

Action Brief

THE VALUE OF BIOSIMILARS

Improving Treatment Access and Lowering Costs



ACTION STEPS FOR EMPLOYERS:

- 1. Quantify the biosimilar opportunity** by initiating conversations with vendors about fill rates and savings potential.
- 2. Partner with vendors** to determine how best to drive appropriate promotion, adoption and utilization of biosimilars.
- 3. Review specialty pharmacy benefit design** to ensure it supports appropriate use and access.
- 4. Educate all employees** about the value of biosimilars to enable more informed decision making.

Biosimilar drugs and their potential benefits to employers and employees is showing great promise—in terms of dramatically lowering costs and improving access and outcomes. One estimate suggests that robust uptake of biosimilar products could reduce direct spending on biologic drugs by \$54 billion by 2026 by creating competition in a marketplace that has traditionally been noncompetitive. Biosimilars used in combination with tactics like prior authorization, utilization management, and step therapy are expected to provide even more cost savings and may even decrease stop loss premiums given a reduction in medication costs.

So, what is a biosimilar? Biosimilars are often confused with generic versions of branded drugs, but there are some fundamental and important differences. Generics are chemically identical to their synthetic brand-name counterparts. A biosimilar product is a biologic product that is approved based on demonstrating that it is highly similar to an FDA-approved biologic product, known as a reference product, and has no clinically meaningful differences in terms of safety, purity or potency. The FDA allows only minor differences in clinically inactive components in biosimilar products, so employers and patients can have confidence in their use.

While biosimilars have enormous potential for altering the trend on specialty drugs, it's a confusing and murky marketplace because it's so new. For example:

- ▶ **Insurance plans commonly include fail-first or step therapy policies** requiring patients to use lower-price generic drugs before more expensive brand-name drugs are used. For biosimilars, this policy works in reverse, allowing use of less expensive biosimilars only if patients first fail on the more expensive biologics.
- ▶ **There is a problem of current biologic contracting practices** that link insurers' rebates to minimum volume thresholds to rebates on other medical devices. This creates another reimbursement disincentive that biases the market against lower-priced biosimilars.

But employers can take action to influence change that will ultimately lead to more options for employees and their dependents who are dealing with diseases like cancer, rheumatoid arthritis, inflammatory bowel disease, diabetes, multiple sclerosis, kidney disease, and severe psoriasis.



The public health benefits of a robust, competitive market for biosimilars are impossible for us to ignore. Strong market incentives are critical to future biosimilar development in the same way these incentives are key for the development of innovator drugs and biologics.

— Scott Gottlieb, M.D,
FDA Commissioner

EMPLOYER TIP

Employers should insist on NDC codes to receive clearer data that enables them to better manage specialty drug (including biosimilars) use and spend. Currently, about 40% of specialty drug spend is under the *medical benefit* using a non-specific J Code. Drugs reimbursed through the *pharmacy benefit* include an NDC code, identifying the specific brand, dosage and number of units administered.

ACTION STEPS FOR EMPLOYERS

1. QUANTIFY THE BIOSIMILAR OPPORTUNITY by initiating conversations with vendors about fill rates and savings potential (e.g., health plans, pharmacy benefit managers, specialty pharmacies)

Work closely with vendors to better understand and advance the savings, access and outcomes opportunities biosimilars present. [This June 2018 case study](#) reveals that cost savings could be significant by providing access to and driving increased use of biosimilars.

Since biosimilars offer significant potential cost savings but are not widely prescribed, employers can work with vendors and providers to drive uptake and acceptance. Bringing purchaser expectations to light helps all specialty drug stakeholders understand, evaluate and improve the marketplace.

2. PARTNER WITH VENDORS to determine how best to drive appropriate adoption and utilization of biosimilars

As of June 2018, the FDA has approved 11 biosimilars. With 63 more in the pipeline, employers should stay apprised of biosimilar advances and FDA approvals and develop a strategy with their vendors that best supports the needs of their workforces. Because biosimilar products are relatively new, it is important for employers to have discussions with their vendors that include best practice decisions on driving uptake of biosimilars. Employers need to make expectations clear, so they can best address gaps in care and improve health outcomes and lower costs.

3. REVIEW BENEFIT DESIGN to ensure it supports appropriate use and access

A thoughtful approach to adding biosimilars to pharmacy benefit strategies can help employees and their dependents make informed decisions and experience greater productivity and quality of life, lower costs, and better outcomes. For example:

- ▶ **Tiered plan design** for preferred and non-preferred biologics and biosimilars.
- ▶ **Restricting or excluding certain drugs** when equally effective, lower-cost choices are available.
- ▶ **Requiring prior authorization and step therapy** where patients use less-expensive biosimilars before even more costly biologics are prescribed.
- ▶ **Incentives** to influence desired behavior such as reduced out-of-pocket costs.

4. EDUCATE ALL EMPLOYEES about biosimilars to enable more informed decision making

Health literacy—the ability to obtain, process and understand basic health information and services to make appropriate health decisions—is essential to good health. Yet only 12 percent of U.S. adults have proficient health literacy. With the biosimilar market in its infancy, it will be important to work with vendors to build employee knowledge and understanding of available therapy options. Just as when generic drugs were new, employees will need to learn about biosimilars, so they can trust in their safety and efficacy, use benefits appropriately, have informed discussions with doctors, and manage care effectively.

RESOURCES FOR EMPLOYERS

- [National Alliance Specialty Drug Marketplace Initiative: Five Rights Framework](#)
- [Embracing Competition to Empower Biosimilars](#)
- [State Laws and Legislation Related to Biologic Medications and Substitution of Biosimilars](#)
- [FDA Biosimilar Education Initiative](#)
- [Top-selling Drugs in 2018: Biosimilar Competition is FDA Approved but Not Marketed](#)
- [US Biosimilars 2018: Opportunities and Challenges](#)
- [How Can the U.S. Catch Up on Biosimilars?](#)
- [We Can Expand Cancer Patients' Care](#)
- [Gottlieb Calls Out 'Rigged' System That's Hurting Biosimilars, Pledges FDA Fight to Boost Uptake](#)
- [New Study on Savings with Biosimilars](#)

Based on the current prices of the biologic and biosimilar version of infliximab, I estimate that biosimilar versions of the medicine could save between \$2,050 and \$4,370 per patient... the aggregate annual savings would be between \$262 million and \$315 million. And these are savings for just one biosimilar....

— Wayne Winegarden, *Forbes Magazine*

Biosimilars will create long-term cost savings and efficiencies, free up resources for other important aspects of cancer care, and allow earlier intervention to help improve patient outcomes and quality of life. In doing so, biosimilars could expand cost-effective care to millions more patients—a much-needed step in reducing spending.

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KEY QUESTIONS FOR VENDORS

- Of the FDA-approved biosimilars, which ones do you recommend making available to employees and why?
- What are the potential savings if we transition certain biologics to biosimilars?
- Are any biosimilars not recommended at this time? Why?
- How can we keep our finger on the pulse of the biosimilars pipeline to plan ahead?
- What incentives are in place to encourage appropriate use and adherence and uptake of biosimilars?
- How can we contribute to accelerating the uptake of biosimilars in the marketplace?
- How can we effectively communicate with employees to ensure they will confidently accept the use of biosimilars?



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