



Transforming Pharmacy Benefits: *The Role of Biosimilars*

Specialty medications, of which **biologics and biosimilars** is a large part, are a good news/bad news scenario that employers are grappling with. On the good news side, innovation in drug discovery has brought forth a number of new medications. These medications have brought relief to people with medical conditions that previously had limited or no options. According to **PwC**, in 2010 80% of medications that employers were paying for were non-biologic drugs and 20% were biologic drugs. According to **IQVIA**, this number has changed drastically over the last several years. In 2018 the number of biologic drugs that employers were paying for jumped to 42%. Unfortunately, the clinical relief

has created a new challenge for both employers and patients in need, financial insecurity. The financial impact of these medications is the bad news part of the scenario and it is driven by three factors:

1. Number of biologic drugs available
2. Utilization of biologic drugs
3. Cost of biologic drugs

Let's look at the third factor on the cost of biologic drugs. In an article written by **AARP**, prices rose by more than 7% in 2017. This is more than 3x the overall rate of inflation. This was not a one-time event. Costs continue to escalate year over year, and per capita spending has increased by up to 49%. The cost impact of this alone creates a significant burden on employers. In addition to struggling with how to manage these costs, recent

Throughout this report you will see quotes from human resources/health benefits professionals that represent mid, large and jumbo companies.



Look for this icon.

events such as COVID-19 will cause employers to actively seek out solutions to modify overall health care costs. Strategies that mitigate risk, such as member education around plan cost difference, product switching by providers and innovative benefit coverage, are more important than ever.

Employers Need Support and Guidance in Managing Specialty Drugs

Managing specialty drug costs continues to be a top priority for employers. Because they serve as the "real payors" of health care, employers are under increased pressure to reduce costs, optimize plan performance and generate savings for the plan and participants. One of the biggest challenges they face today is the role of pharmacy benefit managers (PBMs) whose economic model and consolidated power can result in employers losing a lot of leverage due to PBM transparency issues on pricing, rebates and contracting. This can result in misaligned incentives which can lead to price increases without providing equivalent value for the purchasers of benefits.

Employers need to:

- Think differently about how to manage the pharmacy benefit.
- Take action on addressing waste, low-value drugs and excess costs often caused by PBMs and other pharmacy benefit middlemen.
- Make ethical and logical decisions over what a drug is worth and the employer's ability to pay – as plan sponsor and fiduciary, it's critical that dollars are used efficiently for plan beneficiaries.
- Focus on innovative approaches to specialty drug management.

For over 10 years, MBGH's **National Employer Initiative on Specialty Drugs** has

supported health benefits professionals in making critical and informed decisions to better manage specialty drug costs and offers guidance, tools and resources to support their efforts. **Check out the back page for more information and links to no-cost employer resources from this important employer-directed initiative. Look for this logo!**



"Transparency, truth and collaboration is what's needed to fix pharmacy benefits today. MBGH wants to help employers get there by giving them more control and confidence to ensure each patient gets the right drug at the right price. This is MBGH's stake in the ground!"

Cheryl Larson, President & CEO, MBGH

Looking for Solutions

Employers have been actively seeking solutions to managing specialty drugs while looking at their impact on total health care costs. The first step to creating solutions is to identify the value proposition. Does this medication bring value to the patient, the employer, neither or both? In order to identify value one must look at both the impact and the cost of the medication. The cost equation must include costs attributed to the distributor (e.g., McKesson, Cardinal or Amerisource Bergen), the PBMs and other middlemen. Each of these organizations increase the cost of the medication to the employer. Thus, employers need to ask themselves, do these organizations just add to the cost or do they bring additional value? As costs continue to rise and the pressure mounts, employers need effective cost management strategies but have few levers to pull. What can an employer do to impact specialty drug spend trend today?

One of the last major transformations in managing medication costs was employer use of "generics first." Although adoption was slow, once generic competition gained momentum, costs went down significantly. Today, almost 90% of all prescriptions dispensed are generic. By increasing volume and lowering the total cost, employers can provide the benefit of low to no copays when a generic is dispensed.

The Role of Biosimilars

Although biosimilars are not the same as generics, there was hope that they would hold the same promise and offer employers the option of a less costly alternative to the brand name originator or reference drug (biologic), while offering employees and family members the clinical impact that these medications had to offer. While employers understand that the cost of biosimilars will not drop to that of a traditional, non-biologic generic, it is still likely that biosimilars can bring cost relief to the high cost of biologic medications.



