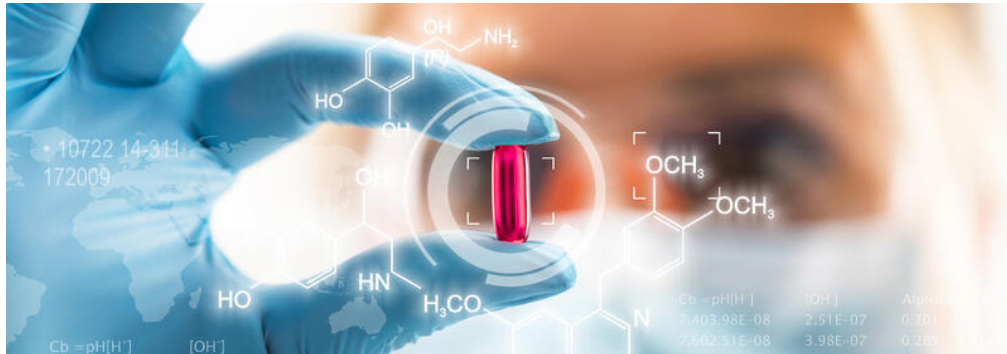


## Employers & Biosimilars: Stories from the Real World



### Pharmaceutical Products Landscape

Today's landscape is rapidly changing, with new and emerging therapies appearing around the world. These changes are having a profound impact on how medicine is practiced, and care is delivered. We must ask, how are providers expected to keep up with all the new treatments and protocols for care delivery? Consider these statistics:

- Up to 20,000 products have been approved by the [FDA](#).
- 500 cell and gene therapies are in the pipeline awaiting FDA approval.

This quandary produces a new set of challenges for employers who are struggling with achieving the best health outcomes at the lowest unit cost. This is especially important because the clinical community has not fully established standards of care for new pharmaceutical therapies, which is slowing the adoption of biosimilar drugs as replacements for originator drugs. History reminds us how long it took for generic drugs to become widely accepted.

### LOOK FOR THIS ICON



Throughout the action brief look for this icon which represents quotes from health benefits professionals on their perspectives related to biosimilars. You will also find real employer stories on:

- Leading practices with opportunities around savings.
- Navigating the process of increasing access and adoption.
- Shaping the design and administration of your strategy.
- Determining barriers that exist when confronting inclusion and payment.
- Understanding how artificial price increases for rebates are being used to discourage adoption.
- Recognizing the support needed to educate physicians and patients.



*MBGH launched this project to spotlight biologics and the role of biosimilars as a strategic initiative to improve health outcomes while generating substantial saving. As a coalition they are focused on best practices and work closely with employers who are early adopters and innovators to capture their stories.*

*Clinicians need to gain more experience with biosimilars. Employers promote this by placing them on a lower cost prescription tier.*



## Good News/Bad News

Specialty and biologic drugs represent [53% of drug spend, up from 27% in 2010 and driven by growth in autoimmune and oncology therapies](#). These medications account for the good news/bad news scenario that keeps employers awake at night. The good news is these innovations have provided relief for people with medical conditions that previously had little or no options. The financial impact of these medications is the bad news and is driven by three factors: 1) significant number available; 2) increased utilization; and 3) cost. As costs continue to rise and financial pressure mounts, employers need effective cost management strategies, but have few levers to pull.

### What is a Biosimilar?

Biosimilars are “highly similar” to the FDA-approved biologic drug and have no clinically meaningful differences from the biologic originator in terms of safety, purity and potency. They also have the same route of administration, strength, and dosage form and share the same potential side effects. Biosimilars meet all of the FDA’s rigorous approval standards.



