

Improving Drug Management

Employer Strategies on Biosimilars

TABLE OF CONTENTS

Executive Summary	3
Key Observations	3
Recommended Actions for Employers	4
Project Overview	5
Employer Roundtable Discussions	6
Key Themes	6
Plan Designs	7
Formulary Design	8
Drug Pricing and Rebates	9
Biosimilar Availability	10
Site of Care and Drug Administration	10
Top Priorities for Employers/Purchasers over the Next Two Years	11
Employer Pre-Roundtable Survey Results	12
Participant Demographics	12
Key Observations	12
Employer Post-Roundtable Survey Results	13
Participant Demographics	13
Key Observations	13
Additional Background	14
Defining Biosimilars	14
Population Health and Precision Medicine	15
The Biosimilar Pipeline	17
Why is Europe Ahead of the US?	17
US Employers and their Move toward Biosimilar Adoption	18
Appendix: Approved Biosimilars	19
Project Team	21
Participating Coalitions	22

Sponsor Acknowledgment

The Biosimilars Forum is a nonprofit organization working to advance biosimilars in the United States with the goals of expanding access and availability and improving healthcare outcomes. Since its inception, the Forum has worked to expand the uptake of biosimilars throughout the healthcare system through policies that will increase access for patients and lower costs through increased competition. Forum members represent companies with the most significant U.S. biosimilars development portfolios.

EXECUTIVE SUMMARY



Biosimilars have garnered significant press over the past few years, with a primary focus on savings for employers. This savings is significant, as increased use of biosimilars will allow for a more competitive drug marketplace. Reduced barriers to biosimilar adoption could generate savings of about **\$25 billion over 10 years**, or roughly 0.5% of national spending on prescription drugs. However, other organizations, such as the Association for Accessible Medicines (AAM), indicate biosimilars savings could project upwards of **\$133 billion by 2025**, but only if policymakers encourage greater biosimilar adoption.

To help employers overcome these obstacles, the National Alliance of Healthcare Purchaser Coalitions (National Alliance) brought together seven regional coalitions and more than 60 employers for a series of roundtables across the country. Participating coalitions include:

- ▶ Economic Alliance for Michigan
- ▶ Florida Alliance for Healthcare Value
- ▶ HealthCare 21 Business Coalition
- ▶ Houston Business Coalition on Health
- ▶ Memphis Business Group on Health
- ▶ Lehigh Valley Business Coalition on Healthcare
- ▶ Washington Health Alliance

Key Observations

- ▶ Specialty drugs in the form of biologics have transformed the science and economics of drug management, and biosimilars are key to preserving economic competition in the drug marketplace, especially after patent expiration of the reference product (i.e., original biological product already approved by the FDA).
- ▶ The market is shifting from “standardized mass treatment,” with the patient as the end consumer, to a more personalized treatment model based on individual therapies — from “pills in a bottle” to “cells in a bag.”

- ▶ Lack of transparency and misaligned incentives in the US drug market have contributed to purchasers' lack of engagement and reduced adoption of biosimilars.
- ▶ Although biosimilars have begun to gain traction in the US, the European Union is several years ahead, with many blockbuster biologics reaching the market sooner and subject to competition from multiple biosimilars, resulting in lower prices and higher biosimilar uptake.
- ▶ The use of biosimilars will continue to expand in the US over the next few years, and purchasers should address key issues to take advantage of this market opportunity and continue to expand biosimilar adoption.

Recommended Actions for Employers

The roundtable discussions identified the following five areas where employers can take specific actions, which are detailed throughout the report:

- ▶ **Plan Design** — Amend coverage and communications to prioritize biosimilars and cover biomarker testing; implement an overall plan design that minimizes member disruption; limit any changes or grandfather current members' treatment cycles.
- ▶ **Formulary Design** — Insist on total transparency on formulary placement and specifically the economics of biosimilars; consider custom formulary design and targeted utilization management.
- ▶ **Drug Pricing and Rebates** — Focus on low-net-cost, while also considering the impact of gross costs on employee cost-sharing; understand how rebates affect overall drug pricing.
- ▶ **Drug Availability** — Ensure coverage of high-value biosimilars at an appropriate tier level, as lack of coverage can stagnate the market over time; use incentives to encourage adoption of all biosimilars in the same drug class over the reference product.
- ▶ **Sites of Care and Drug Administration** — Focus on the impact of the site of care on the cost of delivery; consider a preferred/tiered site-of-care policy.



PROJECT OVERVIEW



The National Alliance brought together seven regional coalitions from across the country to conduct roundtable discussions with their employer members about the current biosimilar landscape, current challenges to implementing biosimilars, and best practice strategies for making formulary and benefit design decisions.

More than 60 employers of various sizes and industries participated. To determine the appropriate starting point for the discussion, a pre-survey was disseminated to gain insights into employer challenges in adopting biosimilars, as well as other pharmacy-benefit trends and key concerns. Aggregate results are highlighted at the end of this report. Although the results were mixed, it was evident that some employers were quite far along in their adoption of biosimilars, while others were seeking to understand the shifting dynamics of the market, including what currently works and what is in the drug pipeline.

This report offers a summary of those conversations, employer strategies, and recommended actions employers can use in discussions with benefits consultants and payer partners as employers shape their own strategies.