According to the [RAND Corporation](#), use of biosimilars in the US could lead to a reduction of \$54 billion in direct spending on biologics between now and 2026 – with a range of \$24 to \$150 billion.

Similarly, according to the [CenterforBiosimilar.com](#), pricing competition between biologics and biosimilars may actually lower prices overall or force out competition as a result.

Regardless of the lack of success to date, more and more employers are intrigued by the idea that biosimilars might offer a lower-cost option for those who need expensive biologic drugs. In [Willis Towers Watson's 24th Best Practices in Health Care Employer Survey](#), 30% of employers have appropriate formulary strategies to leverage available biosimilars when with another 39% planning to take a more active approach in the next two years.

"We need to develop a public document that states: Here are 25 biosimilars, and here is the drug each matches up against, and have employers take that document to their next PBM meeting vs. rely on their consultant."

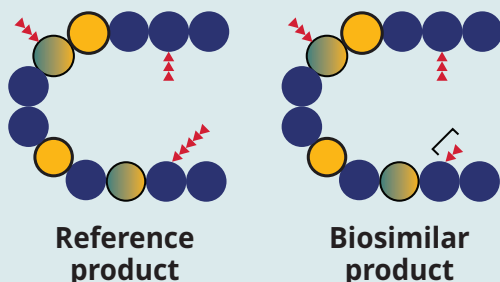


"Clinicians also need to gain more experience with biosimilars. Employers can put biosimilars on a lower tier to start. Following these steps, employers can then demand that biosimilars have a lower co-pay."

What is a Biosimilar?

Biologic drugs are the [fastest growing class](#) of therapeutic products in the US and account for a substantial and increasing portion of health care costs. According to the FDA, a biosimilar is a drug that is “highly similar” to its biologic originator. Unlike a generic, which is chemically the same as the brand name drug, a biosimilar’s molecular make-up may vary from the biologic reference drug in its “clinically inactive components.” However, it is no less safe and effective. Biosimilars are thoroughly tested and must ultimately meet the FDA’s rigorous approval standards for the medical conditions described on the product labeling.

Although relatively new in the United States, the [European Union](#) has approved a large number of biosimilars with widespread uptake. They have the most extensive experience with the use of biosimilars, providing clinical evidence that they can be as safe and effective as biologic products for approved indications. In addition to the clinical evidence and efficacy of biosimilars, the EU found that once a biosimilar was introduced, financial competition between the biologic and the biosimilar ensued which lowered the cost of the biologic drug causing savings across the specialty medication environment. Of note, the EU and US’s FDA have a different regulatory environment and approval system. Drug interchange is not relevant in the EU.



Brackets are used to show sites with minor variations.
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Why Has Biosimilar Adoption Been Slow?

First, it is important to understand why employers, providers and patients have not embraced the use of biosimilars. There may be several reasons for this, including:

- ▶ Biosimilars are subject to strict FDA regulations, often slowing down the approval process.
- ▶ Biosimilars were initially priced less competitively than expected, making it easy for the originator drug to compete.
- ▶ Multiple patents can be in place to protect a biologic product and block biosimilars from entering the marketplace.
- ▶ Price negotiations with payers like PBMs that rely heavily on rebates and discounts to get a drug on formulary may favor the use of a biologic originator over a biosimilar.

Physician adoption of biosimilars has also been low due to lingering concerns and uncertainty about the efficacy and safety of the products and/or that carriers may not cover them. Much of these concerns mimic preference experiences with generic drug adoption from years ago. Unlike generics which are “interchangeable” with the brand drug, biosimilars are not “interchangeable” with the biologic drug. When a drug is shown to be interchangeable and approved by the FDA, it means it may replace the biologic drug without consulting the doctor because the same clinical results are achieved with the interchangeable drug (biosimilar). This means that today, physicians must prescribe the biosimilar in order for the patient to receive it over the biologic.

According to a [2018 HRI survey](#) of clinicians, 55% were unfamiliar with biosimilars and 35% said they had never prescribed one; 65% of those surveyed said they would be more willing to prescribe biosimilars if there was a meaningful cost difference for their patient.

As part of the Affordable Care Act (ACA), the government created the [Biologics Price Competition and Innovation Act](#), an abbreviated licensure pathway for biologic products that are demonstrated to be “biosimilar” to or “interchangeable” with a biologic product that is no longer protected by a patent. View the [Purple Book](#), a database of FDA approved biological products. As of today, no biosimilars have been designated interchangeable but this could change in the future as it has in many other countries.