*Transparency, truth and collaboration is what’s needed to fix pharmacy benefits today. MBGH wants employers to get there by helping them have more control and confidence to work with their vendor partners so that each patient gets the right drug the first time, at the right site of administration and the right price. Protecting and empowering employers is our stake in the ground. Using biosimilars can help!*

*Cheryl Larson, President & CEO, Midwest Business Group on Health*



### Generics First



Almost 90% of all prescriptions dispensed today are generic, with prices being 80-85% lower than brand counterparts. The opportunity to execute the same strategy for biosimilars is relatively easy and makes good sense. Adding a lower copay or coinsurance tier, along with a good education campaign, can promote both patient and physician adoption.

Two pricing tiers can also facilitate a biosimilar first strategy with the patient being required to pay the difference between the cost of the biosimilar and the originator drug when the originator is favored. Patients can have great influence on physicians and their prescribing patterns when they are economically involved.

### Seeking Value-Based Solutions

Rapidly rising costs are driving the need for employers to begin making tough ethical and financial decisions about the value of a drug and the organization’s ability to pay for it. As plan sponsors, they need to ensure their dollars are being used efficiently for plan beneficiaries. Progressive employers are actively seeking value-based solutions that focus on the total cost of care and asking: **Does this medication bring value to the patient, the employer, neither or both?**

To identify value, employers must look at both the clinical and cost impacts of the medication. These analyses must involve the expertise of carrier/PBM medical and pharmacy experts and consultants to provide unbiased answers to the value equation, identify opportunities to eliminate wasted spend (more cost-effective



drug distributors, lower cost sites of care, self-administration, etc.), and assist in plan coverage decisions.



## Employers Economics of Biologics & Biosimilars

The IQVIA Institute's Report on [Biosimilars in the United States 2020-2024](#) reveals:

- 64% of biologics (\$135 billion) are potentially open to biosimilar competition.
- Currently, there are [40 FDA approved biosimilars](#). The availability and use of biosimilars has accelerated and is on track to reduce drug costs by \$100 billion over the next five years.
- Since the passage of the [Biosimilars Act \(BPCIA\)](#), \$17 billion of biosimilar spending has been associated with saving \$37 billion.
- Savings are expected to increase five-fold over the next five years as newly approved biosimilars launch and existing biosimilars see continued uptake and price reductions.

## Biosimilars & Medical Benefits

Because most drugs run through the medical benefit, it is important to recognize the following:

- Carriers hold the contracts with the providers that dispense the drugs through the medical benefit.
- Carriers usually define the provider contract as proprietary; nothing is known about where they procured the drug or what the negotiated rate is, and no information is provided about the rebate structure or incentive.
- Carrier contracts determine the reimbursement for site of care administration, which can dramatically increase costs.
- The role of Medical Care Management within the carrier can define how and when biosimilars are appropriate and must be used for plan coverage.



*Now is the time for employers to act! With the rapid expansion of specialty drugs in the market, we need to pay attention to opportunities that create savings for our members and the plan through the medical and pharmacy benefit. Our fiduciary status depends on it!*



## Why Has Biosimilar Adoption Been Slow in the US?

[A 2019 assessment of factors affecting health care provider knowledge and acceptance of biosimilar medicines](#) revealed numerous reasons for physician reluctance in prescribing biosimilars, including lingering uncertainty about the safety and efficacy of the drugs as well as concern that carriers may not cover them. Patient reluctance can also be a barrier to use. [Education focused on areas](#) of provider concern – immunogenicity, clinical trial evidence and interchangeability – may help to bridge knowledge gaps and increase prescriber comfort with biosimilars. Providers and patients often voluntarily or are required to seek plan coverage authorization before prescribing, supplying and/or using high-cost specialty drugs. Employers can promote provider and patient education by requiring that carriers/PBMs supply such

education during the authorization process.

To date, biosimilar entry into the US market has been slow, minimally effective at lowering prices, and has failed to overcome the impacts of intermediaries (PBMs, carriers, TPAs). While Congress and state policymakers continue to evaluate additional policy changes that would increase availability and accessibility of biosimilars, more can be done outside of legislative changes to improve competition and uptake. Plan administrators and employers can't do it all, but there are some things they can do to ensure best practices for adoption of biosimilars. (see Employer Action Steps on page 6)

## International Biosimilar Use Supports US Adoption

The European Union and other international locations have extensive experience with biosimilar use that has:

- Provided clinical evidence that biosimilars are as safe and effective as the biologic originators.
- Demonstrated cost savings of up to 30% by substituting biosimilars for originator drugs.
- Shown how market competition can generate savings across the specialty drug continuum.



