patient Safety and Site of Service for Biologics Position Paper. June 2021. https://www.rheumatology.org/Portals/0/Files/Biologics-Patient-Safety-and- site-of-Service.pdf. Accessed December 9, 2021. **2.** U.S. Food and Drug Administration. Consumer updates: Biosimilar and interchangeable biologics. October 12, 2021. https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices. Accessed November 2, 2021.

HOW ARE BIOSIMILARS USUALLY GIVEN?

Biosimilars can be given by IV infusion or injection, or as prescribed. IV infusions are usually given at a doctor's office, hospital, or infusion center.[1] Injections can often be given at home with a prefilled syringe or pen.

RELATED QUESTIONS

- IS A BIOSIMILAR GIVEN THE SAME WAY AS THE ORIGINAL BIOLOGIC?
- WILL THE DOSE OF A BIOSIMILAR BE THE SAME AS THE DOSE OF THE ORIGINAL BIOLOGIC DRUG?
- WILL MY TREATMENT SCHEDULE CHANGE IF I AM SWITCHED FROM THE ORIGINAL BIOLOGIC TO A BIOSIMILAR?



ABOUT BIOSIMILARS | BIOSIMILARS VS ORIGINAL BIOLOGICS | HOW BIOSIMILARS ARE GIVEN | WHY BIOSIMILARS | HOW BIOSIMILARS ARE MADE | APPROVAL PROCESS | WHEN BIOSIMILARS ARE PRESCRIBED | TALKING WITH YOUR DOCTOR | INSURANCE ISSUES

1. American College of Rheumatology. Patient Safety and Site of Service for Biologics Position Paper. June 2021. https://www.rheumatology.org/Portals/0/Files/Biologics-Patient-Safety-and-site-of- Service.pdf. Accessed December 9, 2021.

WILL THE DOSE OF A BIOSIMILAR BE THE SAME AS THE DOSE OF THE ORIGINAL BIOLOGIC DRUG?

Yes, a biosimilar can be given at the same dose as the original biologic drug.[1]

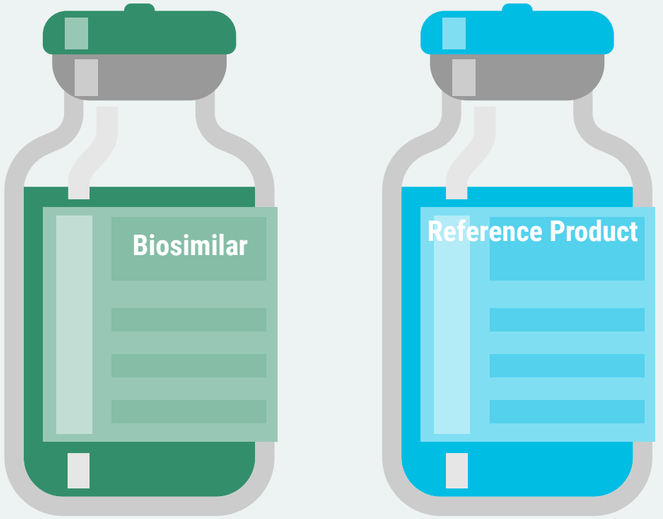
Talk to your doctor or pharmacist if you have questions about the dose you are taking.

RELATED QUESTIONS

HOW ARE BIOSIMILARS USUALLY GIVEN?

IS A BIOSIMILAR GIVEN THE SAME WAY AS THE ORIGINAL BIOLOGIC?

WILL MY TREATMENT SCHEDULE CHANGE IF I AM SWITCHED FROM THE ORIGINAL BIOLOGIC TO A BIOSIMILAR?



ABOUT BIOSIMILARS

BIOSIMILARS VS ORIGINAL BIOLOGICS

HOW BIOSIMILARS ARE GIVEN

WHY BIOSIMILARS

HOW BIOSIMILARS ARE MADE

APPROVAL PROCESS

WHEN BIOSIMILARS ARE PRESCRIBED

TALKING WITH YOUR DOCTOR

INSURANCE ISSUES

1. U.S. Food and Drug Administration. Overview of Biosimilar Products. Updated July 2021. https://www.fda.gov/media/151058/download. Accessed November 10, 2021.

WILL MY TREATMENT SCHEDULE CHANGE IF I AM SWITCHED FROM THE ORIGINAL BIOLOGIC TO A BIOSIMILAR?

No, you should expect to receive treatment on the same schedule as the original biologic.[1] Your doctor can review with you how often you will have treatments and how many treatments you will have.

RELATED QUESTIONS

HOW ARE BIOSIMILARS USUALLY GIVEN?

WILL THE DOSE OF A BIOSIMILAR BE THE SAME AS THE DOSE OF THE ORIGINAL BIOLOGIC DRUG?

IS A BIOSIMILAR GIVEN THE SAME WAY AS THE ORIGINAL BIOLOGIC?

ABOUT BIOSIMILARS

BIOSIMILARS VS ORIGINAL BIOLOGICS

HOW BIOSIMILARS ARE GIVEN

WHY BIOSIMILARS

HOW BIOSIMILARS ARE MADE

APPROVAL PROCESS

WHEN BIOSIMILARS ARE PRESCRIBED

TALKING WITH YOUR DOCTOR

INSURANCE ISSUES

1. U.S. Food and Drug Administration. Consumer updates: Biosimilar and interchangeable biologics. October 12, 2021. https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices. Accessed November 2, 2021.