To date, biosimilar entry into the US market has been slow, minimally effective at lowering prices, and has failed to overcome discounts to middlemen. While [Congress and state policymakers](#) continue to evaluate additional policy changes that would increase availability and accessibility of biosimilars, what else can be done to improve competition and uptake in the US?



"Now is the time for employers to act. The rapid expansion of specialty drugs in the market requires employers to pay close attention to opportunities to create savings for their members and the plan for drugs dispensed through the pharmacy and medical benefits."



Call to Action

If employers are serious about driving down costs, while ensuring their members have access to therapies that treat complex chronic, life threatening and rare medical conditions, this is the time to act on the use of biosimilars. Here are steps employers can take now:

Action Steps for Employers

1. Provide the [FDA's list of approved biosimilars](#) to your carrier and PBM for addition to your formulary and have a discussion on how best to adopt them. Also, see [list of currently approved biosimilars](#) in the US by administration/dispensing through the medical and/or pharmacy benefit.
 - Where a biosimilar is indicated for administration through the medical plan, talk to your carrier and consider a carve out to the pharmacy benefit to ensure equal management.
 - Where a biosimilar is indicated for dispensing through the pharmacy, talk to your PBM and ensure proper medication therapy management measures are in place (see bullets 5 and 6).
2. Clearly define biosimilars in your contracts.
3. Ensure your contract has 100% pass-through of all rebates received and that audit rights are in place.
4. Track utilization by drug class in medical and pharmacy data to determine where the greatest opportunity to increase the use of biosimilars exists.
5. Manage the prior authorization of biologic drugs through an independent pharmacy and therapeutic committee to avoid a conflict of interest due to misaligned financial incentives to approve one drug over another.
6. If #5 is not possible or feasible, ensure the correct prior authorization or step therapy protocols are in place for each biosimilar.
7. Ask for clinical criteria, including coverage for conditions that the biologic is approved for, but the biosimilar is not.
8. Consider utilization of pharmacogenetics/genomics testing prior to filling a biosimilar prescription (if not in place for the biologic drugs, consider a wide application).
9. Reduce the copay or coinsurance when a biosimilar is administered (consider Tier 1 or Tier 2 if your plan is multi-tiered).
10. For new prescriptions, require utilization of biosimilars first (step therapy consideration).
11. Grandfather members currently receiving the originator biologic based on meeting consistent and established clinical criteria (see non-medical switching below).
12. Consider and discuss future plans for appropriate transition of the grandfathered members at a later date.
13. Talk to carriers about educating and incenting providers to prescribe the lowest cost, most efficacious drug first.

"Biosimilars will bring additional complexity and cost to pharmacy benefits and we need to be prepared to address the complexity and help control the costs."



"Most progressive employers have put biosimilars on their formulary, others do not even know they exist."

Impacts:Non-Medical Switching

For many patients, finding the right therapy was a painstaking process of trial and error. Using a less costly drug alternative makes sense most of the time, but for patients with chronic and complex illnesses who depend on advanced medical therapies to stabilize their condition, switching to a less costly drug for reasons not related to efficacy or side effects may create treatment complications and increase total cost of care.

Prior Approval and other drug management review tactics need to be aligned for the best outcomes of therapy from both a clinical and economic perspective. 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 the originator biologic may be appropriate but should require consultation with the physician regarding potential biosimilar use.

The physician/patient relationship is also key in determining whether non-medical switching is appropriate with each involved in the discussion.

Employer Research, Resources & References

See examples of how employers and other stakeholders are using biosimilar strategies that translate into savings.

[The Case for Letting Biosimilars Compete](#), Health Affairs, Sameer Awsare, Anthony Barrueta, Amy Gutierrez, Polly F. Webster, December 2019

