



## **BIOSIMILARS IN THE PHARMACY BENEFIT**

## EMPLOYERS DRIVING APPROPRIATE USE AND TRANSPARENCY

## ACTION STEPS FOR EMPLOYERS:

- Apply value-based purchasing strategies that encourage market adoption, formulary placement, and appropriate use of biosimilars.
- 2. Use practical strategies to view and interpret biosimilar benefits.
- Learn how biosimilars can help employers save money without compromising quality.
- Know the right questions to ask health plans, PBMs, specialty pharmacies, consultants and other advisors.
- 5. Educate employees about the value of biosimilars.

Despite the fact that less than 2% of the US population uses biologic drugs, <u>they account for</u> 26% of national prescription drug spending. Biosimilars can expand options, enhance affordability, and increase access to therapy. It's been estimated that biosimilars could save patients and the healthcare system from <u>\$54 to \$250 billion</u> over their first 10 years on the market without compromising outcomes.

But while biosimilars hold great promise to alter the price trend on specialty pharmaceuticals, it's a confusing and murky marketplace. Uptake on many biosimilars has been slow, in part because employers are often unsure about how to take appropriate action to encourage more—and more affordable pharmaceutical options for employees and their dependents.

"Drug costs in the US have increased 41% in the last 10 years from \$236 billion to \$333 billion. The biggest contributor to this growth is the rising cost of brand-name drugs and biologics. In fact, the top two highest cost drug products were biologics, with employers spending more than \$7.5 billion on those two treatments alone."

> — Elizabeth Mitchell President & CEO, Pacific Business Group on Health (AJMC, January, 2020)



## 1. Apply value-based purchasing strategies that encourage market adoption, formulary placement, and appropriate use of biosimilars.

The National Alliance Medical Director Advisory Council has developed an "<u>Employer Rx Value Assessment</u> <u>Framework</u>" with six key employer action steps to build the bridge to sustainability. The framework is highly relevant to purchasing strategies for biosimilars.

Support and promote appropriate use of biosimilars. In the European Union (EU), <u>58</u> biosimilars have been approved. In the US, as of May 2020, <u>26</u> biosimilars have been approved by the FDA; only 17 have been launched, and uptake of many is low. Employers can advocate for biosimilar use with health plans, pharmacy benefit managers (PBMs), specialty pharmacies, consultants and other stakeholders.

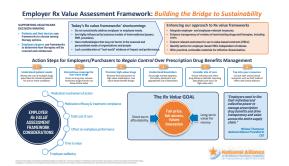
#### **Biosimilars Explained**

A biosimilar is a type of biologic product that is licensed by the FDA because it is highly similar to a biological product that is already FDA-approved. The originally approved product, known as the biological reference product, and the biosimilar must also have been shown to have no clinically meaningful differences in potency, safety and purity.

Biologics are important and successful, but very expensive, medicines used to treat numerous serious diseases. Biosimilars are a more affordable option for patients and plan sponsors.

(See FDA biosimilar educational resources here.)

- Comprehensive medication management. Patient-level pharmacy review can significantly reduce individual costs and improve medication adherence among patients with complex healthcare needs.
- Active formulary management. Focus more on the drug mix and less on the standard bundle of drugs, ensuring that biosimilars are included as appropriate. Remove drugs of negligible clinical value. Because the biosimilar market is evolving so rapidly, it is also important to monitor the <u>robust pipeline</u> to anticipate future formulary decisions.
- Bring greater clinical intensity to formulary discussions. This



can include tapping onsite clinical resources such as company or health plan chief medical officers and clinical advisors. They not only can inform discussions about which biosimilars to include on the formulary but can also recommend utilization management strategies like prior authorization and step therapy.

Value considerations can help guide benefit design. Eliminate financial barriers to high-value medications such as biosimilars; reduce financial support for low-value medications; eliminate prescriptions that have no value.

### Review sites of care for medication administration.

Drug costs can more than double when administered in a hospital instead of an outpatient department or infusion center. Determine the cost and quality of high-value sites so infusions and other drug delivery are provided in the most cost-effective setting.