WHY SHOULD I CONSIDER A BIOSIMILAR?

If you are living with a serious or chronic illness, biosimilars may give you more options for treating your condition.[1] Although biosimilars may be new to you, some original biologic medicines have been around for 40 years.[2] Biosimilars have been approved in Europe since 2006,[3] in Canada since 2009,[4] and in the US since 2015.[5]

It's important to know that approved biosimilar medicines are as safe and effective as the original biologic medicines on which they are based. As more biosimilars come on the market, patients will have more treatment options. Competition in the health care market may increase, which could help drive down drug costs for everyone.[1]

RELATED QUESTIONS

WHAT ARE THE MOST IMPORTANT THINGS TO KNOW ABOUT BIOSIMILARS?

HOW LONG HAVE BIOSIMILARS BEEN AROUND?

HOW CAN I LEARN MORE ABOUT BIOSIMILARS?

ABOUT BIOSIMILARS | BIOSIMILARS VS ORIGINAL BIOLOGICS | HOW BIOSIMILARS ARE GIVEN | WHY BIOSIMILARS | HOW BIOSIMILARS ARE MADE | APPROVAL PROCESS | WHEN BIOSIMILARS ARE PRESCRIBED | TALKING WITH YOUR DOCTOR | INSURANCE ISSUES

1. U.S. Food and Drug Administration. Overview of Biosimilar Products. Updated July 2021. https://www.fda.gov/media/151058/download. Accessed November 10, 2021. **2.** George K, et al. *BioDrugs*. 2019;33:447-451. **3.** European Medicines Agency. Biosimilar EMA reports results. 2020. https://www.ema.europa.eu/en/medicines/field_ema_web_categories%253Aname_field/Human/ema_group_types/ema_medicine/field_ema_med_status/authorized_36/ema_medicine_types/field_ema_med_biosimilar/search_api_aggregation_ema_medicine_types/field_ema_med_biosimilar?sort=field_ema_med_market_auth_date&order=desc. Accessed December 10, 2021. **4.** GaBi. Biosimilars Approved in Canada. https://www.gabionline.net/biosimilars/general/biosimilars-approved-in-canada. Accessed December 10, 2021. **5.** FDA. Biosimilar Product Information. https://www.fda.gov/drugs/biosimilars/biosimilar-product-information. Accessed December 10, 2021.

WHAT ARE THE MOST IMPORTANT THINGS TO KNOW ABOUT BIOSIMILARS?

Here's a recap of important things to know about biosimilars:

- Biosimilars are safe and effective medicines for treating many conditions such as arthritis, cancer, diabetes, kidney disease, and inflammatory bowel diseases (IBDs) such as Crohn's disease and ulcerative colitis[1]
- Biosimilars are biologic drugs made from living cells, so they cannot be exact copies of original biologic medicines[1]
- A biosimilar is highly similar to an original biologic medicine that has been approved to treat one or more conditions. This means you can expect to[2]
  - Take the biosimilar the same way the original biologic is given
  - Have the same treatment benefits and possible side effects
  - Get the same strength and dosing
  - Follow the same treatment schedule
- Biosimilars go through a rigorous review process to make sure they are as safe and effective as the original biologic medicine to which they are compared[3]
- Tight controls and careful monitoring through every step of the manufacturing process to check that the biosimilar meets the same standards of quality, purity, and potency as the original biologic[2]
- The high standards required for approval of biosimilar medicines help make sure that biosimilars will be as safe and effective as the original biologics approved to treat the same conditions[3]

RELATED QUESTIONS

WHY SHOULD I CONSIDER A BIOSIMILAR?

HOW LONG HAVE BIOSIMILARS BEEN AROUND?

HOW CAN I LEARN MORE ABOUT BIOSIMILARS?

ABOUT BIOSIMILARS

BIOSIMILARS VS ORIGINAL BIOLOGICS

HOW BIOSIMILARS ARE GIVEN

WHY BIOSIMILARS

HOW BIOSIMILARS ARE MADE

APPROVAL PROCESS

WHEN BIOSIMILARS ARE PRESCRIBED

TALKING WITH YOUR DOCTOR

INSURANCE ISSUES

1. U.S. Food and Drug Administration. Biosimilar basics for patients. October 7, 2020. https://www.fda.gov/drugs/biosimilars/patient-materials. Accessed November 2, 2021. **2.** U.S. Food and Drug Administration. Consumer updates: Biosimilar and interchangeable biologics. October 12, 2021. https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices. Accessed November 2, 2021. **3.** U.S. Food and Drug Administration. Overview of Biosimilar Products. Updated July 2021. https://www.fda.gov/media/151058/download. Accessed November 10, 2021.

HOW LONG HAVE BIOSIMILARS BEEN AROUND?

Biosimilars have been used in Europe since 2006.[1] In the United States, the first biosimilar was approved in 2015.[2] Since then, biosimilars have been approved to treat cancer, diabetes, arthritis, psoriasis, Crohn's disease, ulcerative colitis, chronic kidney disease, and eye disorders such as macular degeneration.[2,3]

RELATED QUESTIONS

WHAT ARE THE MOST IMPORTANT THINGS TO KNOW ABOUT BIOSIMILARS?

WHY SHOULD I CONSIDER A BIOSIMILAR?