## Employer Stories

In 2021-2022, MBGH conducted a project on employer experiences with biosimilars that focused on:

- Increasing their acceptance as appropriate therapy
- Tracking utilization by drug class in both medical and pharmacy data
- Reducing copays and coinsurance to make them more affordable

Project activities included employer interviews, work groups and a panel at the *Employer Forum on Pharmacy Benefits & Specialty Drugs* in June 2022. The employer panel shared insights on their experience implementing a biosimilar strategy. Their stories and the lessons learned are provided below.



*Most progressive employers have integrated biosimilars into their plan design, while others need more information to ask the right questions with their vendor partners.*

### Employer Story #1 – A Proven Solution

Employer is a Midwest-based, Fortune 500 Construction Equipment Manufacturer Company (approximately 144,000 employees):

- Of the \$13.2 million adjudicated on biosimilars and innovator drugs over a three-year period, \$2.4 million, or 18% were for biosimilars. The employer was not concerned about low utilization because biosimilars were not available during the entire study period.
- Over 90% of biosimilar utilization was adjudicated under the medical plan and compliance was almost 100% with 2 different carriers. When biosimilars were not being used, biologic originator utilization was clinically or financially appropriate.
- 10% of biosimilar utilization was covered under the pharmacy benefits plan where plan design levers, such as formulary and prior authorizations, produced 100% compliance with biosimilar utilization.
- Biosimilars were negotiated at about 30% less than the biologic originator drugs; there were a few exceptions where biosimilars were intentionally not used when lower net cost opportunities were available.
- While biosimilar pricing was good in the pharmacy benefit, there was more opportunity to improve unit cost in the medical benefit based on the

delivery cost of infusible drugs. When considering total unit cost of care the employer discovered they could have saved an additional \$4 million if their members had consistently used a more cost-efficient site of service. Future prioritizing to appropriate sites of care will serve as an important cost saving strategy.

- Make sure to conduct research on how carriers are promoting appropriate use of biosimilars and if they are not, be change agents for performance improvements.

#### Key Takeaways

- Ensure your carriers have appropriate biosimilar language incorporated in medical management practices.
- Review carrier guidelines for site of care and bundled pricing to ensure lowest total unit cost of care.
- Confirm how carriers intend to address pipeline drugs.
- Early and ongoing dialogue, along with contractual language with your carrier and PBM, are key in requiring biosimilar utilization as a high priority.
- Using a data warehouse will enable you to get the data, or your contract terms should require it is provided to you in a way that is meaningful and easily evaluated.

### Employer Research, Resources & References

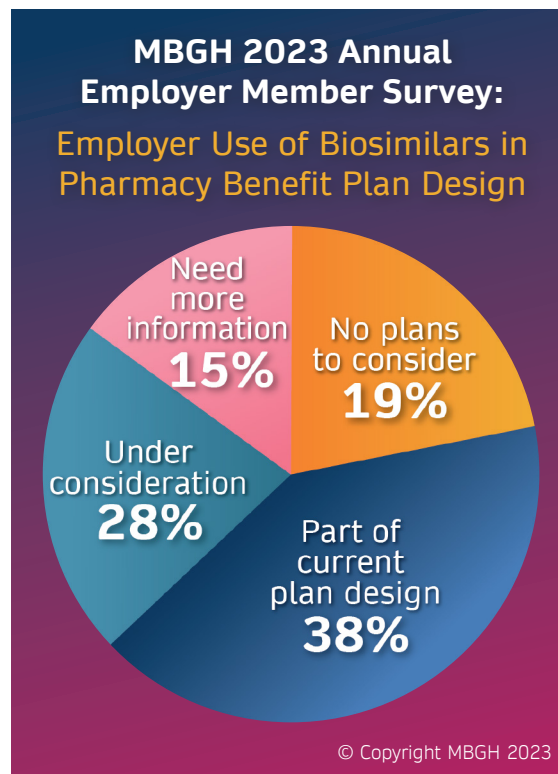
According to the [\*\*RAND Corporation\*\*](#), use of biosimilars in the US could lead to a reduction of \$24 - \$150 billion in direct spending on biologics between now and 2026.

