

Understanding Biosimilars

Essential Information for Health Care Providers



As a health care professional, you are the most trusted source of health information for patients. When they have a new diagnosis or medication, you are the one they want to hear from to better understand their diagnosis, treatment options and their implications. And you are the one who is best positioned to discuss biosimilar medications and their potential implications with patients.

According to an Arthritis Foundation survey, nearly half of patients weren't familiar with biosimilars. That's probably because the only ones available in the U.S. were used in infusions. Now, at least nine biosimilars are available just for [adalimumab](#), which is sold as Humira. While they all are the compound adalimumab, each is sold under a different brand name.

So you can expect to hear from a growing number of patients who may be receiving letters from their insurers informing them that their biologic is no longer covered and they are being switched to a biosimilar. In coming years, as other patents lapse, biosimilars for more originator, or "reference," biologics will be coming on the market.

Here are some points to keep in mind when patients come to you for answers and reassurance:

Clinical Considerations:

- Biosimilars are biologics.
- Biosimilars undergo rigorous trials before receiving FDA approval, and they have been used successfully in this country and others for years. Additional studies also have found that they are as safe and effective as their original biologic.
- Biosimilars have no clinically significant differences from the brand-name, originator biologics. They are as just safe and effective as the original.
- They are administered in the same ways, although the pens and prefilled syringes produced by different companies may look and feel different.
- They have the same benefits, risks and side effects as their originator biologic. That also applied to immunogenicity: If a patient has built up immunity to a biologic, that immunity will persist with its biosimilar.
- Patients will have concerns about safety and potential side effects. You are the right person to assure them that, before starting them on a new biologic or biosimilar, their health care provider will make sure they don't have health conditions

that raise their risk for serious side effects. And it's important to remind patients that, untreated, their arthritis can lead to complications that can be more serious and permanent than the medication side effects.

- Remind patients that — as when starting any new medication — there is some risk of side effects. With biosimilars or any other medication, the patient needs to alert their health care team to any new or changing symptoms, even if they don't think it has anything to do with arthritis.
- In the quarter century since biologics have been used for rheumatic conditions, they have extended people's lives and greatly improved their quality of life. Reassure patients that their health care provider will not prescribe a medication whose risks outweigh the benefits for the patient.

Financial Implications:

The cost of biologics burden many patients. Biosimilars were intended to lower costs, partly through competition, and to make them accessible to more people. Biosimilar manufacturers are providing co-pay cards and other discount programs, but costs to patients are still largely controlled by individual insurance plans.



Patients who take or may start taking biologic medications should understand what their insurance plan does and doesn't cover. If the plan adds a biosimilar to its formulary, the patient may be forced to switch. As a health care provider, you can help educate, prepare and reassure them:

While [biosimilars](#) are shown to be as safe and effective as the originals, there are very slight differences, although the active ingredients are the same. Patients should understand their [insurance](#) appeals process in case the biosimilar doesn't work quite as well for them, and you should be prepared to deal with insurance denials and appeals.

Medicare does not cover self-injectable biologics, and it remains to be seen whether a biosimilar will be covered. Patients receiving a self-injected biologic might switch to an infusion, which is covered under Part D. Patients on [Medicare](#) should closely review that section as well as Part B, which covers prescription medications.

The “Substitution” Challenge:

As a trusted health care provider, you should also be prepared to explain the concept of [“interchangeability”](#) to patients. The FDA may approve a biosimilar as interchangeable with its reference product if it has gone through additional testing, in which patients switch back and forth between the two medications multiple times to ensure the biosimilar is as safe and effective as the reference product.

In states where it is permitted by law, a pharmacist may substitute the original biologic for its biosimilar. While this may raise concerns, the patient can be assured that it has gone through extra rigorous testing — and the ability for a pharmacist to make that switch without adding burden to the medical staff and waiting time for the patient could be a plus.

Effective Patient Communication:

You play a pivotal role in initiating meaningful discussions with patients about biosimilars. Recent focus groups conducted by the Arthritis Foundation shed light on patient knowledge and attitudes about biosimilars. Health care providers — including doctors, nurse practitioners and physician assistants — are by far the top preferred source of information for new treatments.

Most patients have at least some knowledge of biologics — especially those on private insurance rather than Medicare — but only about half said they were familiar

with biosimilars. And while biologic-naïve patients were most interested in safety and efficacy, biologic-experienced patients were more concerned with details, like the formulation and administration of biosimilars, cost impacts and immunogenicity.

Patients prefer in-person discussions, but also rely on other forms of communication, including emails, portals and web resources. Here are recommended steps:

Education: Educate patients on fundamental biosimilar concepts, emphasizing their similarity to reference products and clinical relevance.

Address Concerns: Encourage patients to voice their concerns and questions. Provide concise, clear information to alleviate uncertainties.

Resource Referral: Direct patients to reputable information sources, including our website, [arthritis.org](#) and [arthritis.org/biosimilars](#), and our [Helpline](#) at 1-800-283-7800.

Insurance Guidance: Offer guidance on navigating insurance-related changes and accessing potential cost-saving opportunities through biosimilars. Inform patients about available manufacturer discount coupons, accessible via platforms like [goodrx.com](#). For Medicare beneficiaries, review Part B and Part D to determine applicability to their biologic or biosimilar.

Collaborative Care: Emphasize the significance of open communication lines. Patients should feel comfortable discussing medication changes, including substitutions, with you, and make sure they know the best way to contact you and others on their health care team with additional questions or concerns between visits.

Health care providers like you are key to empowering patients with knowledge and confidence, and facilitating informed decision-making regarding biosimilars, ultimately enhancing the quality of patient care. Find more resources to help your patients at [arthritis.org/health-care-provider](#).