HOW CAN I LEARN MORE ABOUT BIOSIMILARS?

ABOUT BIOSIMILARS

BIOSIMILARS VS ORIGINAL BIOLOGICS

HOW BIOSIMILARS ARE GIVEN

WHY BIOSIMILARS

HOW BIOSIMILARS ARE MADE

APPROVAL PROCESS

WHEN BIOSIMILARS ARE PRESCRIBED

TALKING WITH YOUR DOCTOR

INSURANCE ISSUES

1. European Medicines Agency. Biosimilar EMA reports results. 2020. https://www.ema.europa.eu/en/medicines/field_ema_web_categories%253Aname_field/Human/ema_group_types/ema_medicine/field_ema_med_status/authorized_36/ema_medicine_types/field_ema_med_biosimilar/search_api_aggregation_ema_medicine_types/field_ema_med_biosimilar?sort=field_ema_med_market_auth_date&order=desc. Accessed December 10, 2021.
2. FDA. Biosimilar Product Information. 2021. https://www.fda.gov/drugs/biosimilars/biosimilar-product-information. Accessed December 10, 2021. **3.** FDA. FDA Approves First Biosimilar to Treat Macular Degeneration. September 17, 2021. www.fda.gov/news-events/press-announcements/fda-approves-first-biosimilar-treat-macular-degeneration-disease-and-other-eye-conditions. Accessed November 10, 2021.

HOW CAN I LEARN MORE ABOUT BIOSIMILARS?

In the United States, visit **FDA.gov** for basic information about biosimilars.

In Europe, visit the **European Medicines Agency** (EMA) for patient resources on biosimilars.

To learn about biosimilar treatments for specific medical conditions, speak with your doctor. In addition, you can visit health advocacy organizations that support people with your condition for fact sheets and information on biosimilars.

RELATED QUESTIONS

WHAT ARE THE MOST IMPORTANT THINGS TO KNOW ABOUT BIOSIMILARS?

HOW LONG HAVE BIOSIMILARS BEEN AROUND?

WHY SHOULD I CONSIDER A BIOSIMILAR?

ABOUT BIOSIMILARS

BIOSIMILARS VS ORIGINAL BIOLOGICS

HOW BIOSIMILARS ARE GIVEN

WHY BIOSIMILARS

HOW BIOSIMILARS ARE MADE

APPROVAL PROCESS

WHEN BIOSIMILARS ARE PRESCRIBED

TALKING WITH YOUR DOCTOR

INSURANCE ISSUES

HOW ARE BIOSIMILARS MADE?

The process of making a biosimilar is complex.

Drug makers start by studying the original biologic (reference product) to learn about its structure and how it functions.[1] They analyze everything that could affect the safety, effectiveness, and quality of the medicine. Then they combine this knowledge with state-of-the-art tools and equipment to create a process for making each biosimilar medicine.[2] This precise process is perfected through continuous testing and monitoring.[1] If needed, changes are made to confirm quality and to produce a medicine that is highly similar to the original biologic and that meets the high standards for safe and effective use in patients.[1,2]

RELATED QUESTIONS

WHAT KIND OF EXPERIENCE IS NEEDED TO CREATE A BIOSIMILAR THAT WILL BE AS SAFE AND EFFECTIVE AS THE ORIGINAL BIOLOGIC?

WHAT STEPS DO DRUG MAKERS TAKE TO MAKE SURE THAT A BIOSIMILAR WILL BE AS SAFE AND EFFECTIVE AS THE ORIGINAL BIOLOGIC?

ABOUT BIOSIMILARS
BIOSIMILARS VS ORIGINAL BIOLOGICS
HOW BIOSIMILARS ARE GIVEN
WHY BIOSIMILARS
HOW BIOSIMILARS ARE MADE
APPROVAL PROCESS
WHEN BIOSIMILARS ARE PRESCRIBED
TALKING WITH YOUR DOCTOR
INSURANCE ISSUES

1. U.S. Food and Drug Administration. Guidance for Industry. Scientific Considerations in Demonstrating Biosmilarity to a Reference Product. 2015. **2.** U.S. Food and Drug Administration. Overview of Biosimilar Products. Updated July 2021. https://www.fda.gov/media/151058/download. Accessed November 10, 2021.

WHAT KIND OF EXPERIENCE IS NEEDED TO CREATE A BIOSIMILAR THAT WILL BE AS SAFE AND EFFECTIVE AS THE ORIGINAL BIOLOGIC?

It takes a lot of scientific knowledge, advanced technology, and manufacturing experience to create a biosimilar that will be as safe and effective as the original biologic.[1,2]

Biosimilars are grown in living cells and cannot be exact copies of original biologics. The process of making the original biologic is unique to each manufacturer. Therefore, scientists making biosimilars must develop new processes to make products that are highly similar to and provide the same quality, purity, safety, and effectiveness as original biologics. The knowledge, skill, and experience that are applied to this challenge maintain that quality through every step of the biosimilar manufacturing process.[3]

RELATED QUESTIONS

HOW ARE BIOSIMILARS MADE?

WHAT STEPS DO DRUG MAKERS TAKE TO MAKE SURE THAT A BIOSIMILAR WILL BE AS SAFE AND EFFECTIVE AS THE ORIGINAL BIOLOGIC?

