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PERSPECTIVES

Biosimilar Business Deals Keep Up 'Musical Chairs' Game of Formulary Construction

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IN COLLABORATION WITH CSRO

As the saying goes, "The more things change, the more they stay the same." That is particularly true when it comes to the affordability of drugs for our patients even after the launch of so many Humira biosimilars. And we still have the "musical chairs" game of formulary construction — when the music stops, who knows whether your patient's drug found a chair to sit on. There seems to be only a few chairs available for the many adalimumab biosimilars playing the game.

Nothing has changed since my testimony before the FDA Arthritis Advisory Committee in July 2016 during the approval hearing of the first Humira biosimilar. Below is a quote from that meeting where I was speaking predominantly about the pharmacy side of drugs.

"I'd like to highlight the term 'access' because none of us are really naive enough to believe that just approving a biosimilar gives a patient true, hands-on access to the medication, because even if the biosimilar is offered at a 30% discount, I don't have any patients that can afford it. This means that access is ultimately controlled by third-party payers."

My prediction, that approving and launching biosimilars with lower prices would not ensure patient access to the drug unless it is paid for by insurance, is now our reality. Today, a drug with an 85% discount on the price of Humira is still unattainable for patients without a "payer."

Competition and Lower Prices

Lawmakers and some in the media cry for more competition to lower prices. This is the main reason that there has been such a push to get biosimilars to the market as quickly as possible. It is abundantly clear that competition to get on the formulary is fierce. Placement of a medication on a formulary can make or break a manufacturer's ability to

get a return on the R&D and make a profit on that medication. For a small biotech manufacturer, it can be the difference between "life and death" of the company.

Does anyone remember when the first interchangeable biosimilar for the reference insulin glargine product Lantus (insulin glargine-yfgn; Semglee) came to market in 2021? Janet Woodcock, MD, then acting FDA commissioner, called it a "momentous day" and further said, "Today's approval of the first interchangeable biosimilar product furthers FDA's longstanding commitment to support a competitive marketplace for biological products and ultimately empowers patients by helping to increase access to safe, effective and high-quality medications at potentially lower cost." There was a high-priced interchangeable biosimilar and an identical unbranded low-priced interchangeable biosimilar, and the only one that could get formulary placement was the high-priced drug.

Patients pay their cost share on the list price of the drug, and because most pharmacy benefit managers' (PBMs') formularies cover only the high-priced biosimilar, patients never share in the savings. So much for the "competitive marketplace" creating lower costs for patients. This is just one of hundreds of examples in which lower-priced drugs are excluded from the formulary. It is unfortunate that the bidding process from manufacturers to PBMs to "win" preferred formulary placement is like an art auction, where the highest bidder wins.

Biosimilars and Formulary Construction

For those of us who have been looking into PBMs for many years, it is no surprise that PBMs' formulary construction has become a profit center for them. Now, with so many adalimumab biosimilars having entered the market, it has become the Wild West where only those with the most money to fork over to the PBMs get preferred placement. Unfortunately, many of the choices that make money for the PBM cost employers and patients more.

How did we get here? In the 1980s and 90s, the price of medications began to increase to the point that many were not affordable without insurance. And who better to construct the list of drugs that would be covered by insurance (formulary) than the PBMs who were already adjudicating the claims for these drugs. The Federal Trade Commission (FTC) realized the power inherent in constructing this list of medications known as the formulary. So when the manufacturer Merck acquired the PBM Medco in the mid-1990s, the FTC stepped in. The FTC surmised that making the drugs and deciding which ones will be paid for created a "conflict of interest" with anticompetitive ramifications.

So, in 1998, William J. Baer, director of the FTC's Bureau of Competition, said, "Our investigation into the PBM industry has revealed that Merck's acquisition of Medco has reduced competition in the market for pharmaceutical products … We have found that Medco has given favorable treatment to Merck drugs. As a result, in some cases, consumers have been denied access to the drugs of competing manufacturers. In addition,

the merger has made it possible for Medco to share with Merck sensitive pricing information it gets from Merck's competitors, which could foster collusion among drug manufacturers." Wow!

These anticompetitive behaviors and conflicts of interest resulting from the Medco acquisition led the FTC to propose a consent agreement.

The agreement would require Merck-Medco to maintain an "open formulary" — one that includes drugs selected and approved by an independent Pharmacy and Therapeutics Committee regardless of the manufacturer. Medco would have to accept rebates and other price concessions and reflect these in the ranking of the drugs on the formulary. Merck would have to make known the availability of the open formulary to any drug maker with an agreement with Medco.

Let's hope the FTC of 2024 remembers the stance of the FTC in the 1990s regarding anticompetitive behavior involved in formulary construction.

Conflicts of Interest

But today it is apparent that crafting formularies that pay only for the drugs that make the most money for the PBM is not a conflict of interest. In its policy manual, Cigna directly tells employers and employees that they are collecting and keeping rebates and fees on medical pharmaceuticals, and they are not for the benefit of the employer or the plan.

And now, in August 2023, CVS launched Cordavis, a subsidiary wholly owned by CVS. Cordavis/CVS has partnered with Sandoz, which makes Hyrimoz, an adalimumab biosimilar. There is a high-priced version that is discounted 5% from Humira, a lower-cost unbranded version that is discounted 80% off the list price of Humira, and a co-branded CVS/Sandoz version of Hyrimoz that is lower priced as well.

It isn't a surprise that CVS' Standard and Advanced Commercial and Chart formularies are offering only Sandoz adalimumab biosimilar products. While these formularies have excluded Humira, CVS has entered into an agreement with AbbVie to allow Humira on a number of their other formularies. It can be very confusing.

As stated earlier, in the 1990s, the FTC frowned upon manufacturers owning PBMs and allowing them to construct their own formularies. Here we have CVS Health, mothership for the PBM CVS Caremark, owning a company that will be co-producing biosimilars with other manufacturers and then determining which biosimilars are on their formularies. The FTC knew back then that the tendency would be to offer only their own drugs for coverage, thus reducing competition. This is exactly what the CVS-Cordavis-Sandoz partnership has done for their Standard and Advanced Commercial and Chart formularies. It is perhaps anti-competitive but certainly profitable.

Perhaps the FTC should require the same consent agreement that was given to Merck in 1998. CVS Caremark would then have to open their formularies to all competitors of their co-branded, co-produced Sandoz biosimilar.

Summary

It is the same old adage, "The more things change, the more they stay the same." PBMs are still constructing formularies with biosimilars based on their profitability, with huge differences between gross and net cost. Patients still pay their cost share on the list (gross) price. With the CVS-Cordavis-Sandoz partnership, more vertical integration has led to yet another profit river. Self-funded employers are still getting the wool pulled over their eyes by the big three PBMs who threaten to take away rebates if they don't choose the preferred formularies. The employers don't realize that sometimes it is less expensive to choose the lower-priced drugs with no rebates, and that holds true for biosimilars as well.

Let's hope that the FTC investigates the situation of a PBM partnering with a manufacturer and then choosing only that manufacturer's drugs for many of their formularies.

We need to continue our advocacy for our patients because the medication that has kept them stable for so long may find itself without a chair the next time the music stops.

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