Biosimilars Offer Potential for Significant Savings for Health Plans

Written By Laura Carabello

The buzz around biosimilars and their potential for health plan savings has been building since these drugs entered the market in 2015.

Fast forward to April 2025, when the US House Ways and Means Health subcommittee on the health of the biosimilar market reported that biosimilars had saved the entire US healthcare system over $23.6 billion. Committee members anticipate that biosimilars are poised to save the health care system up to $181 billion over five years if they are able to be adopted – although projected savings differ, depending upon the source, as shown to the right.

Witnesses testified that biosimilars lead to a 53 percent reduction in the average sales price for both the name brand and biosimilar medication and have added 344 million more days of therapeutic care than patients would have otherwise received. They reported that biosimilars launched at prices up to 35 percent lower than branded drugs and can drive further savings when they compete with drugs already on the marketplace. Biosimilars, say the legislators, will provide safe and effective treatment options for patients.

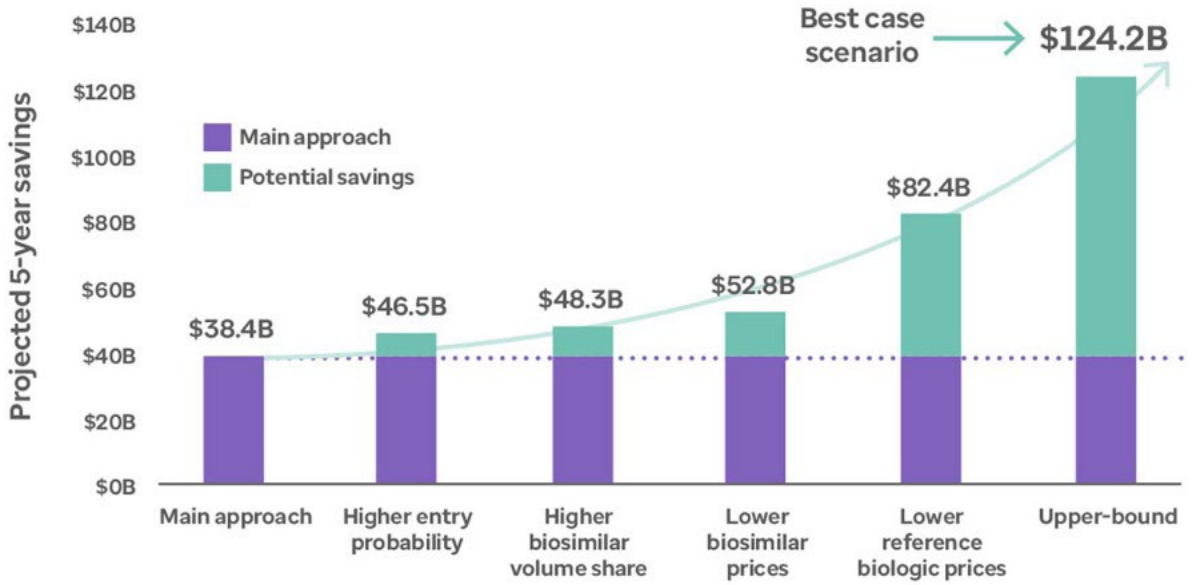


Image adapted from: Fresenius Kabi USA, LLC. Biosimilars: Realizing the potential in the US. Published March 8, 2023.

WHAT IS A BIOSIMILAR?

The Food and Drug Administration (FDA) defines a biosimilar as a biological product used in the prevention or treatment of disease and highly similar to an FDA-approved biologic (known as a brand reference product).

Biosimilars are medications with complex manufacturing compared to traditionally developed medications. They are intricately designed molecules that must demonstrate clinical similarity to their brand reference product. Biosimilars increase competition within a therapy class and will often drive down costs over time.

The biosimilar has no clinically meaningful difference from a reference product and is FDA-approved for use after rigorous evaluation and testing is demonstrated by the manufacturer applicant.

Source: Epiphany Rx

Lawmakers also contend that biosimilars help to increase drug supply and availability and have been used in nearly 700 million days of patient therapy. The committee calls for significant efforts going forward to ensure access -- from making drug reimbursement systems work correctly to incentivizing market competition to improve education and awareness among patients and providers.

As prescription medications represent the most influential part of the health plan spend, Glenn Fisher, CEO, NavMD, believes that biosimilars present a high-value, clinically equivalent alternative to costly biologics—especially in managing autoimmune conditions.