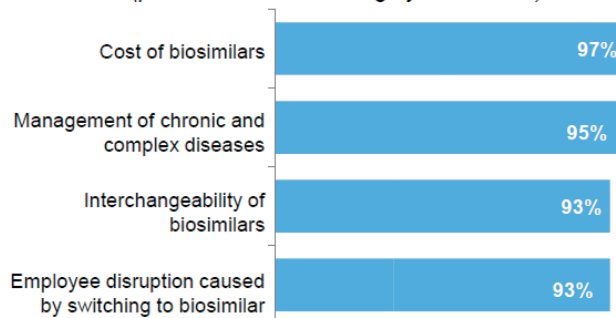
Summary: In testimony to the House Energy and Commerce Committee in March 2019, Anthony Barrueta, senior vice president of government relations for Oakland, California-based Kaiser Permanente, said that the biosimilar Inflectra is used 75% of the time in place of the biologic Remicade at Kaiser Permanente, compared to only 3% for the rest of the market. In his testimony, Barrueta attributed Kaiser Permanente's success to "...evidence-driven formularies developed by our physicians and pharmacists, our ability as an integrated system to generate and disseminate unbiased information about drugs and our restrictive approach to marketing by pharmaceutical sales representatives in our facilities."

[Biosimilar Medications: Savings Opportunities for Large Employers](#), ERIC (the ERISA Industry Committee) and John Hopkins University, March 2020

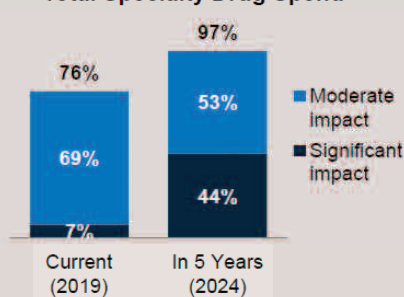
Summary: Members of ERIC (The ERISA Industry Committee) conducted a study to identify the savings that large employers could realize if the current demand for biologics was replaced by biosimilars.

Benfield/Gallagher Survey of Employer & Coalition Trends in Health Management, September 2019

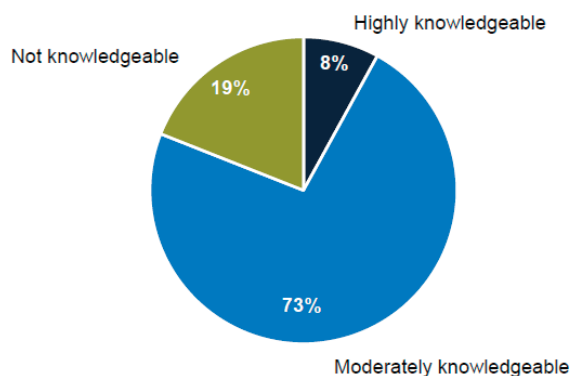
Concerns Pertaining to Biosimilars
(percent moderate to highly concerned)



Expected Impact of Biosimilars on Total Specialty Drug Spend



Employer Familiarity with Biosimilars
(including rules around interchangeability)



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"Don't accept the status quo. There is a lack of willingness to change and employers need disruption and transformation. The easiest way to do this is through pharmacy benefits. If one PBM doesn't want to play, there are others waiting."

13 large, self-insured employers looks at two highly utilized biologic/biosimilar drugs. The study found compelling savings when utilizing biosimilars as compared to their biologic counterpart.

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

Summary: This large employer case study highlighted a manufacturer offering a high deductible health plan covering 80,000 members. It focused on 17 biologics with upcoming biosimilar competition. The study demonstrated three savings tiers dependent on utilization: Base Case: 30% savings (below biologic prices) with a 30% utilization; Optimistic Case: Up to 40% savings with a 50% utilization; or Best Case: 40% savings at a 75% utilization. The study recognizes that employers will have challenges to shift the utilization and suggests some possible interventions.

Employer Rx Value, National Alliance of Healthcare Purchaser Coalitions & the National Alliance Medical Director Advisory Council (NAMDAC), 2020

Summary: Stemming from a Spring 2019 roundtable meeting, the NAMDAC was asked to provide employers with a framework to address 4 key areas: High drug costs; Contracting for value strategies; Enhancing benefit design approaches; and Improving formulary management. This paper discusses the framework which also focuses on biosimilar utilization.

24th Annual Best Practices in Health Care Employer Survey, Willis Towers Watson, October 2019

Summary: The paper highlights key pharmacy cost control measures to address the continued rise in pharmacy costs for employers at over 5% in 2020. Of the control measures highlighted, the first one discusses improving formulary design inclusive of leveraging biosimilars to reduce costs.

Employer Strategies for Use of Biosimilar Pharmaceuticals, prepared for the ERISA Industry Committee (ERIC) by Segal, March 2020

Summary: This paper introduces biosimilars, the market challenges facing them and the strategies employers can follow to increase their use and/or help manage ongoing utilization. Of note, the first section covers the employer's role in promoting biosimilars with four solid steps employers can take to address this new opportunity.

