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# Specialists Are 'Underwater' With Some Insurance-Preferred Biosimilars

**Publish date:** May 16, 2024

By Madelaine (Mattie) A. Feldman, MD

Rheumatology News

IN COLLABORATION WITH CSRO

*Editor's note: This article is adapted from an explanatory statement that Dr. Feldman wrote for the Coalition of State Rheumatology Organizations (CSRO).*

According to the Guinness Book of World records, the longest time someone has held their breath underwater voluntarily is 24 minutes and 37.36 seconds. While certainly an amazing feat, UnitedHealthcare, many of the Blues, and other national "payers" are expecting rheumatologists and other specialists to live "underwater" in order to take care of their patients. In other words, these insurance companies are mandating that specialists use certain provider-administered biosimilars whose acquisition cost is higher than what the insurance company is willing to reimburse them. Essentially, the insurance companies expect the rheumatologists to pay them to take care of their patients. Because of the substantial and destabilizing financial losses incurred, many practices and free-standing infusion centers have been forced to cease offering these biosimilars. Most rheumatologists will provide patients with appropriate alternatives when available and permitted by the insurer; otherwise, they must refer patients to hospital-based infusion centers. That results in delayed care and increased costs for patients and the system, because hospital-based infusion typically costs more than twice what office-based infusion costs.

## Quantifying the Problem

To help quantify the magnitude of this issue, the Coalition of State Rheumatology Organizations (CSRO) recently conducted a survey of its membership. A shocking 97% of respondents reported that their practice had been affected by reimbursement rates for some biosimilars being lower than acquisition costs, with 91% of respondents stating that this issue is more pronounced for certain biosimilars than others. Across the board, respondents most frequently identified Inflectra (infliximab-dyyb) and Avsola (infliximab-axxq) as being especially affected: Over 88% and over 85% of respondents identified these two products, respectively, as being underwater. These results support the ongoing anecdotal reports CSRO continues to receive from rheumatology practices.

However, the survey results indicated that this issue is by no means confined to those two biosimilars. Truxima (rituximab-abbs) — a biosimilar for Rituxan — was frequently mentioned as well. Notably, respondents almost uniformly identified biosimilars in the infliximab and rituximab families, which illustrates that this issue is no longer confined to one or two early-to-market biosimilars but has almost become a hallmark of this particular biosimilars market. Remarkably, one respondent commented that the brand products are now cheaper to acquire than the biosimilars. Furthermore, the survey included respondents from across the country, indicating that this issue is not confined to a particular region.

## How Did This Happen?

Biosimilars held promise for increasing availability and decreasing biologic costs for patients but, thus far, no patients have seen their cost go down. It appears that the only biosimilars that have made it to "preferred" status on the formulary are the ones that have made more money for the middlemen in the drug supply chain, particularly those that construct formularies. Now, we have provider-administered biosimilars whose acquisition cost exceeds the reimbursement for these drugs. This disparity was ultimately created by biosimilar manufacturers "over-rebating" their drugs to health insurance companies to gain "fail-first" status on the formulary.

For example, the manufacturer of Inflectra offered substantial rebates to health insurers for preferred formulary placement. These rebates are factored into the sales price of the medication, which then results in a rapidly declining average sales price (ASP) for the biosimilar. Unfortunately, the acquisition cost for the drug does not experience commensurate reductions, resulting in physicians being reimbursed far less for the drug than it costs to acquire. The financial losses for physicians put them underwater as a result of the acquisition costs for the preferred drugs far surpassing the reimbursement from the health insurance company that constructed the formulary.

While various factors affect ASPs and acquisition costs, this particular consequence of formulary placement based on price concessions is a major driver of the underwater situation in which physicians have found themselves with many biosimilars. Not only does

that lead to a lower uptake of biosimilars, but it also results in patients being referred to the hospital outpatient infusion sites to receive this care, as freestanding infusion centers cannot treat these patients either. Hospitals incur higher costs because of facility fees and elevated rates, and this makes private rheumatology in-office infusion centers a much lower-cost option. Similarly, home infusion services, while convenient, are marginally more expensive than private practices and, in cases of biologic infusions, it is important to note that physicians' offices have a greater safety profile than home infusion of biologics. The overall result of these "fail-first underwater drugs" is delayed and more costly care for the patient and the "system," particularly self-insured employers.