Glenn Fisher

"To maximize their impact, data analytics is key," says Fisher. "By analyzing claims data, organizations can identify high-cost biologic utilization, model cost-savings scenarios, and track biosimilar adoption trends. Integrating clinical outcomes data ensures biosimilars are delivering comparable results."

He observes that some employers are realizing 15–30% savings with no drop in care quality, noting, "PBMs are leveraging data to redesign formularies, align incentives, and drive education campaigns. Biosimilars do drive value without compromising outcomes. With data in hand, the question isn't *can* you take advantage—it's, *will* you?"

Beckie Fenrick

As more manufacturers continue to enter the biosimilar market, plan sponsors have unprecedented opportunities to control costs while maintaining access to the therapies members need most.

Beckie Fenrick, Pharm D, MBA, chief pharmacy officer, Navion, affirms, "Biosimilars deliver substantial market value—and at Navion, we strongly recommend that plan sponsors embrace proactive strategies to promote biosimilar adoption. By driving utilization toward clinically equivalent, lower-cost options, organizations can enhance both affordability and access across their populations."

She says biologics are a cornerstone in treating many autoimmune conditions—yet their high costs are often a barrier to care, adding, "The introduction of biosimilars has the power to reshape this landscape, injecting meaningful price competition and driving down treatment costs for patients and plan sponsors alike. Biosimilars make advanced therapies more accessible, ensuring that cost does not stand in the way of care."

WHAT'S THE DIFFERENCE? BIOSIMILARS VS. GENERICS

Both biosimilar and generic drugs are unbranded versions of existing medications offered at lower costs. Biosimilars and generics are each approved through different abbreviated pathways that avoid duplicating costly clinical trials. However, biosimilars are not generics, and there are important differences between biosimilars and generic drugs.

Biosimilar drugs describe large-molecule medications that are extracted from living organisms and are often overly complex medications such as vaccines. Generic drugs involve small-molecule medicines, such as aspirin or ibuprofen, which use synthetic chemicals and are much simpler to reproduce.

Generics and biosimilars account for 90% of prescriptions dispensed in the US but only 13% of total drug spending, and their widespread adoption over the last decade has saved the healthcare system an astounding $3.1 trillion, reports the Association for Accessible Medicines.

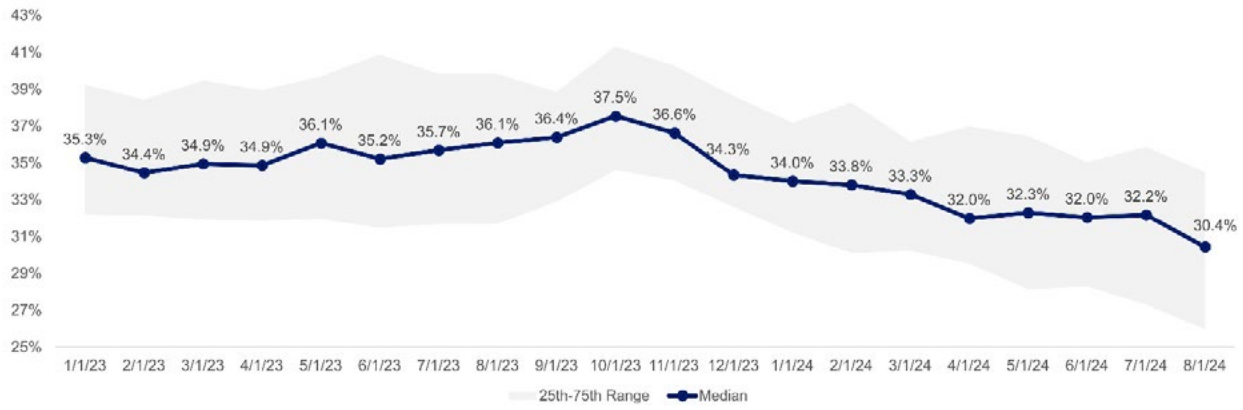
Sources: 2025 Amneal Biosciences; Medical Packaging.

WHY BIOSIMILARS ARE FALLING BEHIND

Despite their proven value, biosimilar adoption has been slow, and there is a lot of finger-pointing to account for this trend. An AMA Journal of Ethics cites one strategy originator manufacturers have employed to limit biosimilar uptake: negotiating formulary exclusivity with payers. In one lawsuit, the originator manufacturer entered into contracts with commercial payers to exclude biosimilars from drug formularies or include “fail first” provisions, which would require a patient to have failed on the original product before a biosimilar could be reimbursed.