ABOUT BIOSIMILARS

BIOSIMILARS VS ORIGINAL BIOLOGICS

HOW BIOSIMILARS ARE GIVEN

WHY BIOSIMILARS

HOW BIOSIMILARS ARE MADE

APPROVAL PROCESS

WHEN BIOSIMILARS ARE PRESCRIBED

TALKING WITH YOUR DOCTOR

INSURANCE ISSUES

1. Mellstedt H, et al. *Ann Oncol.* 2007;19:411-419. **2.** Miletich J, et al. *mAbs.* 2011;3:318-325. **3.** Lee JF, et al. *Curr Med Res Opin.* 2012;28:1053-1058.

WHAT STEPS DO DRUG MAKERS TAKE TO MAKE SURE THAT A BIOSIMILAR WILL BE AS SAFE AND EFFECTIVE AS THE ORIGINAL BIOLOGIC?

Drug makers take four major steps to create a biosimilar that will be as safe and effective as the original biologic.

STEP 1: Analyze the structure and function of the original biologic (also called the reference product). Scientists must learn which features or qualities of the original biologic are critical to its safety and effectiveness.[1]

STEP 2: Design a manufacturing process that creates a biosimilar product that is highly similar to the original biologic. This involves making continuous improvements over repeated steps to produce a biosimilar that offers the same safety, purity, and potency as the original biologic.[1,2]

STEP 3: Conduct clinical studies to show the biosimilar will be as safe and effective for patients to take as the original biologic. In order for the biosimilar to be approved, the biosimilar is tested in humans to show that any slight differences between the biosimilar and the original biologic will not affect how well the drug works or how safe it is to take.[1]

STEP 4: Conduct more studies, if needed, to meet the strict standards required for approval of a biosimilar medicine. Providing more information about manufacturing practices and how the biosimilar affects patients who take it helps make it clear that the biosimilar will safely and effectively treat the conditions for which it is approved.[1]

RELATED QUESTIONS

WHAT KIND OF EXPERIENCE IS NEEDED TO CREATE A BIOSIMILAR THAT WILL BE AS SAFE AND EFFECTIVE AS THE ORIGINAL BIOLOGIC?

HOW ARE BIOSIMILARS MADE?

ABOUT BIOSIMILARS

BIOSIMILARS VS ORIGINAL BIOLOGICS

HOW BIOSIMILARS ARE GIVEN

WHY BIOSIMILARS

HOW BIOSIMILARS ARE MADE

APPROVAL PROCESS

WHEN BIOSIMILARS ARE PRESCRIBED

TALKING WITH YOUR DOCTOR

INSURANCE ISSUES

1. U.S. Food and Drug Administration. Guidance for Industry. Scientific Considerations in Demonstrating Biosmilarity to a Reference Product. 2015. **2.** Lee JF, et al. *Curr Med Res Opin.* 2012;28:1053-1058.

HOW ARE BIOSIMILARS APPROVED FOR USE?

Because drugs made from living sources cannot be copied exactly, the biosimilar is studied in more than 100 laboratory tests to see how similar it is to the original biologic.[1] If these laboratory tests show that the biosimilar is highly similar to the original biologic, clinical trials may be carried out in patients, before it is approved for use, to make sure that the biosimilar works in the same way and is as safe as the original biologic.[2]

Government agencies that approve biosimilars, such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA), carefully review all the data, tests, and studies to be sure that any slight differences between the biosimilar and the original biologic will not affect the safety of the biosimilar or how well it works.[3,4]

As part of the approval process, the agencies closely monitor every step of the manufacturing process. This helps check that the biosimilar meets the same standards of quality, purity, and potency as the original biologic.[5,6]

RELATED QUESTIONS

DO NATIONAL AGENCIES THAT REVIEW AND APPROVE NEW MEDICINES, SUCH AS THE FDA IN THE UNITED STATES OR THE EMA IN EUROPE, PLAY THE SAME ROLE IN EVALUATING BIOSIMILARS AS ORIGINAL BIOLOGICS?

WHAT KINDS OF TESTS ARE DONE TO MAKE SURE THE BIOSIMILAR IS AS SAFE AND EFFECTIVE AS THE ORIGINAL BIOLOGIC?

ABOUT BIOSIMILARS
BIOSIMILARS VS ORIGINAL BIOLOGICS
HOW BIOSIMILARS ARE GIVEN
WHY BIOSIMILARS
HOW BIOSIMILARS ARE MADE
APPROVAL PROCESS
WHEN BIOSIMILARS ARE PRESCRIBED
TALKING WITH YOUR DOCTOR
INSURANCE ISSUES

1. Blauvelt A, et al. *Br J Dermatol.* 2016;174(2):282-286. **2.** U.S. Food and Drug Administration. Biological Regulatory Review and Approval. https://www.fda.gov/media/151061/download. Accessed November 5, 2021. **3.** U.S. Food and Drug Administration. Overview of Biosimilar Products. Updated July 2021. https://www.fda.gov/media/151058/download. Accessed November 10, 2021. **4.** European Medicines Agency (EMA), European Commission. What I need to know about Biosimilar Medicines: Information for patients. July 2016. https://ec.europa.eu/docsroom/documents/26643. Accessed December 20, 2021. **5.** U.S. Food and Drug Administration. Consumer updates: Biosimilar and interchangeable biologics. October 12, 2021. https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment-choices. Accessed November 2, 2021. **6.** U.S. Food and Drug Administration. Guidance for Industry. Scientific Considerations in Demonstrating Biosmilarity to a Reference Product. 2015.