The Biologic Patent Transparency Act, sponsored by Senators Susan M. Collins and Tim Kaine, cosponsored by Senators Portman, Shaheen, Braun, and Stabenow

Summary: This proposed legislation, if passed, will impact biologics and patent disputes and "...requires the

"Biologics will force employers into a one-payor system if costs are not adjusted, so there needs to be a generic off-flow."



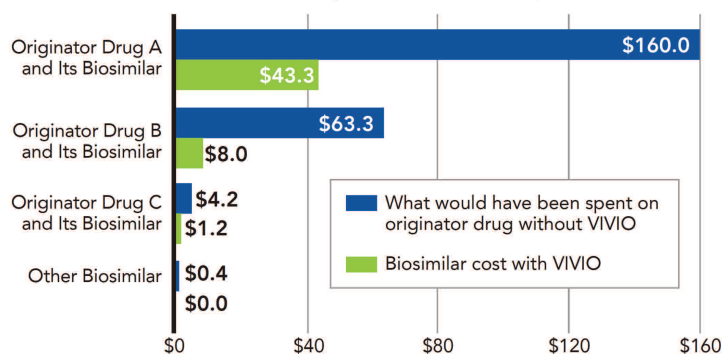
"Rebates are blocking the utilization of biosimilars. We tell everyone to use a generic first, and we should be doing the same with biosimilars."

manufacturers of approved products to disclose and list patents covering their products with the FDA (FDA list is commonly referred to as the "Purple Book"). By requiring patent information to be published, the bill imposes transparency requirements that are similar to what are required for small molecule drugs.

Integrated Benefits for Specialty Pharmaceuticals: Access and Management, Access Market Intelligence Winter 2019

Summary: This purchasable paper (\$49.95) covers a wide range of solutions and steps employers can take to manage overall costs with specialty pharmaceuticals. It discusses the role biosimilars will have on the overall cost reduction in this area.

Dean Foods Biosimilars Cost Savings in 2019
(Thousands of Dollars)



Dean Foods Case Study

About this Report

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

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National Employer Initiative on
Specialty Drugs & Biopharma
Employer Focused, Employer Driven



Midwest Business Group on Health
Campaign for Change in Health Care & Benefits

New Benefit Services & No-Cost Resources for Employers

- **EmployeeRxEvolution (ERxE)** – Progressive employer members are taking a bold step by integrating this fully-vetted service into their pharmacy benefit. ERxE enables employer members to leverage the total lives that MBGH represents for best contract terms, custom formularies, direct contracts with retail pharmacies and evidenced-based prior authorization for specialty drugs.
- **Online Specialty Drug Employer Toolkit** – Offers no cost tools, resources and checklists to support employer efforts, including:
 - **Drawing a Line in the Sand: Employers Must Rethink Pharmacy Benefit Strategies**
 - **Resolving to Control Drug Costs: Your PBM Contract Really Matters**
 - **Designing Specialty Drug Benefits Checklist**
 - **PBM Contract Checklist**
 - **PBM Audit Recommendations**
 - **Sites of Care Checklist**
 - **Plan Member Education Strategy**

New Report Coming Fall 2020

The National Employer Initiative on Specialty Drugs will release its next report later this year with a focus on:

- Drugs Running Through the Medical Benefit
- Oncology and Specialty Drugs
- Pharmacogenomics Medicine

The Power of MBGH!

Midwest Business Group on Health (MBGH) is one of the nation's largest non-profit coalitions of leading employers. Members are represented by human resources/health benefits professionals – collectively we serve as catalysts for change in addressing the US's health care challenges.



130+ Members

Self-insured
employers of all sizes



\$12+ Billion

Employer members' annual
health care benefits spend



4 Million

Total lives
represented

Report Highlight on Pharmacogenomics Medicine

Sometimes, a doctor does not know if a drug will be effective. Running a special "biomarker" test using blood or saliva will show if the drug will be effective, what dosage should be administered and if there will be adverse side effects. The use of pharmacogenomic testing to proactively determine if a drug works in a patient is growing. Although none of the biosimilars approved by the FDA currently include biomarker tests, employers and members can still save money by knowing in advance if a treatment works for that specific member. Learn as much as you can about pharmacogenomic tests and what you should cover.