According to the Segal 2025 Trends Report on Biosimilars, for medications with available biosimilars, generally, less than 10 percent of prescriptions have been for a biosimilar. However, the percentage increased significantly in Q2 2024, resulting from changes in pharmacy benefit manager (PBM) practices.

Consequently, they say, rebates create a perverse incentive where physicians are able to make money on the higher-cost drug because of the rebate, while biosimilars are "underwater" because the physician's reimbursement is less than their cost. Relatedly, insurance plans with a PBM frequently limit the number of biosimilars covered by their formulary, which further restricts patient and physician choice.



Biosimilars as a Percentage of Monthly Biologic Prescriptions

Source: 2024 Segal’s SHAPE data warehouse,
https://www.segalco.com/consulting-insights/q1-2025-trends-focus-biosimilars

Advisors at Segal say that manufacturers often use stalling tactics to delay the launch of competing biosimilar drugs, utilizing various tactics that include patent litigation and settlement agreements that effectively extend the monopoly period of the originator biologic. These tactics, often referred to as "stalling tactics," can include exploiting patent loopholes, engaging in "pay-for-delay" schemes or utilizing complex “patent thickets” to create an overlapping of patents that makes it difficult for others to develop or commercialize competing products without infringing on those patent rights.

Segal also says the way biosimilars are positioned within the formulary and represented in the PBM contract may discourage their use. To maximize rebates, PBMs and insurers may favor more expensive brand-originator products over lower-cost biosimilars.

As a result, the rebates create a contrary incentive where physicians are able to realize profits on the higher-cost drug because of the rebate, while biosimilars are marginalized because the physician's reimbursement is less than their cost. Health plans with a PBM frequently limit the number of biosimilars covered by their formulary, which further restricts patient and physician choice.

Additionally, Segal advisors voice concerns that prescribing providers may be hesitant to convert to biosimilars due to efficacy concerns and often find inconsistency in insurers' policies. Some physicians may not want to disrupt a prescription for a patient whose condition is stable, while patients may be reluctant to switch because they don't understand biosimilars, including their safety, efficacy, and potential cost savings. Plan sponsors may also wish to avoid disrupting participants' treatments.

WHAT IS AN INTERCHANGEABLE?

A manufacturer developing an interchangeable product must demonstrate that its product is expected to produce the same clinical result as the reference product in any given patient. Evaluation is required to determine the risk of administering a product to a patient more than once. This assessment is critical in terms of the safety and reduced efficacy of switching back and forth between an interchangeable product and a reference product.

While pharmacy laws and practices vary from state to state, interchangeable products may be substituted at the pharmacy level without the intervention of the healthcare provider who prescribed the reference product. A healthcare provider can also prescribe an interchangeable product just like they would prescribe a biosimilar or a reference product.

Source: 2025 Drugs.com

The Biosimilars Council cites two additional barriers to biosimilar adoption:

- Regulatory Burdens: The FDA's approval process for biosimilars is still plagued by redundant and costly requirements, including unnecessary clinical efficacy studies and confusion about biosimilars vs interchangeable biologics. This slows down development and drives up costs, deterring investment in biosimilar pipelines.
- The Inflation Reduction Act's Unintended Consequences: Instead of fostering biosimilar adoption, the IRA's drug pricing policies have actually discouraged development by making it less financially viable for manufacturers to enter the market.

The new IQVIA report identifies yet another challenge with respect to sites of care (SOC). Hospital outpatient departments–which typically receive higher overall payments than physician offices–are less likely to adopt biosimilars, in part driven by higher relative reimbursement ratios for reference products. Furthermore, a Bernstein Research report finds that hospitals increase the charges for reference products with biosimilar competition more than for biosimilars. This creates a financial incentive for hospitals to stock reference products.

Sabine Enright

Sabine Enright, PharmD, VP of Integration, Payer Business Unit, AscellaHealth, shares, "The adoption of biosimilars and the optimization of SOC strategies are both highly effective in reducing costs individually. When combined, their impact on cost reduction is significantly greater."

She says that focusing on both strategies is essential for lowering expenses while ensuring the continued delivery of high-quality patient care and effective disease management: "While both strategies may encounter resistance from members or providers on different fronts, this can be overcome through education and increased awareness in the marketplace."

Finally, regulatory burdens in the form of the FDA approval process for biosimilars are still plagued by redundant and costly requirements. This includes unnecessary clinical efficacy studies and confusion about biosimilars vs interchangeable biologics, slowing down development, driving up costs and deterring investment in biosimilar pipelines.