## What Is Being Done to Correct This?

Since ASPs are updated quarterly, it is possible that acquisition costs and reimbursements might stabilize over time, making the drugs affordable again to practices. However, that does not appear to be happening in the near future, so that possibility does not offer immediate relief to struggling practices. It doesn't promise a favorable outlook for future biosimilar entries of provider-administered medications if formularies continue to prefer the highest-rebated medication.

This dynamic between ASP and acquisition cost does not happen on the pharmacy side because the price concessions on specific drug rebates and fees are proprietary. There appears to be no equivalent to a publicly known ASP on the pharmacy side, which has led to myriad pricing definitions and manipulation on the pharmacy benefit side of medications. In any event, the savings from rebates and other manufacturer price concessions on pharmacy drugs do not influence ASPs of medical benefit drugs.

The Inflation Reduction Act provided a temporary increase in the add-on payment for biosimilars from ASP+6% to ASP+8%, but as long as the biosimilar's ASP is lower than the reference brand's ASP, that temporary increase does not appear to make up for the large differential between ASP and acquisition cost. It should be noted that any federal attempt to artificially lower the ASP of a provider-administered drug without a pathway assuring that the acquisition cost for the provider is less than the reimbursement is going to result in loss of access for patients to those medications and/or higher hospital site of care costs.

## A Few Partial Fixes, But Most Complaints Go Ignored

Considering the higher costs of hospital-based infusion, insurers should be motivated to keep patients within private practices. Perhaps through insurers' recognition of that fact, some practices have successfully negotiated exceptions for specific patients by discussing this situation with insurers. From the feedback that CSRO has received from rheumatology practices, it appears that most insurers have been ignoring the complaints from physicians. The few who have responded have resulted in only partial fixes, with some of the biosimilars still left underwater.

## Ultimate Solution?

This issue is a direct result of the "rebate game," whereby price concessions from drug manufacturers drive formulary placement. For provider-administered medications, this results in an artificially lowered ASP, not as a consequence of free-market incentives that benefit the patient, but as a result of misaligned incentives created by Safe Harbor–protected "kickbacks," distorting the free market and paradoxically reducing access to these medications, delaying care, and increasing prices for patients and the healthcare system.

While federal and state governments are not likely to address this particular situation in the biosimilars market, CSRO is highlighting this issue as a prime example of why the current formulary construction system urgently requires federal reform. At this time, the biosimilars most affected are Inflectra and Avsola, but if nothing changes, more and more biosimilars will fall victim to the short-sighted pricing strategy of aggressive rebating to gain formulary position, with physician purchasers and patients left to navigate the aftermath. The existing system, which necessitates drug companies purchasing formulary access from pharmacy benefit managers, has led to delayed and even denied patient access to certain provider-administered drugs. Moreover, it now appears to be hindering the adoption of biosimilars.

To address this, a multifaceted approach is required. It not only involves reevaluating the rebate system and its impact on formulary construction and ASP, but also ensuring that acquisition costs for providers are aligned with reimbursement rates. Insurers must recognize the economic and clinical value of maintaining infusions within private practices and immediately update their policies to ensure that physician in-office infusion is financially feasible for these "fail-first" biosimilars.

Ultimately, the goal should be to create a sustainable model that promotes the use of affordable biosimilars, enhances patient access to affordable care, and supports the financial viability of medical practices. Concerted efforts to reform the current formulary construction system are required to achieve a healthcare environment that is both cost effective and patient centric.

*Dr. Feldman is a rheumatologist in private practice with The Rheumatology Group in New Orleans. She is the CSRO's vice president of advocacy and government affairs and its immediate past president, as well as past chair of the Alliance for Safe Biologic Medicines and a past member of the American College of Rheumatology insurance subcommittee. You can reach her at rhnews@mdedge.com.*