

Biosimilar drugs are cheaper than biologics. Are they similar enough to switch?

September 27 2021, by Michelle Andrews



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It took years for Elle Moxley to get a diagnosis that explained her crippling gastrointestinal pain, digestion problems, fatigue, and hot, red rashes. And after learning in 2016 that she had Crohn's disease, a chronic inflammation of the digestive tract, she spent more than four years trying medications before getting her disease under control with a

biologic drug called Remicade.

So Moxley, 33, was dismayed to receive a notice from her insurer in January that Remicade would no longer be covered as a [preferred drug](#) on her plan. Another drug, Inflectra, which the Food and Drug Administration says has no meaningful clinical differences from Remicade, is now preferred. It is a "biosimilar" drug.

"I felt very powerless," said Moxley, who recently started a job as a public relations coordinator for Kansas City Public Schools in Missouri. "I have this decision being made for me and my doctor that's not in my best interest, and it might knock me out of remission."

After Moxley's first Inflectra infusion in July, she developed a painful rash. It went away after a few days, but she said she continues to feel extremely fatigued and experiences gastrointestinal pain, constipation, diarrhea and nausea.

Many [medical professionals](#) look to biosimilar drugs as a way to increase competition and give consumers cheaper options, much as [generic drugs](#) do, and they point to the more robust use of these products in Europe to cut costs.

Yet the U.S. has been slower to adopt biosimilar drugs since the first such medicine was approved in 2015. That's partly because of concerns raised by [patients](#) like Moxley and their doctors, but also because brand-name biologics have kept biosimilars from entering the market. The companies behind the brand-name drugs have used legal actions to extend the life of their patents and incentives that make offering the brand biologic more attractive than offering a biosimilar on a formulary, listing which drugs are covered on an insurance plan.

"It distorts the market and makes it so that patients can't get access," said

Dr. Jinoos Yazdany, a professor of medicine and chief of the rheumatology division at Zuckerberg San Francisco General Hospital.

The FDA has approved 31 biosimilar medications since 2015, but only about 60% have made it to market, according to an analysis by NORC, a research organization at the University of Chicago.

Remicade's manufacturer, Johnson & Johnson, and Pfizer, which makes the Remicade biosimilar Inflectra, have been embroiled in a long-running lawsuit over Pfizer's claims that Johnson & Johnson tried to choke off competition through exclusionary contracts with insurers and other anti-competitive actions. In July, the companies settled the case on undisclosed terms.

In a statement, Pfizer said it would continue to sell Inflectra in the U.S. but noted ongoing challenges: "Pfizer has begun to see progress in the overall biosimilars marketplace in the U.S. However, changes in policy at a government level and acceptance of biosimilars among key stakeholders are critical to deliver more meaningful uptake so patients and the healthcare system at-large can benefit from the cost savings these medicines may deliver."

Johnson & Johnson said it is committed to making Remicade available to patients who choose it, which "compels us to compete responsibly on both price and value."

Biologic medicines, which are generally grown from living organisms such as animal cells or bacteria, are more complex and expensive to manufacture than drugs made from chemicals. In recent years, biologic drugs have become a mainstay of treatment for autoimmune conditions like Crohn's disease and rheumatoid arthritis, as well as certain cancers and diabetes, among other conditions.

Other drugmakers can't exactly reproduce these biologic drugs by following chemical recipes as they do for generic versions of conventional drugs.

Instead, biosimilar versions of [biologic drugs](#) are generally made from the same types of materials as the original biologics and must be "highly similar" to them to be approved by the FDA. They must have no clinically meaningful differences from the biologic drug, and be just as safe, pure and potent. More than a decade after Congress created an approval pathway for biosimilars, they are widely accepted as safe and effective alternatives to brand biologics.

Medical experts hope that as biosimilars become more widely used they will increasingly provide a brake on drug spending.

From 2015 to 2019, drug spending overall grew 6.1%, while spending on biologics grew more than twice as much—14.6%—according to a report by IQVIA, a health care analytics company. In 2019, biologics accounted for 43% of drug spending in the U.S.

Biosimilars provide a roughly 30% discount over brand biologics in the U.S. but have the potential to reduce spending by more than \$100 billion in the next five years, the IQVIA analysis found.

In a survey of 602 physicians who prescribe biologic medications, more than three-quarters said they believed biosimilars are just as safe and effective as their biologic counterparts, according to NORC.

But they were less comfortable with switching patients from a brand biologic to a biosimilar. While about half said they were very likely to prescribe a biosimilar to a patient just starting biologic therapy, only 31% said they were very likely to prescribe a biosimilar to a patient already doing well on a brand biologic.

It can be challenging to find a treatment regimen that works for patients with complicated chronic conditions, and physicians and patients often don't want to rock the boat once that is achieved.

In Moxley's case, for example, before her condition stabilized on Remicade, she tried a conventional pill called Lialda, the biologic drug Humira and a lower dose of Remicade.

Some doctors and patients raise concerns that switching between these drugs might cause patients to develop antibodies that cause the drugs to lose effectiveness. They want to see more research about the effects of such switches.

"We haven't seen enough studies about patients going from the biologic to the biosimilar and bouncing back and forth," said Dr. Marcus Snow, chair of the American College of Rheumatology's Committee on Rheumatologic Care. "We don't want our patients to be guinea pigs."

Manufacturers of biologic and biosimilar drugs have participated in advertising, exhibit or sponsorship opportunities with the American College of Rheumatology, according to ACR spokesperson Jocelyn Givens.

But studies show a one-time switch from Remicade to a biosimilar like Inflectra does not cause side effects or the development of antibodies, said Dr. Ross Maltz, a pediatric gastroenterologist at Nationwide Children's Hospital in Columbus, Ohio, and former member of the Crohn's & Colitis Foundation's National Scientific Advisory Committee. Studies may be conducted by researchers with extensive ties to the industry and funded by drugmakers.

Situations like Moxley's are unusual, said Kristine Grow, senior vice president of communications at AHIP, an insurer trade group.

"For patients who have been taking a brand-name biologic for some time, health insurance providers do not typically encourage them to switch to a biosimilar because of a formulary change, and most plans exclude these patients from any changes in cost sharing due to formulary changes," she said.

Drugmakers can seek approval from the FDA of their biosimilar as interchangeable with a biologic drug, allowing pharmacists, subject to state law, to switch a physician's prescription from the brand drug, as they often do with generic drugs.

However, the FDA has approved only one biosimilar (Semglee, a form of insulin) as interchangeable with a biologic (Lantus).

Like Moxley, many other patients using biologics get copay assistance from [drug](#) companies, but the money often isn't enough to cover the full cost. In her old job as a radio reporter, Moxley said, she hit the \$7,000 maximum annual out-of-pocket spending limit for her plan by May.

In her new job, Moxley has an individual plan with a \$4,000 maximum out-of-pocket limit, which she expects to blow past once again within months.

But she received good news recently: Her new plan will cover Remicade.

"I'm still concerned that I will have developed antibodies since my last dose," she said. "But it feels like a step in the direction of good health again."

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Citation: Biosimilar drugs are cheaper than biologics. Are they similar enough to switch? (2021,

September 27) retrieved 26 April 2024 from <https://medicalxpress.com/news/2021-09-biosimilar-drugs-cheaper-biologics-similar.html>

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