

Biologics & Biosimilars in Rheumatology



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Biologic drugs, including biosimilars, are increasing the number of effective treatments for rheumatic diseases.

Biologics are derived from living organisms, such as microorganisms or human tissue. And the number of these drugs available to patients has increased exponentially in recent decades. Today, biologics are used to treat a range of conditions, including chronic illnesses such as cancers, multiple sclerosis and rheumatic diseases.

Now patients also benefit from an expanding number of biosimilar drugs. These medications have comparable molecules to original biologics, have been similarly produced, and have undergone equivalent monitoring and quality assurance. FDA-approved biosimilars are “highly similar” to and have “no clinically meaningful differences” from the reference biologic they resemble.¹

Though subtle, the differences between biosimilars and their reference biologics can create challenges for health care providers, who must navigate the growing range of products and educate their patients about them. These distinctions can also make policymaking and regulation difficult.



Treating Rheumatology Patients

Biologics and biosimilars are increasingly important for treating rheumatic diseases — autoimmune and inflammatory conditions that cause a patient's immune system to attack their joints, muscles, bones and organs. If left untreated, rheumatic diseases can cause damage to vital organs. They also may result in severe conditions that make daily tasks like dressing, bathing and walking difficult or even impossible.²

Alongside physicians and nurse practitioners, registered nurses play a critical role in managing

rheumatic diseases. They're instrumental in developing individual plans of care for patients to manage pain, improve function and maximize independence. They also provide patient education, strengthen coping strategies and improve access to resources.³

In short, nurses are often the health care providers most closely connected to rheumatology patients, so they are essential in educating patients about their treatment options, including biologics and biosimilars.

Opportunities for Patient-Centered Care

For rheumatology patients, biologics and biosimilars provide additional choices for a treatment plan. Patients not finding relief from one medication may look to another as an alternative. Because rheumatic diseases are typically degenerative, quick access to an effective alternative can save precious time in a patient's overall course of treatment.⁴

Increasing access to biosimilars can also help lower prescription drug costs. One study found that expanding the use of biosimilars to treat serious illnesses like cancer or autoimmune diseases could reduce a patient's out-of-pocket costs by 17%.⁵

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Educating Patients & Health Care Providers about Biosimilars

When biosimilars for rheumatic diseases first came to market, questions about the efficacy and rigor of clinical trials for biosimilars slowed uptake, as did general unfamiliarity. With the help of information provided by manufacturers, as well as educational resources from the U.S. Food and Drug Administration, biosimilars are becoming more of a known quantity.

But even now, patients often have questions about biosimilars. Efficacy and cost questions often emerge in those conversations, which can be delicate.

Patients want assurance that the biosimilar will offer equal clinical benefit to them. They also want to understand if another party — the health care provider, the practice or the insurance company,

for example — will benefit financially from the patient taking a biosimilar as opposed to the originator biologic medication.

For health care practices, the goal is to equip nurses with concise but thorough information. As the frontline of patient education, nurses must be able to speak intelligently and clearly on the issue of biologics and biosimilars, but without overwhelming patients.

As interchangeable biosimilars enter the market, the need for education will grow. This new category of biosimilars, which can be interchanged without the prescribing clinician's knowledge, may prove a challenge to communicate.

Insurance Coverage Challenges

Conversations about biosimilars typically arise because of insurance coverage barriers or switching.

Health plans often organize prescription drugs into coverage tiers, assigning cost sharing that incentivizes patients to use the drug preferred by the insurer. They may also use prior authorization or step therapy to dissuade patients from using non-preferred medications. With prior authorization, patients and their health care providers must complete paperwork to obtain the insurer's permission to use a specific medication.

The process can be onerous and time consuming. With step therapy, the insurer requires that a patient try and fail on the insurer-preferred medication before gaining coverage for the treatment prescribed by their health care provider.

Even after a patient is established on a medication, insurers can still disrupt their treatment regimen. When a patient's treatment is changed for reasons other than efficacy, side effects or adherence, and is most likely related to their insurers' efforts to maximize profits, the practice is known as "non-medical switching."⁶

Biosimilars & Non-Medical Switching

A rise in switching or utilization management that drives patients to biosimilars has coincided with an increase in patients switching insurances during the COVID-19 pandemic.

As a result, nurses sometimes spend an inordinate amount of their workday dealing with a backlog in the prior authorization process, re-verifying benefits and re-authorizing prescriptions. They also bear the responsibility of talking patients through the switches initiated by their insurer and answering their questions.

As one example of widespread switching practices, one of South Carolina's largest insurers unexpectedly changed its formulary mid-year in 2021. This switch moved affected patients from the widely prescribed rheumatology reference

drug infliximab to a biosimilar. Patients received letters about the switch just weeks before it took effect, leaving nurses to absorb the sudden and significant administrative burden all at once.

Rheumatology nurses agree that it is important to communicate proactively in such situations. The first time that patients hear about a switch in their drug should not be when they come in for their regular infusion. Many nurses will try to call them ahead of time to prevent the surprise and carefully explain what a biosimilar is and how it works.

Some patients moving from an originator biologic to an alternative biosimilar do experience a difference, but it can be difficult to reverse the insurer's decision.



The prior authorization process can be onerous and **time consuming.**

Giving Patients Choices

Biosimilars were developed to give patients more choices, not force them into a non-medical switch. Too often, however, more options end up meaning insurance companies can just mandate different drugs.

The patient rarely has a choice. Providers may have an option, for example, to prescribe a TNF or drug with a different mechanism of action. But within the treatment class, decisions about which specific drug is used typically fall to the insurer.

The insurer's position is not always supported by the science or expertise. Many biosimilars are not considered interchangeable, yet an insurance company may treat them as if they are. Though pharmacists cannot switch drugs, insurers — who are not health care professionals of any variety — can do so with impunity.

Conclusion

As more biosimilars make their way into the health care system, there will be an even greater need for information and education — for both health care providers and their patients.

There will also be an enhanced need to return to a patient-centered form of care, where treatment selection resides with a health care provider who knows and treats a patient directly, rather than falling to insurers and their profit-driven decisions.

If used properly, biosimilars — like biologics before them — can benefit both health care providers and patients by providing more opportunities to customize care and improve quality of life for rheumatology patients.



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