According to the [\*\*CenterforBiosimilar.com\*\*](#), pricing competition between biologics and biosimilars may actually lower prices overall or force out higher priced drugs.

[\*\*Willis Towers Watson's 24th Best Practices in Health Care Employer Survey\*\*](#) found that 30% of employers have appropriate formulary strategies to leverage available biosimilars. An additional 39% of employers are planning to take a more active approach in the near future.

The FDA's current list of licensed biological products with biologic originator drug exclusivity and biosimilarity or interchangeable evaluations can be found in the [\*\*Purple Book\*\*](#).

- Analyze data from both medical and pharmacy claims and continue to assess lowest net cost opportunities and have clinical paths redirect to biosimilars, as appropriate.
- Better pricing opportunities through the medical benefit will need to continue to be explored as more drugs emerge and sites of care delivery evolve.
- Available pharmaceutical reports that include biosimilar trends are very useful tools if they benchmark employer utilization against other like employers and the national market.
- Be mindful of ever emerging drugs and therapies in the pipeline, especially with drugs like Humira coming off patent.



*Rebates are a large part of a biosimilar replacement strategy as the reference product Humira and others like it will still be offering rebates even after patent expiration.*



## Employer Story #2 – Incremental Gains

Employer is a Midwest-based, Fortune 500 mutual insurance and financial services company (approximately 7,700 employees):

- This employer stated, “a biosimilars strategy should be as much as 30% cheaper than the originator drugs to make switching to them cost effective.”
- Unfortunately, because of issues with their payer, switching to biosimilars did not have the predicted savings. In fact, some biosimilar pricing was not cheaper than the drugs they were intended to replace; this demonstrates how PBM pricing, formulary decisions, and rebates can distort actual biosimilar prices when they are covered under the pharmacy benefit.
- To address cost management on the medical claims side, they added a point solution to manage specialty drug total cost of care. The solution conducted a clinical analytics review for drug therapy, dosing and site of care administration to optimize cost and outcomes. The clinically

appropriate use of biosimilars then becomes standard practice, which avoids disruptions in treatment plans.

- Employer plans to target rheumatoid arthritis biosimilars because the biologic originator drug’s patent protection is ending.

### Key Takeaways

- Biosimilars will not always be the most cost effective choice.
- Due to the variability in PBM contracting, biosimilars may not always be less expensive; this must be assessed and explicitly included in the contract.
- Look at solutions in your medical and pharmacy benefit for interventions and select point solutions that specialize in specific areas of clinical management.
- Re-evaluate your organization’s biosimilar strategy annually as this is a rapidly changing environment.
- Do not rely on a general consulting firm or your PBM to have all the answers; they may not always have the necessary expertise to provide accurate, up-to-date information.

### Cost/Benefit Analysis with Disappointing Results

An employer conducted a biosimilars cost/benefit analysis with their PBM:

- They learned the cost savings of implementing biosimilars would not be large enough to justify losing rebates on originator biologics.
- They shared their concerns with the PBM, indicating this would result in continued high prices for biosimilars because an originator rebate chasing strategy would inhibit biosimilar market access and growth.
- Unfortunately, these concerns fell on deaf ears as the PBM said they had to do what was right for their employer clients and could not worry about the market.