AVOIDING THE "BIOSIMILAR VOID"

While biosimilars have delivered billions in savings for patients, employers, and taxpayers, a new analysis from the IQVIA Institute has revealed a massive 'biosimilar void': a staggering 90% of biologic drugs losing patent exclusivity over the next ten years have no biosimilar competition in the pipeline.

This year, 25 high-revenue drugs, including Ozempic, Keytruda, and Eliquis, are set to lose patent protection, paving the way for biosimilar manufacturers to expand their portfolios and cater to a growing demand for affordable treatments. Moreover, the Biosimilars Council discloses that 118 biologics will lose patent protection between 2025 and 2034, but currently, only 12 of these medicines have biosimilars in development.

If action is not taken quickly, analysts at these organizations warn that millions of patients will be locked out of potential savings and forced to pay higher prices for essential medications.

THREAT OF PRIVATE LABEL BIOSIMILARS

Concerns have emerged around the growing use of these PBM-driven private-label biosimilars as being detrimental to future biosimilar development. By selling their own private-label products, the PBMs are incentivized to market (and cover) their own products over others, raising issues of transparency and conflict of interest. The biosimilar makers who do not reach private-label agreements with these PBMs may be blocked from sales to a large portion of the covered population, which can jeopardize biosimilar competition and, thus, biosimilar savings for all. Limiting the growth in biosimilars available or closing off a manufacturer's pathway to future revenue can stunt interest by manufacturers to pursue new biosimilars. Commentary from Dr. F. Randy Vogenberg, Principal, Institute for Integrated Healthcare, and board leader, Employer Provider Council, reveals, "In this scenario, PBMs can sell private-label, low-wholesale acquisition cost (WAC) versions to their employer clients, thereby offering a "savings" opportunity. However, PBMs and manufacturing firms share the remaining revenues with contracted distributors,

creating additional income back to the PBM. For example, a product sold at an 80% WAC discount leaves 20% left for revenue sharing with the PBM's distributor and biosimilar manufacturer. This new income to the PBM's parent can offset potential losses to rebate revenue or audit efforts by employer plans."

Recently, the BR&R Biosimilar Report published an update that demonstrates the impact of PBM-driven private-label biosimilars. Optum Rx will exclude Humira and prefer FDA-approved adalimumab biosimilars effective January 1, 2025, for patients new to therapy. Amjevita®, the unbranded version of this biosimilar, will be the primary biosimilar covered on its commercial formularies and will also be offered as a private-label product through Nuvaila, a subsidiary of UnitedHealth Group. All other adalimumab biosimilars (and Humira) will be excluded from its Premium and Select formularies.

Vogenberg says the promotion of PBMs' private-label biosimilars may offer some savings today for plan sponsors, but it may also be threatening future savings opportunities, adding, "In the US, employer plan sponsors and their vendors have more than $100 billion in potential savings with a competitive, fully open, and transparent biosimilars marketplace. That opportunity derives from growing biologic patent expirations, increasing access to biosimilars across populations, and eliminating unnecessary middlemen pricing policies that can hinder long-term savings associated with biosimilars."

IN DEFENSE OF PBMS

"Leading PBMs are deploying a variety of innovative tactics to accelerate biosimilar adoption and drive down drug spend," says Fenrick, offering the following strategies that not only lower costs but also increase access to life-changing therapies for members:

- Formulary Strategy: Preferring or exclusively covering biosimilars over higher-cost originators.
- Utilization Management: Requiring step therapy or trials of biosimilars before allowing access to reference products.
- Prescriber Engagement: Providing academic detailing and outreach to support evidence-based transitions to biosimilars.
- Specialty Pharmacy Support: Facilitating member transitions with dedicated outreach and copay assistance for eligible members.
- Concierge & Digital Tools: Offering member support services and digital resources to spotlight cost-saving opportunities with biosimilars.
- Expanded Pharmacy Access: Including disruptors like Mark Cuban's Cost-Plus Drug Company to broaden access to affordable medications, including biosimilars.

Jay Gulley, PharmD, President, LeadwayRx, a 20-year-old transparent PBM that utilizes RxLogic claims processing, characterizes the challenge: "The original biologic product has name recognition with the

doctors plus the TV ads and commercials during the Super Bowl that attract consumers. When the drug loses its patent, and depending upon the manufacturer, a biosimilar can be introduced. Initially, there may not be significant adoption, but when employers start to calculate the savings of adding a biosimilar to the formulary, they are readily convinced."

He says PBMs typically support the employer in evaluating the opportunity. Some self-insured companies may not want to make any of their members switch to a biosimilar, while others say they need all the savings they can get and want the least expensive option – although the least expensive option is still costly.