## 2. Use practical strategies to view and interpret biosimilar benefits.

Employers must have the right incentives in place to encourage the use of biosimilars over brand-name reference biologics and have the ability to see clearly across medical and pharmacy benefits to ensure biosimilars (and other specialty drugs) are effectively managed.

The right incentives. Selfinsured employers are able to use plan design to promote the use of biosimilars. Plan design that places biosimilars on the preferred tier and reference-based products on the nonpreferred/specialty tier—or leaves reference products off the formulary altogether—will result in significant savings and satisfied employees, as will applying the six action steps described in Step 1, above.

Why cover under the medical **benefit?** Commonly used in medical benefits, J code billing allows one code to be used for many drugs and services, making it impossible for employers to discern costs specific to a particular drug and the cost to administer it. Currently, about 40% of specialty drug spending occurs under the medical benefit. Covering certain drugs under the medical benefit may be the right choice in certain cases where specialized medical care is required (e.g., intravenous chemotherapy drugs) or when discounts and fee schedules are lower under the medical benefits. The key is for employers

Click on the image above to view the infographic.

#### Specialty Drug Cost Variations for Active and Non-Medicare Retirees'

	Herceptin®		Neulasta®		Avastin®		Perieta®	
	Physician	Outpatient Hospital	Physician	Outpatient Hospital	Physician	Outpatient Hospital	Physician	Outpatient Hospital
Minimum	\$99	\$150	\$4,682	\$4,314	\$75	\$71	\$12	\$17
Median	\$107	\$205	\$4,688	\$9,442	\$81	\$161	\$12	\$24
Maximum	\$116	\$396	\$7,477	\$18,004	\$91	\$301	\$13	\$46
* Prices shown are allowed amounts Source: Segal (2019)								

"Data analytics can help employers understand whether coverage of a biologic or biosimilar under a medical or pharmacy benefit will provide the best pricing."

#### - <u>Employer Strategies for Use of</u> <u>Biosimilar Pharmaceuticals</u>

to make informed decisions about *exceptions* for paying under the medical benefit.

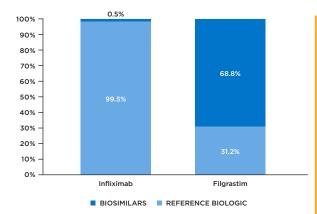
Why cover biosimilars under the pharmacy benefit? In general, covering biosimilars and other specialty drugs under the pharmacy benefit provides a much higher level of specificity. Pharmacy benefit billing uses a National Drug Code (NDC), which is a unique 11-digit code assigned to each drug upon FDA approval. When employers can see precisely what they are paying for prescription drugs, they can more easily manage cost, quality and access.

### 3. Learn how biosimilars can help employers save money without compromising quality.

A groundbreaking study from the ERISA Industry Committee (ERIC) released in March 2020 looked at the use of infliximab and filgrastim at 13 of America's largest employers from a variety of industries. The two drugs were used by only 0.06% of each company's beneficiaries, yet related spending represented up to 2.7% of annual spending on drugs. There was also marked variation in biosimilar utilization across different vendors for the same company.

When matched for a series of characteristics to ensure an appropriate comparison, the biosimilar offered a median discount of 32% over the price of the reference biologic for infliximab and a median discount of 26% over the price of the reference biologic for filgrastim. Further, the study showed filgrastim biosimilar uptake is much more advanced than that for infliximab, with biosimilars representing nearly 70% of filgrastim claims, but only 0.5%of infliximab claims. Full biosimilar substitution on just these two drugs could have saved, on average, \$1.5 million in 2018.

"For the biosimilars market to promote price competition and successfully generate savings, it is important that plan sponsors reconsider their options based on the full savings potential offered by each product," the study said. "Increased transparency and greater access to information are an important first step."



#### Infliximab Biosimilars Have Smaller Market Share Relative to Filgrastim Biosimilars<sup>a</sup>

Infliximab is used mainly as an immunosuppressant to treat patients with autoimmune conditions like rheumatoid arthritis, Crohn's disease, and ulcerative colitis. Filgrastim stimulates the production of white blood cells and is used in other autoimmune conditions where white blood cell counts are too low.