## Employer Story #3 – There are STILL Challenges with Getting Your Data

Employer is a financial services company (approximately 6,000 employees):

- Like many others, this employer had very little knowledge or information about the plan's volume, utilization or data on biosimilars.
- They set out on a journey to gather all the necessary information from the carrier and PBM and submitted a well-defined request for data on all brand drugs and biosimilars,
- The intent was to receive three years of data, including the tax ID number (TIN) of all treating providers and all costs contained in the J, Q and M codes used by the carrier.
- The employer needed detailed data to understand the plan's experience, patterns of utilization and where the opportunities for biosimilar substitution could be cost effective.
- The carrier and PBM sent the requested information in raw format rather than as a categorized summary of results, making it difficult for the employer to assess where beneficial

change could be made. This receipt of unusable data resulted in contract changes with both the carrier and PBM.

### Key Takeaways

- As employers, we must recognize that KNOWLEDGE IS POWER.
- For employers to effectively manage plans, we must have full access to our data and understand how to interpret it in a meaningful way. This is especially important in our role as plan sponsor.

## Employer Action Steps

1. Review the [FDA's Purple Book](#) list of approved biosimilars in the US. This list includes the biosimilar product, along with the originator biologics (reference) product.
2. Ensure that your Carrier and PBM are evaluating each new biologic prescription for appropriate coverage to your plan:
  - a. Where a biosimilar is indicated for administration through the medical plan, work with your carrier to assure delivery to appropriate sites of care.
  - b. Where a biosimilar is indicated for dispensing through the pharmacy plan, work with your PBM to assure proper medication therapy management measures are in place.
3. Clearly define biosimilars in your contracts and ensure language prohibits the use of an originator drug over a biosimilar based exclusively on carrier/PBM financial gains.
4. Require your contract language explicitly states:
  - a. Your organization's right to independently audit all data and ensure that the processes are clearly defined.
  - b. Provider networks are required to use biosimilars when clinically appropriate.
5. Establish standard reporting from carriers/PBMs that analyze utilization specific to biosimilars.
6. Consider and discuss plans for the appropriate transition of grandfathered members at a future date.
7. Require carriers develop and implement educational and/or incentive programs to motivate providers to prescribe the most clinically efficacious and financially efficient drugs first.
8. Require use of pharmacogenomic and biomarker testing prior to distribution of certain biologics or biosimilars as clinically appropriate; called test to treat, this will reduce unnecessary prescriptions.
9. Require carriers/PBMs establish medical guidelines for new biologics in a time efficient manner that address appropriate biosimilar substitution and the use of cost-efficient sites of care.
10. Grandfather members that are currently receiving a biologic originator based on meeting consistent and established clinical criteria (see non-medical switching).
11. Add a lower cost share tier within the benefit plan design to drive biosimilar utilization.
12. Consider a carve-out for specialty pharmacy for improved utilization management; ensure you have contract language protection that states you will not have to pay more or will lose rebates as a result of a carve-out.
13. Ensure effective and efficient prior authorization (PA) or step therapy protocols are in place.
14. Consider managing PA through an independent pharmacy and therapeutic committee (P&T) to avoid favoritism towards an originator biologic due to misaligned financial incentives; ask what their PA approval rate is and remove PA for drugs with approval rates greater than 85% as the cost to administer outweighs the savings.
15. For new prescriptions, require the use of biosimilars first when there are no clinical criteria to avoid doing so.
16. Consider use of narrow networks and/or centers of excellence to promote biosimilar uptake.

Regardless of the type of drug, employers should require 100% pass-through of all monies, rebates, credits and incentives received by the carrier/PBM from the drug manufacturer for the use of any specialty and non-specialty drugs by a covered plan member.