DO NATIONAL AGENCIES THAT REVIEW AND APPROVE NEW MEDICINES, SUCH AS THE FDA IN THE UNITED STATES OR THE EMA IN EUROPE, PLAY THE SAME ROLE IN EVALUATING BIOSIMILARS AS ORIGINAL BIOLOGICS?

Yes, national agencies such as the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) follow rigorous review and approval processes to make sure that biosimilars and original biologics meet the same high standards for safety, effectiveness, and quality.[1,2]

To approve a biosimilar, regulatory agencies carefully review information, studies, and tests showing[2,3]

- How well the biosimilar works compared to the original biologic
- How safe it is for people who take it
- How the quality of the biosimilar is maintained through every step of the manufacturing process

RELATED QUESTIONS

HOW ARE BIOSIMILARS APPROVED FOR USE?

WHAT KINDS OF TESTS ARE DONE TO MAKE SURE THE BIOSIMILAR IS AS SAFE AND EFFECTIVE AS THE ORIGINAL BIOLOGIC?

ABOUT BIOSIMILARS

BIOSIMILARS VS ORIGINAL BIOLOGICS

HOW BIOSIMILARS ARE GIVEN

WHY BIOSIMILARS

HOW BIOSIMILARS ARE MADE

APPROVAL PROCESS

WHEN BIOSIMILARS ARE PRESCRIBED

TALKING WITH YOUR DOCTOR

INSURANCE ISSUES

1. U.S. Food and Drug Administration. Overview of Biosimilar Products. Updated July 2021. https://www.fda.gov/media/151058/download. Accessed November 10, 2021. **2.** European Medicines Agency (EMA), European Commission. What I need to know about Biosimilar Medicines: Information for patients. July 2016. https://ec.europa.eu/docsroom/documents/ 26643. Accessed December 20, 2021. **3.** U.S. Food and Drug Administration. Consumer updates: Biosimilar and interchangeable biologics. October 12, 2021. https://www.fda.gov/consumers/consumer-updates/biosimilar-and-interchangeable-biologics-more-treatment- choices. Accessed November 2, 2021.

WHAT KINDS OF TESTS ARE DONE TO MAKE SURE THE BIOSIMILAR IS AS SAFE AND EFFECTIVE AS THE ORIGINAL BIOLOGIC?

Makers of biosimilars do more than 100 tests to see if the biosimilar is as safe and effective as the original biologic.[1] These include:[2]

- ✔ Laboratory tests to analyze the structure, function, and quality of the biosimilar and compare it to the original biologic to make sure they are very similar
- ✔ Studies in animals and healthy people to make sure the biosimilar will be as safe for patients as the original biologic
- ✔ Clinical studies to show that the biosimilar and the original biologic
  - ○ Have the same effectiveness
  - ○ Work at the same dose and can be given the same way
  - ○ Have the same possible side effects or immune reactions
- ✔ More clinical studies, if needed, to help prove that any slight differences between the biosimilar and the original biologic will not affect how well the drug works or how safe it is to take

RELATED QUESTIONS

DO NATIONAL AGENCIES THAT REVIEW AND APPROVE NEW MEDICINES, SUCH AS THE FDA IN THE UNITED STATES OR THE EMA IN EUROPE, PLAY THE SAME ROLE IN EVALUATING BIOSIMILARS AS ORIGINAL BIOLOGICS?

HOW ARE BIOSIMILARS APPROVED FOR USE?

ABOUT BIOSIMILARS | BIOSIMILARS VS ORIGINAL BIOLOGICS | HOW BIOSIMILARS ARE GIVEN | WHY BIOSIMILARS | HOW BIOSIMILARS ARE MADE | APPROVAL PROCESS | WHEN BIOSIMILARS ARE PRESCRIBED | TALKING WITH YOUR DOCTOR | INSURANCE ISSUES

1. Blauvelt A, et al. *Br J Dermatol.* 2016;174(2):282-286. **2.** U.S. Food and Drug Administration. Biosimilar Regulatory Review and Approval. https://www.fda.gov/media/151061/download. Accessed November 5, 2021.

WHEN MIGHT MY DOCTOR PRESCRIBE A BIOSIMILAR FOR ME?

In a recent survey, doctors said they were most likely to prescribe biosimilars to patients starting on a new biologic treatment. Many were also comfortable switching patients who were doing well on an original biologic to a biosimilar. They were less likely to prescribe a biosimilar to patients who had only modest success with the original biologic medicine. The doctors in the survey were specialists who regularly prescribe biologics to their patients.[1]

If you and your doctor think you might benefit from treatment with a biologic medicine, your doctor will carefully consider your health, medical history, and response to previous treatment to see if a biosimilar may be right for you.

RELATED QUESTIONS

WHY WOULD MY DOCTOR START ME ON A BIOSIMILAR?

HOW WOULD I KNOW IF MY CURRENT TREATMENT IS THE ORIGINAL BIOLOGIC OR A BIOSIMILAR?

IF MY CURRENT TREATMENT IS WORKING, WHY WOULD MY DOCTOR SWITCH ME TO A BIOSIMILAR?