STELARA

Everyone working or observing the biosimilar industry is watching the seven FDA-approved Stelara biosimilars, with two others under FDA review and a third in late-phase clinical development.

Some analysts say the experience that payers have had with Humira biosimilars may make for earlier and broader coverage of the Stelara biosimilars. The catch: No payer has announced plans to remove the brand name Stelara from 2025 formularies.

The uptake of Stelara biosimilars will largely depend on how quickly brand-name Stelara is removed from formularies — not when biosimilars are added — and that may not happen until 2026.

Source: IPD Analytics LLC

A key point of discussion is transparency regarding rebates.

Gulley continues, "Historically, there has been very, very little transparency in that space, but I think it has grown over the last couple of years as the drug spend has continued to climb and become such an issue for employers. People are starting to look a lot closer at these expenditures and wondering why it is so high. It is probably above their medical and hospital spend."

With so many factors impacting a high drug spend, employers and brokers are really starting to hammer down and look a lot more closely at transparency for rebates.

"There's a big role for PBMs to work with pharmacies -- not against them -- to help lower drug costs for the employers, not just to pull in as much money as they can," he quips. "PBMs are well-positioned to take on the complex challenges of advancing adoption of biosimilars. There may even be some manufacturers who say if you exclude a certain drug, you're not going to get rebates on any of our other ones. It's a big game. But when you start to see much lower prices, there is no argument. "

When it comes to interchangeability with biologics, he maintains that doctors will prescribe whatever biosimilar the insurance will pay for. Some states will even allow the pharmacist to make that change without a new prescription, while other states still require a new prescription for that particular biosimilar.

"I think there is great potential for biosimilars, especially with the newer pricing models that you're starting to see that carry some very significant discounts as opposed to the original branded product," says Gulley.

"With more discounts resulting in lower costs, the more utilization there's going to be – and much of that has to do with transparency."

SCALING THE REBATE WALLS

Rebate "traps" occur when a drug manufacturer pays list price discounts to health plans or pharmacy benefit managers (PBMs) based on meeting market share targets. Health policy analysts at Duke University explain that while such practices appear to lower net costs in the short term for a particular drug or biologic, they also have the effect of blocking patient use of competing, lower-priced products – like biosimilars.

Duke analysts maintain that rebate walls are particularly challenging in the context of biosimilar competition: "While biosimilars are as safe and effective as the originator biologic and offered at a reduced list price, demand for products has been slow to shift from incumbents, especially if clinicians and patients do not regard the products as clinically equivalent. The result can be harmful to patients and the healthcare system through reduced access to drugs that are just as safe and effective but cost less. Furthermore, growth in rebates has been linked to a growth in list prices, and highly rebated products are often accompanied by higher out-of-pocket costs for patients."

Fenrick concurs, "While rebate structures can complicate formulary decisions, the net cost advantage of biosimilars is clear. Many biosimilars are priced 85% to 90% below the originator brands, often yielding deeper savings even after rebates are applied to the innovator. Navion advises clients to carefully analyze net costs, not just rebates when evaluating formulary options. In nearly every case, biosimilars deliver superior value—helping plans achieve both clinical and financial objectives."

Employers should be aware that CVS/Caremark, Express Scripts and OptumRx have all formed joint ventures to manufacture private-label biosimilar drugs. It may be prudent to confirm that the PBM contract specifies that the formulary includes low-cost biosimilars from companies unaffiliated with the PBM.

PLAN SPONSORS CAN ENCOURAGE BIOSIMILAR ADOPTION

Despite this myriad of challenges, biosimilars are projected to generate substantial cost savings as adoption increases. Segal suggests several strategies that plan sponsors can use to encourage their utilization:

- Education and awareness campaign. Educate stakeholders, including providers, pharmacies, and participants, about the safety and increased availability of biosimilars. Interchangeable biosimilars may be automatically substituted by a pharmacist for the original biologic or reference product, like a generic substitution for brand-name medications, while non-interchangeable biosimilars require prescriber approval. Note that applicable laws vary by state.
- Plan design and utilization management. Revise the plan design to include incentives that encourage adoption. Consider the use of utilization management, such as step therapy, to require patients to try lower-cost options first or prior authorization for expensive biologics and include biosimilars as preferred alternatives.
- Financial incentives. Introduce provider incentives, either through a direct contracting arrangement or by working with the insurer or third-party administrator (TPA) to ensure that the contracted

providers are aware of and are considering biosimilars as a treatment option.