## News Alert from the Biosimilars Forum



The Center for Medicare & Medicaid Services (CMS) recently released guidance for implementation of ASP+8% policy, a provision included in the Inflation Reduction Act. **This policy change is effective for five years beginning October 1, 2022.** CMS' formal guidance, entitled 'Temporary Increase in Medicare Part B Payment for Certain Biosimilar Biological Products', outlines new Medicare Part B payment reimbursement raises for certain biosimilar drugs. Specifically, the ASP+8% policy works to incentivize the use of safe and effective biosimilars through a two percent additional increase in Medicare payments

for certain biosimilars – added to the prior 6% increase. Now that this has been passed and signed into federal law, we are pleased

that CMS is initiating guidance and working to inform applicable providers about this important adjustment. You can also find our posts on the [Biosimilars Forum website](#), [Twitter](#), and [LinkedIn](#) regarding this change. We encourage you to keep in touch with our social channels for important information and updates from the Forum.

<https://biosimilarsforum.org/about-us/>

**Biosimilars**  
F O R U M

## Guidance on Non-Medical Switching

For many patients, finding the right medication was a painstaking process of trial and error. Using a less costly alternative makes sense most of the time, but for patients with chronic and complex illnesses who depend on advanced medical therapies to stabilize their conditions, switching to a less costly drug for reasons not related to improved clinical efficacy or decreased side effects may create

treatment complications and increase total cost of care. Drug management review tactics need to be aligned for the best outcomes of therapy from both the clinical and economic perspectives. Benefit strategies and tactics need to be consistent throughout the continuum – prescribing, coverage determination, dispensing, patient use – to avoid unintended adverse consequences.

Use of grandfathering or exceptions for those currently receiving a biologic originator may be appropriate but should require consultation with the physician regarding a plan for future biosimilar use, particularly when there is evidence supporting improved clinical outcomes, reduced side effects, improved quality of life and/or lower costs.

## Employer Research, Resources & References

See these examples of how employers and stakeholders are using biosimilar strategies to achieve savings.

- [The Case for Letting Biosimilars Compete](#), *Health Affairs*, Sameer Awsare, Anthony Barrueta, Amy Gutierrez, Polly F. Webster, December 2019
- [Biosimilar Medications: Savings Opportunities for Large Employers](#), ERIC (the ERISA Industry Committee) and John Hopkins University, March 2020
- [Biosimilar Savings Opportunities in the Medical Benefit: A Large-Employer Case Study](#), Business Group on Health, Matrix Global Advisors; A. Brill & C. Robinson, August 2019
- [Employer Rx Value](#), National Alliance of Healthcare Purchaser Coalitions & the National Alliance Medical Director Advisory Council (NAMDAC), 2020
- [Employer Strategies for Use of Biosimilar Pharmaceuticals](#), prepared for the ERISA Industry Committee (ERIC) by Segal, March 2020
- [The Biological Product Patent Transparency \(BPPT\)](#), Amendments to 42 U.S.C. 262(k) of the Biologics Price Competition and Innovation Act (BPCIA)
- [Dean Foods: Carving Out Specialty Pharmacy & Using Biosimilars to Control Specialty Spend](#), *AJMC*, October 17, 2020



*Don't accept the status quo. If your vendor partner doesn't want to play, there are others waiting. Just make sure their biosimilars offer the best price – sometimes the originator biologic is more cost effective!*

## About MBGH

MBGH is one of the nation's leading and largest non-profit employer coalitions. Members are represented by human resources and health benefit professionals for over 150 mid, large and jumbo self-insured public and private companies who provide health benefits for over 4 million lives. Employer members spend over \$15 billion annually on health care. Since 1980, members have used their collective voice to serve as catalysts to improve the cost, quality and safety of health care benefits.

[mbgh.org](https://mbgh.org)

Click on more information about MBGH below.

## Authors



Cheryl Larson  
President & CEO  
MBGH



Alex Jung  
Founder  
Alex Jung  
Consulting, LLC



Kim Dwyer  
Vice President  
Inspira Health



Sandra Morris  
Principal  
About Quality Benefits  
Design, LLC

The information provided in this resource is based on the authors' and contributors' experiences working in the health benefits and health care industry. For more information on any aspect of this report, please contact [info@mbgh.org](mailto:info@mbgh.org).



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