ABOUT BIOSIMILARS

BIOSIMILARS VS ORIGINAL BIOLOGICS

HOW BIOSIMILARS ARE GIVEN

WHY BIOSIMILARS

HOW BIOSIMILARS ARE MADE

APPROVAL PROCESS

WHEN BIOSIMILARS ARE PRESCRIBED

TALKING WITH YOUR DOCTOR

INSURANCE ISSUES

1. NORC at the University of Chicago. Understanding Stakeholder Perception of Biosimilars. https://www.norc.org/PDFs/Biosimilars/20210405_AV%20-%20NORC%20Biosimilars%20Final %20Report.pdf. Accessed December 20, 2021.

WHY WOULD MY DOCTOR START ME ON A BIOSIMILAR?

If there is a biosimilar treatment option for your condition, your doctor might recommend starting with a biosimilar because it would be as safe and effective as the original biologic and might lower your drug cost.[1] However, if you are not sure why your doctor is recommending a certain treatment, it's a good idea to talk to your doctor about it.

RELATED QUESTIONS

WHEN MIGHT MY DOCTOR PRESCRIBE A BIOSIMILAR FOR ME?

HOW WOULD I KNOW IF MY CURRENT TREATMENT IS THE ORIGINAL BIOLOGIC OR A BIOSIMILAR?

IF MY CURRENT TREATMENT IS WORKING, WHY WOULD MY DOCTOR SWITCH ME TO A BIOSIMILAR?

ABOUT BIOSIMILARS

BIOSIMILARS VS ORIGINAL BIOLOGICS

HOW BIOSIMILARS ARE GIVEN

WHY BIOSIMILARS

HOW BIOSIMILARS ARE MADE

APPROVAL PROCESS

WHEN BIOSIMILARS ARE PRESCRIBED

TALKING WITH YOUR DOCTOR

INSURANCE ISSUES

1. U.S. Food and Drug Administration. Biosimilar basics for patients. October 7, 2020. https://www.fda.gov/drugs/biosimilars/patient-materials. Accessed November 2, 2021.

HOW WOULD I KNOW IF MY CURRENT TREATMENT IS THE ORIGINAL BIOLOGIC OR A BIOSIMILAR?

There are several ways to learn more about your current treatment:

- ✔ Ask your doctor if you are getting an original biologic or a biosimilar as part of your treatment
- ✔ If your medicine is given by infusion, the doctor or nurse who will be giving you your treatment should be able to tell you if it's an original biologic or a biosimilar
- ✔ If your medicine is given by self-injection, you can ask the nurse or pharmacist who shows you how to prepare and give yourself the injection if you have been prescribed an original biologic or a biosimilar[1]

RELATED QUESTIONS

WHY WOULD MY DOCTOR START ME ON A BIOSIMILAR?

WHEN MIGHT MY DOCTOR PRESCRIBE A BIOSIMILAR FOR ME?

IF MY CURRENT TREATMENT IS WORKING, WHY WOULD MY DOCTOR SWITCH ME TO A BIOSIMILAR?

1. U.S. Food and Drug Administration. Biosimilar basics for patients. October 7, 2020. https://www.fda.gov/drugs/biosimilars/patient-materials. Accessed November 2, 2021.

IF MY CURRENT TREATMENT IS WORKING, WHY WOULD MY DOCTOR SWITCH ME TO A BIOSIMILAR?

It's important to discuss this with your doctor. If the doctor has recommended making a switch to a biosimilar, you can ask why.

Even when an original biologic is working, your doctor might consider switching to a biosimilar that would be as safe and effective as the original biologic and may save you money.[1]

To learn about a prescription being switched to a biosimilar at the pharmacy, see **Who makes the decision about being switched to a biosimilar medicine?**

RELATED QUESTIONS

WHY WOULD MY DOCTOR START ME ON A BIOSIMILAR?

HOW WOULD I KNOW IF MY CURRENT TREATMENT IS THE ORIGINAL BIOLOGIC OR A BIOSIMILAR?

WHEN MIGHT MY DOCTOR PRESCRIBE A BIOSIMILAR FOR ME?

ABOUT BIOSIMILARS

BIOSIMILARS VS ORIGINAL BIOLOGICS

HOW BIOSIMILARS ARE GIVEN

WHY BIOSIMILARS

HOW BIOSIMILARS ARE MADE

APPROVAL PROCESS

WHEN BIOSIMILARS ARE PRESCRIBED

TALKING WITH YOUR DOCTOR

INSURANCE ISSUES

1. U.S. Food and Drug Administration. Biosimilar basics for patients. October 7, 2020. https://www.fda.gov/drugs/biosimilars/patient-materials. Accessed November 2, 2021.

HOW WILL I KNOW IF I AM GETTING A BIOSIMILAR?

The best way to know if you are getting a biosimilar is to ask your doctor, nurse, or the pharmacist who filled the prescription.[1]

It's important to talk with your doctor about all the medicines you are taking to be sure you understand how they may help you and what possible side effects you may have.

The pharmacist can tell you what medicine was prescribed for you and what medicine you were given.[1]

RELATED QUESTIONS

HOW CAN I FIND OUT IF THERE IS A BIOSIMILAR FOR THE BIOLOGIC I AM TAKING?

HOW CAN I BE SURE A BIOSIMILAR WORKS WELL FOR THE CONDITION I HAVE?

WHO MAKES THE DECISION ABOUT BEING SWITCHED TO A BIOSIMILAR MEDICINE?

