Explanatory Statement: "Underwater" Biosimilars

Introduction

The Coalition of State Rheumatology Organizations (CSRO) continues to receive reports from practices nationwide about the financial challenges posed by certain biosimilars for which acquisition costs exceed reimbursement levels. This problem was first noted with Inflectra® (infliximab-dyyb), a biosimilar for Remicade®, but has now extended to Avsola® (infliximab-axxq), another Remicade® biosimilar, as well as several Rituxan® (rituximab) biosimilars. Due to the substantial and destabilizing financial losses incurred, some practices have been forced to cease offering these biosimilars. Rheumatologists will provide patients with appropriate alternatives if 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, 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® and Avsola® 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® – 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.

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How did this happen?

Biosimilars hold promise for reducing healthcare costs and increasing patient access to biologic therapies but, thus far, reality has fallen short of that promise. Although there may be many factors contributing to the low uptake and high patients costs of biosimilars, one key factor for several biosimilars administered in-office is that the acquisition cost exceeds the reimbursement for these drugs. This disparity creates immediate financial strain on rheumatology practices and leads to an unsustainable financial situation in the long run.

The competition among drug manufacturers for favorable preferred formulary placement plays an important role in this issue. For example, the manufacturer of Inflectra offered substantial rebates to pharmacy benefit managers (PBMs) and insurers for "fail-first" 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 cost 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, 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 due to facility fees and elevated rates, so private rheumatology in-office infusion centers are a much lower-cost option than hospitals infusion centers. 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," including 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. Nor does it promise a favorable outlook for future biosimilar entries of provider-administered medications if formularies continue to prefer the highest rebated medication. As a side note, this dynamic 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 of 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.

Although the *Inflation Reduction Act* provided a temporary increase in the add-on payment for biosimilars from ASP+6% to ASP+8%, so long as the biosimilar's ASP is lower than the reference brand's, that does not appear to make up for the large differential between ASP and acquisition cost on these underwater biosimilars. 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.

In fact, many practices have stopped offering the biosimilar mentioned as examples herein due to significant financial losses. These practices have sought alternatives for patients based on insurer approval or have directed them to hospital-based infusion centers when necessary. 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 one of the biosimilars still left underwater.

Some insurers encourage stopgap mechanisms such as white bagging, where medications are shipped directly to the clinic from a pharmacy. While intended to reduce costs, white bagging presents financial and logistical challenges for rheumatology practices. The protracted supply chain increases the risk of medication spoilage or contamination, compromising patient safety and practice efficiency. Thus, that does not offer a viable solution to this particular issue of biosimilars' acquisition costs exceeding reimbursement – and may even carry risk to patients.

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 PBMs, 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.

Conclusion

The challenges faced by private practices in administering certain preferred biosimilars, primarily due to the disparity between acquisition costs and reimbursement levels, underscore a systemic problem within the healthcare industry. The current rebate system has driven biosimilars with the highest price concessions for the PBM to preferred ("fail first") formulary placement. That then rapidly lowers the ASP of these drugs to the point where physicians are financially "underwater" and can no longer afford to administer these medications. This has resulted in an increased reliance on hospital-based infusion centers (if available), which paradoxically contributes to higher overall healthcare costs for patients and self-insured employers.

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 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. Ultimately, concerted efforts to reform the current formulary construction system are required to achieve a healthcare environment that is both cost-effective and patient-centric.