- Formulary management. Place biosimilars in preferred tiers with lower copayments to incentivize their use or remove the originator product from the formulary. Regularly update the formulary to include newly approved biosimilars and remove (or deprioritize) more expensive reference biologics.
- Real-time benefit programs. Consider implementing real-time benefit programs that integrate with prescribers' electronic health record systems and provide comparative pricing for originators and biosimilars when providers e-prescribe.
- Monitoring and reporting. Ask the medical administrator and PBM for a current utilization report showing biosimilar vs. reference product utilization under both the medical and pharmacy benefits. This will help identify opportunities to encourage more biosimilar use.

Barbora P. Howell, Co-founder & CEO, True Claim, offers this guidance, "Biosimilars offer meaningful savings, but realizing their value depends on making the switch easy for members and financially aligned for all stakeholders. In an ideal world, that means no new prior authorizations, no changes in how the medication is administered, and no revenue compromised by any vendor involved."

Barbora P. Howell

She also thinks that plans should "walk the talk" and offer financial incentives to members, such as lower copays.

"Finally, PBMs must support biosimilar adoption through formulary design and aligned contracting...so selecting the right PBM partner is key," continues Howell. "When switching to a biosimilar is simple, transparent, and cost-effective, companies and members can save money without disrupting care."

CHALLENGES AND OPPORTUNITIES

While biosimilars offer significant potential for cost savings, there are also challenges to consider, such as the need to address potential interchangeability issues and the potential for brand-name manufacturers to offer discounts to counter biosimilar competition. The role of members – as healthcare consumers – is equally important.

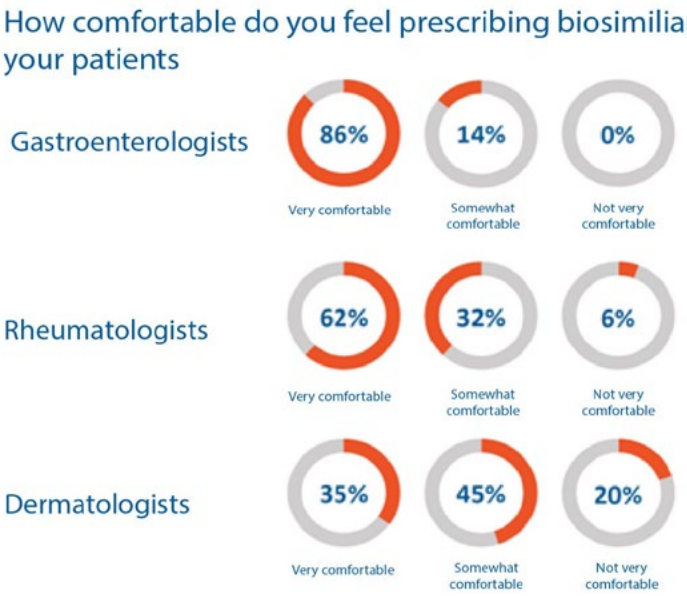
"Drug costs have increased every year, forcing consumers to evaluate their options," observes Joe Dore, President, USBenefits Insurance Services. "This would include generic brands and other options, such as biosimilars. Unfortunately, due to financial considerations, some consumers drop the needed medication."

Joe Dore

Today, the cost of prescriptions represents about 20% of the healthcare expenditures on average, as Dore predicts, "This is expected to worsen, especially with increased usage of high-cost drugs, which will only increase the pressure on the employer groups to seek out alternative risk management strategies. It will also force the insurance industry to manage

towards premium adequacy for the additional exposure."

He invites this topic for discussion on pharmaceutical company earnings, drug distribution channels, PBM models and potential conflicts of interest that affect the cost to the consumer.



The role of providers cannot be discounted. Physicians and hospitals play a critical role in biosimilar adoption, highlighting the importance of examining ways to remove obstacles that may discourage providers from utilizing lower cost biosimilars with their patients.

Source: 2025 Innovative Rx Strategies

Case in point: In a survey of US rheumatologists' beliefs and knowledge about biosimilars, nearly all respondents were familiar with the FDA definition of a biosimilar product. They were aware that an infliximab biosimilar -- an unbranded version of Remicade indicated for the treatment of adults living with moderately to severely active rheumatoid arthritis (RA) -- was FDA-approved.

Most respondents (84%) understood that an approved biosimilar was not automatically deemed interchangeable by the FDA. Researchers concluded that rheumatologists were more likely to initiate biosimilar treatment for a biologic treatment-naïve patient with RA (73%) than they were to switch to the biosimilar for a patient with RA doing well on the reference product (35%).