1. U.S. Food and Drug Administration. Biosimilar basics for patients. October 7, 2020. https://www.fda.gov/drugs/biosimilars/patient-materials. Accessed November 2, 2021.

HOW CAN I FIND OUT IF THERE IS A BIOSIMILAR FOR THE BIOLOGIC I AM TAKING?

In the United States, check the **Purple Book**, which lists all FDA-approved biologic and biosimilar medicines.

In Europe, check the **EMA list of approved biosimilars**.

The **Generics and Biologics Initiative (GaBI)** keeps updated lists of approved biosimilars for countries around the world.

After a biosimilar is approved, it can take time for it to be available for use.

RELATED QUESTIONS

HOW WILL I KNOW IF I AM GETTING A BIOSIMILAR?

HOW CAN I BE SURE A BIOSIMILAR WORKS WELL FOR THE CONDITION I HAVE?

WHO MAKES THE DECISION ABOUT BEING SWITCHED TO A BIOSIMILAR MEDICINE?

HOW CAN I BE SURE A BIOSIMILAR WORKS WELL FOR THE CONDITION I HAVE?

A manufacturer must show that a biosimilar medicine is highly similar to, and has no clinically meaningful differences from, the original biologic to which it is compared.[1,2]

As part of the approval process for a biosimilar, experts carefully review all of the data on the biosimilar to determine if it is as safe and effective as the original biologic.[1,2]

For a biosimilar to receive approval, experts must decide that the biosimilar would safely and effectively treat one or more conditions that the original biologic is approved to treat. This means that a biosimilar would be approved for your condition only if there is enough evidence showing that it can be expected to work as well as and be as safe as the original biologic for that condition.[1,2]

RELATED QUESTIONS

HOW CAN I FIND OUT IF THERE IS A BIOSIMILAR FOR THE BIOLOGIC I AM TAKING?

HOW WILL I KNOW IF I AM GETTING A BIOSIMILAR?

WHO MAKES THE DECISION ABOUT BEING SWITCHED TO A BIOSIMILAR MEDICINE?

ABOUT BIOSIMILARS

BIOSIMILARS VS ORIGINAL BIOLOGICS

HOW BIOSIMILARS ARE GIVEN

WHY BIOSIMILARS

HOW BIOSIMILARS ARE MADE

APPROVAL PROCESS

WHEN BIOSIMILARS ARE PRESCRIBED

TALKING WITH YOUR DOCTOR

INSURANCE ISSUES

1. U.S. Food and Drug Administration. Biosimilar Regulatory Review and Approval. https://www.fda.gov/media/151061/download. Accessed November 5, 2021. **2.** European Medicines Agency (EMA), European Commission. What I need to know about Biosimilar Medicines: Information for patients. July 2016. https://ec.europa.eu/docsroom/documents/26643. Accessed December 20, 2021.

WHO MAKES THE DECISION ABOUT BEING SWITCHED TO A BIOSIMILAR MEDICINE?

In most cases, the decision to switch patients from an original biologic to a biosimilar is made by the doctor who prescribes the medicine.[1]

In the United States, some states allow pharmacists to fill a prescription for an original biologic with a biosimilar that is expected to affect patients the same way if the biosimilar has been approved by the FDA as an interchangeable product. Approval as an interchangeable product generally entails extra studies showing that switching multiple times between the original biologic and a biosimilar does not make the treatment less effective or increase the possible side effects.[2]

If you are switched to a biosimilar, your doctor or pharmacist will usually tell you that a switch is being made. If you have questions about the medicines that are prescribed for you, talk with your health care team.

RELATED QUESTIONS

HOW CAN I FIND OUT IF THERE IS A BIOSIMILAR FOR THE BIOLOGIC I AM TAKING?

HOW CAN I BE SURE A BIOSIMILAR WORKS WELL FOR THE CONDITION I HAVE?

HOW WILL I KNOW IF I AM GETTING A BIOSIMILAR?

ABOUT BIOSIMILARS

BIOSIMILARS VS ORIGINAL BIOLOGICS

HOW BIOSIMILARS ARE GIVEN

WHY BIOSIMILARS

HOW BIOSIMILARS ARE MADE

APPROVAL PROCESS

WHEN BIOSIMILARS ARE PRESCRIBED

TALKING WITH YOUR DOCTOR

INSURANCE ISSUES

1. Barbier L, et al. *Drugs.* 2021;81:1897-1903. **2.** U.S. Food and Drug Administration. Biosimilar Regulatory Review and Approval. https://www.fda.gov/media/151061/download. Accessed November 5, 2021.

HOW COULD BIOSIMILARS LOWER MY DRUG COSTS?

Depending on what your insurance plan covers, you might have a lower co-pay or get reimbursed for more of the cost with a biosimilar.[1]

Your doctor or nurse may be able to refer you to nonprofit organizations or pharmaceutical patient-support programs that can help you understand your insurance plan and what it covers. You can also learn about patient-support programs by visiting the websites for the biosimilar medicines your doctor recommends for you. These programs are staffed by trained specialists who can help you learn if you qualify for lower co-pays or deductibles to help make your medicine more affordable.

RELATED QUESTIONS

HOW CAN I FIND OUT IF A BIOSIMILAR TREATMENT WILL LOWER MY OUT-OF-POCKET DRUG COSTS?

WHAT CAN I DO IF I CANNOT AFFORD THE COST OF MY MEDICINE?