## 4. Know the right questions to ask health plans, PBMs, specialty pharmacies, consultants and other advisors.

Although each employer has unique formulary goals and objectives, taking time to prepare for conversations with key strategy partners ensures that your expectations will be met. Samples questions are:

- Of the FDA-approved biosimilars, which ones are recommended and not recommended for our formulary and why? Which pipeline biosimilars should I be considering?
- How are you working with providers to increase biosimilar awareness, acceptance and use? With patients?
- How will you ensure the satisfaction of patients moved from a brand-name biologic to a biosimilar? What steps are in place to address patient concerns?
- What are the potential savings of moving from brand-name reference biologics to biosimilars when appropriate?
- How can we dramatically increase coverage under the pharmacy, rather than the medical, benefit?
- What audits are being conducted to validate and manage high-cost specialty drug claims?
- Is outcomes-based or value-based pricing available? How about inflation-protection caps?
- Why are biosimilar discounts so much higher in the EU than the US? What is being done to close the gap?

a Estimates reflect average market share for the biosimilar vs. the biologic among all claims during the year 2016. Data from n=26 (infliximab) and n=28 (filgrastim) medical and prescription drug benefit carriers ('data donrs)' representing 15 ERC member companies.

- What alternatives to rebate-driven approaches will you undertake to help manage costs?
- How can I work with other employers to help drive approval of more biosimilars in order to increase competition and lower costs?

"The production of the average generic drug costs \$2 million to \$5 million over two to three years, while the developmental cost of a biosimilar is currently around \$75 million to \$100 million for five years. This gap is why many experts believe the percent savings driven by biosimilars should be tempered to roughly 20% to 40% of the reference product's cost until enough multisourcebiosimilars are on the market." – Matthew Harman, PharmD, MPH

## 5. Educate employees about the value of biosimilars.

The lack of patient awareness about biosimilars is one of the key reasons for the slow uptake. As biosimilar production and availability grows, clear and consistent communications can increase awareness and use. Most important is to focus on the fact that biosimilars are safe and effective, are FDA-approved, and will save money without compromising care or quality.

Alerting employees to formulary updates and equipping them to have informed conversations with their doctors about lower-cost, highervalue biosimilar options benefits employees and employers alike. The FDA offers a wide variety of patient educational materials that make it easy for employers to share information and for patients to have open conversations with their doctors.

"Availability of biosimilar and interchangeable products that meet the FDA's robust approval standards will improve access to biological products through lower costs and enable greater economies of scale in biosimilar manufacturing." – FDA's Biosimilars Action Plan:

– FDA's Biosimilars Action Plan: Balancing Innovation and Competition



# RESOURCES FOR EMPLOYERS:

- Employer Rx Value: A Framework Developed by the National Alliance Medical Director Advisory Council
- Employer Rx Value Framework
  Infographic
- Specialty Drug Employer Playbook
- Employer Strategies for Use of Biosimilar Pharmaceuticals
- FDA's Biosimilars Action Plan: Balancing Innovation and Competition
- EmployersRx on "Not So Different:" Employers Advocate for Lower Drug Costs Through Biosimilars (January 2020 AJMC podcast)
- Coalition Advocates for Biosimilar Uptake to Help Lower Employers' Drug Cost Burden
- Employers' Prescription for Affordable Drugs
- Employers as the Untapped Stakeholders in Biosimilar Uptake
- Magellan Rx Management Medical Pharmacy Trend Report
- <u>The Breakthrough of</u> <u>Biosimilars: A Twist in the</u> Narrative of Biological Therapy
- ERISA Industry Committee Biosimilars: Cost Savings & Competition (ERIC Initiative)
- Why are Biosimilars Not Living Up to Their Promise in the US?

## ACKNOWLEDGEMENTS

National Alliance acknowledges support from Sandoz Inc., a Division of the Novartis Group, by way of clinical expertise and funding to produce this Action Brief.



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