Other similar surveys have found that patients are satisfied with the outcomes achieved with biosimilar products, including those patients who had begun treatment on a reference product. The only major concerns reported for switching included not knowing enough about the medication (38%), potential side effects (35%), and loss of disease activity control (35%). Patients still have concerns regarding safety and efficacy, and their involvement in the switching decision-making process may allay concerns and enhance biosimilar uptake.

WHAT TO DO NOW

Kathy Oubre, MS, chief executive officer of Pontchartrain Cancer Center, Louisiana, suggests that the current landscape presents an opportunity for employers to revisit the inclusion of biosimilars in their formularies and to develop strategies that will allow their increased use and/or help manage ongoing utilization.

Employers can play a significant role in promoting biosimilars as an alternative to more expensive biologic drugs, where medically appropriate, by 1) Increasing understanding of biosimilars by health plan

participants and health care providers through education and incentives, 2) Adopting clinical management programs, 3) Designing the payment feature of prescription drug benefits to account for biosimilars 4) Addressing biosimilar drugs when negotiating PBM contracts.

There is widespread consensus throughout the industry that employers can maximize savings from biosimilars. Oubre and others suggest starting with these questions when developing and implementing strategies to promote their utilization and then initiating communications with the PBM to encourage biosimilar use:

- What is my PBM's strategy, and how flexible is it in adopting biosimilars?
- Should biosimilars be added as a preferred or non-preferred formulary option?
- Does a brand or generic copayment apply?
- If the plan offers copayment assistance, how will that impact costs?
- Should it be added only for new patients?

EDUCATE MEMBERS -- ENCOURAGE BIOSIMILAR USE

Bruce Roffé

Bruce D. Roffé, President and CEO, H.H.C. Group, a cost containment company using claim negotiation, repricing, and independent review solutions, suggests that employers can provide meaningful education to plan participants regarding biosimilar adoption, highlighting biosimilar use and potential cost savings as well as real-time benefit lookup tools and cost calculators.

Proactively explain to members who started taking a brand-name version before a biosimilar was available that there should be no adverse impact from switching to the biosimilar.

"With a robust pipeline and steady stream of newly launched biosimilars, plan sponsors may find it appropriate to provide updated biosimilar education and demonstrate how biosimilars fit into their plan benefit design," says Roffé. "This type of education can also be communicated to healthcare providers as an opportunity to promote awareness and consideration of biosimilars as a preferred treatment option. The FDA is a great resource for these materials, which can be readily accessed at www.FDA.gov/biosimilars."

REFINE FORMULARY STRATEGY

Ensure PBM formulary includes available biosimilars, will adopt new ones as they are introduced and base their selection on which product offers the lowest net cost to the member and plan. Formularies may exclude coverage for name-brand versions or create a tier that includes them but with significantly higher copays.

Clarify how your plan will handle biosimilars not designated by the FDA as "interchangeable," meaning

that pharmacists (in most states) can substitute them for brand-name biologics. Confirm that your PBM has procedures to encourage doctors to prescribe biosimilars that haven't yet been classified as interchangeable. This issue also impacts "rebate credit" since PBMs may use these provisions to reduce your rebate payments if members switch from high-rebate biologics to no-rebate biosimilars.

Require PBMs to be fully transparent about the rebates they receive and return back to the plan. If the PBM is handling Prior Authorizations, confirm that biosimilars are included in the process as a high-quality, less costly alternative to more expensive biologic drugs.

PLAN DESIGN

Plan design can be used to help mitigate growing prescription drug costs with the goal of balancing quality and cost savings. "Tiering" places equally effective drugs in different tiers to incentivize the use of the least costly tiers and is designed to further drive consumerism around the price of a medication. As the number of biosimilars in the market grows, there may be increased use of multi-tier plan designs, especially for specialty drugs.

During PBM negotiations, there may be consideration of inflation-protection caps, which are intended to shield plans from the full impact of year-over-year price increases. This is a good opportunity for employers to understand how their plan's inflation cap is calculated by the PBM and confirm the PBM delivers these protections to all specialty drugs, including biosimilars.

When it comes to manufacturer rebates associated with biosimilar inclusion, plan sponsors should use this opportunity to ensure that biosimilars are included in rebate payment calculations, review their PBM contract provisions with their benefit advisors and legal counsel and confirm inflation-protection caps and manufacturer rebates.

Finally, employers should confirm that biosimilars are included in the payment provisions of their prescription drug benefit, either through plan design or formulary strategy.