ABOUT BIOSIMILARS

BIOSIMILARS VS ORIGINAL BIOLOGICS

HOW BIOSIMILARS ARE GIVEN

WHY BIOSIMILARS

HOW BIOSIMILARS ARE MADE

APPROVAL PROCESS

WHEN BIOSIMILARS ARE PRESCRIBED

TALKING WITH YOUR DOCTOR

INSURANCE ISSUES

1. U.S. Food and Drug Administration. Biosimilar basics for patients. October 7, 2020. https://www.fda.gov/drugs/biosimilars/patient-materials. Accessed November 2, 2021.

HOW CAN I FIND OUT IF A BIOSIMILAR TREATMENT WILL LOWER MY OUT-OF-POCKET DRUG COSTS?

Check with your insurer to see if a biosimilar treatment is covered or has “preferred status.” Some plans may offer greater savings for biosimilars than for the original biologic drug.

Some manufacturers may have a patient-support program for biosimilar medicines. If one is available, contact them for help understanding your insurance coverage, co-pays, and deductible costs. You may find information about the patient-support program on the website for the biosimilar treatment you are considering.

RELATED QUESTIONS

HOW COULD BIOSIMILARS LOWER MY DRUG COSTS?

WHAT CAN I DO IF I CANNOT AFFORD THE COST OF MY MEDICINE?

ABOUT BIOSIMILARS

BIOSIMILARS VS ORIGINAL BIOLOGICS

HOW BIOSIMILARS ARE GIVEN

WHY BIOSIMILARS

HOW BIOSIMILARS ARE MADE

APPROVAL PROCESS

WHEN BIOSIMILARS ARE PRESCRIBED

TALKING WITH YOUR DOCTOR

INSURANCE ISSUES

WHAT CAN I DO IF I CANNOT AFFORD THE COST OF MY MEDICINE?

If you cannot afford the cost of your medicine, see if you qualify for help from a patient-assistance program sponsored by the pharmaceutical company that makes your treatment. These programs may help you get your medicine for free or at a lower cost.

To find the patient-assistance program for your medicine, visit the website for the medicine your doctor has prescribed for you and look for Support Resources.

You can also use the **Medicine Assistant Tool (MAT)** to search for patient-assistance programs sponsored by pharmaceutical companies and get information about how to pay for your medicines.

RELATED QUESTIONS

HOW CAN I FIND OUT IF A BIOSIMILAR TREATMENT WILL LOWER MY OUT-OF-POCKET DRUG COSTS?

HOW COULD BIOSIMILARS LOWER MY DRUG COSTS?

ABOUT BIOSIMILARS

BIOSIMILARS VS ORIGINAL BIOLOGICS

HOW BIOSIMILARS ARE GIVEN

WHY BIOSIMILARS

HOW BIOSIMILARS ARE MADE

APPROVAL PROCESS

WHEN BIOSIMILARS ARE PRESCRIBED

TALKING WITH YOUR DOCTOR

INSURANCE ISSUES

Bacteria
Tiny living things that have only one cell. Although some kinds of bacteria can cause illness, other bacteria keep us healthy. Bacteria can be used to make proteins in biologic medicines.

Biosimilar
A biologic medicine that is as safe and effective as an original biologic medicine for the medical conditions of the original biologic that it is approved to treat. Biosimilars may offer more treatment options to people with serious or chronic illnesses.

Biologic
A medicine made in living organisms that is used to help prevent, treat, and cure a wide range of diseases and medical conditions.

Cell
The basic building block of living things.

Chronic illness
A long-term health condition that may not have a cure. Chronic illnesses include arthritis, asthma, cancer, Crohn's disease, diabetes, heart disease, and multiple sclerosis.

Clinical studies
Testing done in people to show if a drug is safe and effective for use. Clinical studies can also show if a drug's expected benefits outweigh the possible risks of taking it.

Generic drug
An exact copy of an approved brand-name drug made from chemicals.

Immune reaction
The body's response to a substance, such bacteria, virus, or drug treatment, that appears foreign and harmful to the body.

Injection
A way of giving liquid medicine through a needle, syringe, or a device pre-filled with a single dose, such as a pen or autoinjector. Also called a shot or a jab.

Interchangeable
In the US, it is a term used for a biosimilar that meets certain additional requirements. An interchangeable biosimilar may be substituted for the original biologic by a pharmacist without consulting the prescribing healthcare professional. This pharmacy-level substitution is subject to state pharmacy laws.

IV infusion
Treatment that is given directly into a vein.

Living organism
An animal, plant, or single-cell life form. May be used to make biologic medicines.

Original biologic
An approved biologic medicine to which a biosimilar is compared. Also called the reference product or originator biologic.

Potency
Refers to the amount of a drug needed to have an effect.

Protein
Large molecules that do most of the work in cells and play many different roles in the body.

Purity
Relative absence of extra, unnecessary material.

Reference product
An approved biologic medicine to which a biosimilar is compared. Also called the original biologic or originator biologic.

Self-injection
Giving yourself a dose of a liquid medicine using a syringe, pen, or prefilled device.

Side effect
An unwanted reaction that may be caused by a drug treatment.

Switching
Changing from an original biologic to a biosimilar medicine that is expected to affect patients the same way. May also refer to switching from one biosimilar medicine to another.

Yeast
A one-celled organism that may be used to make biologic medicines.