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5 things payers need to know about the looming biosimilars boom

Since the first biosimilar launched in 2015,[1] the market has grown steadily. Over the past 7 years, the number of biosimilars has increased by almost 12% annually, despite fierce efforts by pharmaceutical companies to protect their brand-name market share. Now, after years of anticipation, biosimilars are gearing up for a game-changing 2023 as market exclusivity ends for Humira®, one of the top-selling drugs of all time.[2]

While hurdles remain, a shifting landscape and robust pipeline mean these emerging therapies are poised to finally deliver on their promise of expanding choice, improving access and increasing affordability. Here are 5 things payers need to know as they brace for the boom.

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1 The end of Humira's originator patent will change everything

Right now, 7 FDA-approved adalimumab biosimilars are waiting to hit the U.S. market. The first, Amgen's Amjevita, is expected to enter in January 2023, and as many as 10 could debut by the end of next year.[3] The impact of this change can't be overstated. Humira, AbbVie's rheumatoid arthritis and anti-inflammatory biologic, generated $20.7 billion in sales in 2021 — topped only by Pfizer's COVID-19 vaccine — and is the second-best selling drug ever.[4]

As a result, these biosimilars' long-awaited debut will have a major impact on U.S. health care. They will likely cost about half of the name-brand biologic, which runs $84,000 annually.[5] In fact, adalimumab biosimilars could generate $19.3 billion in savings by 2025, or 50% of the total savings expected from all biosimilars between 2021 and 2025.[6]

More than a dozen other blockbuster molecules are also going to lose exclusivity between 2020 and 2025, with annual peak sales of $60 billion.[7] Another standout — Janssen's immunosuppressive psoriasis biologic Stelara® — loses its main patent in September 2023, and is likewise already priming the biosimilar pipeline.[8] As U.S. prescribers and patients become more familiar with biosimilars, general uptake will continue to increase and more players will enter the market.

2 Regulators seem on board with the boom

Biosimilars received a serious Medicare boost from the recently passed Inflation Reduction Act. Under the new law, for the next 5 years, eligible biosimilars will earn Medicare reimbursement of the biological reference products' average sales price plus 8%, instead of 6%.[9]

The move is an effort to support biosimilar production to drive down health care costs. And it follows an earlier 2022 report from the Office of the Inspector General recommending biosimilar support to "significantly" reduce Medicare Part D spending.[10]

3 Interchangeability will remain a hot topic

Though approved biosimilars must demonstrate no clinically meaningful difference from the specialty drugs they reference, receiving FDA approval does not allow these drugs to be swapped for a reference drug at the pharmacy level. To be considered interchangeable, these therapies must receive another specific FDA greenlight — and to date, the FDA has only approved interchangeability for 2 biosimilars, Semglee (biosimilar to Lantus)[11] and Cyltezo (biosimilar to Humira).[12] As a result, the U.S. has 2 classes of biosimilars, which has shaken confidence in their overall safety and efficacy while slowing adoption.

In Europe, medical regulators recently clarified the topic by issuing guidance that makes biosimilars broadly interchangeable with their reference products.[13] And in the U.S., the drumbeat for eliminating regulatory interchangeability hurdles has intensified[14,15] as biosimilars pick up steam around the globe.

Payers are closely watching the regulatory landscape, but they also understand that interchangeability concerns don't end there. While payers must constantly seek to control costs, decisions to include a biosimilar in its formulary encompass a nuanced view of quality and overall value, not the price alone.[16] Biosimilars must prove not just product quality, but manufacturer reliability and supply chain consistency. Payers must also consider provider and patient education, which is key to successful adoption, as well as the need to help patients smoothly transition from a reference drug to a new biosimilar.

4 Pregnancy is a special consideration

In the past, medical experts have been concerned about potential neonatal immune suppression if women continue drug therapy during pregnancy. Recent research, however, is clear that use of these drugs does not impact a fetus' immune response.[17] Moreover, uncontrolled autoimmune disorders can spike the risk of pregnancy loss, premature birth and cesarean delivery,[18] while stopping treatment during pregnancy may cause a disease flare or allow antibodies to develop, leading to a decreased response when the drug is resumed.

In fact, while medical experts have been concerned about potential neonatal immune suppression, researchers at University College London Hospital showed that not only did using anti-rheumatic biosimilars during pregnancy create no harmful outcomes for infants, but also that disease flareups caused by treatment cessation are a legitimate concern.[19] These results were consistent with outcomes reported in studies of reference drugs in pregnant women.

But while research is beginning to confirm the safety of biosimilars during pregnancy, the risks and benefits of switching from a biologic to a biosimilar has not been studied extensively in pregnant and breastfeeding individuals, and the impact of the minute differences between a biosimilar and a biologic on this population remains unknown.

Concerns exist over whether switching would create a loss of efficacy of the new drug in treating the disease. This, in turn, could cause a flare, which would increase risk of complications. Similar concerns exist about switching treatment while breastfeeding. If a patient is stable on current medication, stopping or switching the drug can induce a flare, increase an inflammatory response and impede the production of breast milk.[20]

As the push for interchangeability continues, payers should watch for additional research on the impact switching to biosimilars during pregnancy.

5 The pricing impact is a bit of a question mark

Early on, some expected biosimilars would be priced 20% or more below their reference products. But so far, that hasn't been the case. To date, most U.S. biosimilars offer a relatively modest annual cost savings of about 10% to 15% compared to the reference drug.[21] And sometimes, they're not even the cheapest option, as major pharmaceutical manufacturers have deterred biosimilar adoption by offering payers extensive rebates on reference drugs if market share targets are met.[22]

The coming launch of additional biosimilars will clearly shift the pricing landscape, but exactly how remains unclear. As payers assess their pricing strategies, they'll have to factor in everything from patient access and safety to marketplace competition and savings. Patient access programs, manufacturer rebates, and shared-savings arrangements with providers may all add complexity to the equation. That's why strategic formulary and utilization management will be key, both in the short term to manage spend and in the long term, to ensure the competition generated by biosimilars helps drive lower drug costs.

The biosimilars boom is here. And payers are well poised to help this emerging class of therapeutics usher in not just a new era of more sustainable health care costs, but a brighter future for millions of patients.

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