INTRODUCE CLINICAL MANAGEMENT PROGRAMS

By including biosimilars in their utilization management strategies, employers can help safeguard the appropriate use of selected drugs. Prior authorization, one of the most common UM strategies used by employers and payers to contain cost, can advance the adoption of these high-quality, less costly alternatives to more expensive biologic drugs.

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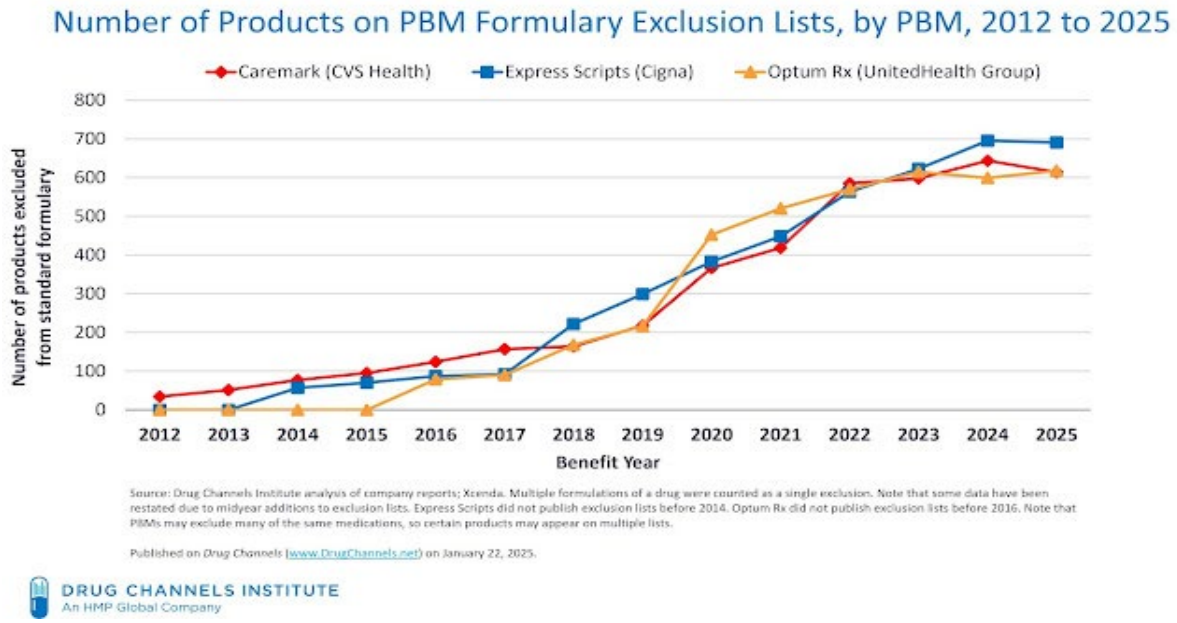
As noted earlier, Site of Care (SOC) management is also a viable clinical management program, enabling employers to evaluate the cost differences among hospitals and community-based practices that dispense the same drug. Several studies show that the outpatient hospital setting incurs higher charges than community-based physicians or home-based administration for the same treatment. This cost differential could lead to potential savings for employers through site-of-care analysis, plan design, and contracting strategies, which avoid high-cost settings.

EMPLOYERS FOLLOW MARKET TRENDS

As of April 30, there have been 74 biosimilars approved by the US Food and Drug Administration (FDA), including at least 15 that are designated by the FDA as interchangeable products. So far this year, 10 biosimilars have already received FDA approval, a robust start on the heels of a record-breaking 19 approvals in 2024.

If the three largest PBMs are any bell weather of what's in store for biosimilars, they have again each excluded hundreds of drugs from their standard formularies. This blocks access to specific products on a PBM's recommended national formulary and emerges as a powerful tool for PBMs to gain additional negotiating leverage against manufacturers.



In turn, manufacturers offer deeper rebates to avoid having their products cut from the formulary. A drug's appearance on an exclusion list does not guarantee that all patients will lose access. Plan sponsors— the PBM's clients— can choose not to adopt their PBM's standard formulary but would then face reduced rebates and/or higher plan costs. It is anticipated that each PBM's formulary will give plan sponsors the option of a high-list-price biosimilar, a lower-priced private label product and a low-list-price unbranded biosimilar.

The combination of formulary exclusion and private labels is creating an increasingly puzzling and crowded

biosimilar marketplace. Whether employers agree or disagree, the financial benefits from these private-label products align with the benefits to plan sponsors and patients. The complexity of the drug pipeline and market dynamics means progress for biosimilar adoption is gradual.

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