EMPLOYER ROUNDTABLE DISCUSSIONS

Key Themes

During the roundtable discussions, several issues constraining biosimilar uptake were explored. From not having biosimilars on the formulary because of PBM restrictions to pricing and rebate concerns, employers are confused about how to control costs and increase utilization. These key themes emerged:

- ▶ Plan design
- ▶ Formulary design
- ▶ Drug pricing and rebates
- ▶ Drug availability
- ▶ Site-of-care and drug administration



Plan Designs

During some of the roundtable discussions, employers raised a concern that adding biosimilars and biologics might create confusion if an individual's treatment regimen were interrupted or triggered reimbursement restrictions. They also indicated their current plan designs did not adequately address coverage, and affordability was a challenge.

Most current plan designs for pharmacy coverage are simple three- or four-tier co-pay plans coupled with high deductibles. Many employers report that these are the designs consultants and PBMs have promoted. Some participants said they have begun to design cost-sharing based on drug classes and are considering further distinctions for cost-sharing for high-cost/high-value products to ensure access and affordability for employees.

Employers can create an additional tier or preferred reimbursement for biosimilars and biologics to reap the savings in unit price, or they can add these products to the branded tier without any need to change cost-sharing/co-pay models.

Recommended Actions for Employers

- ▶ Assess current plan design to ensure access to biosimilars and appropriate affordability for employees; put biomarking testing in place to confirm appropriate drugs.
- ▶ Implement an overall plan design that minimizes member disruption, limiting any changes or grandfathering a current member's treatment cycle.
- ▶ Ensure plan design is focused on a value-based approach that includes strategies to improve high-value care; evaluate financial trade-offs.
- ▶ Develop a strategy for each drug, considering market dynamics and treatment situation; ensure that plans communicate with physicians and members.
- ▶ Review co-pay tiers; consider strategies that limit a patient's cost; use coinsurance or cap out-of-pocket (OOP) maximum by therapy class, as well as co-pays/coinsurance based on drug/therapy class/high-value products.
- ▶ Carve out specialty drugs.
- ▶ Identify separate strategies for cell and gene therapies.



Pharmacy Benefit Design

▶ **TODAY**

3-4 co-pay tiers and a high-deductible plan.

▶ **TOMORROW**

Co-pays and coinsurance based on drug, therapy class, high-value products.

▶ **FUTURE**

Two tiers only (generic and brand), co-pays/coinsurance capped at out-of-pocket max by therapy class.

Formulary Design

Many employers across the discussions agreed their consultants, PBMs, and insurance companies “sold” them on a standardized formulary, telling them they would have to pay for customization if biosimilars and biologics were added. In addition, some employers were told there would be significant fees for customizing the formulary because that would create more work for vendors.

Employers more advanced in their formulary strategy indicated they have already added biosimilars, insisting on their inclusion as soon as they become available.

There is no defensible reason biosimilars cannot be added to the formulary. While some PBMs are restricting access, the employer (as the plan sponsor and fiduciary) can require they be added to the formulary without the additional fees for a custom formulary. There are not enough products to warrant a separate fee or necessitate administering claims differently.

Recommended Actions for Employers

- ▶ Take control of formulary management and implement a formulary that is not rebate-driven.
- ▶ Consider custom formulary design and targeted utilization management, either from administrative services only (ASO) or from a third party.
- ▶ Request an audit of the current formulary; request a utilization review that includes an inpatient/outpatient drug cost comparison.
- ▶ Require that all new biosimilar releases be placed in the generic tier of the formulary.
- ▶ When a new biologic comes to market, ask the ASO:
 - What is the value/logic/reasoning for or against inclusion on the formulary and at the tier selected? Is price/cost a factor in the decision?
 - How will this affect the current formulary for drugs in the same class?
 - Will patients on a drug in the same class know about this change? If so, how? Will they be required to make a change to the new drug?



Formulary Design

- ▶ **TODAY**
PBM-provided formulary of 10k+ drugs pre-authorizations, step edits, and formulary exclusions.
- ▶ **TOMORROW**
Custom formulary design, targeted utilization management.
- ▶ **FUTURE**
Limited formulary (<2k approved products) and full case management for high-cost claims.

Drug Pricing and Rebates

There was significant conversation about drug pricing and how rebates and credits are used. Some employers said their PBMs and payers have told them biosimilars/biologics are more expensive and less safe than the branded counterpart and an unnecessary addition to the formulary.

One of the most common concerns employers expressed was that they have been told they could lose their rebates if they switched patients from branded products to biosimilars and would therefore pay more.

Based on market research and the intent behind their design and approval, biosimilars and biologics should result in price decreases of between 15% and 30% off the branded reference product, in general, and therefore should save the plan money.

While it is true that rebates on a branded product would not be paid on a biosimilar, the difference in cost should, in many cases, offset the loss of rebates. In the long term, this would create better price transparency and a lower out-of-pocket cost to the patient, since rebates are not passed on to individual patients at the point of sale.

Recommended Actions for Employers

- ▶ Understand how rebates impact overall drug pricing and assess how they are positioned in the plan design. Work with an objective consultant to determine the best approach.
- ▶ Adopt a strategy to ensure the lowest net cost even without rebates, or consider a phased approach that reduces (or eliminates) the rebates or non-transparent credits and incentives.
- ▶ Ensure lower costs—don't hesitate to pose tough questions to benefit consultants, plans, or PBMs.
- ▶ Implement best practices for transparent contracting, and consider hiring an expert pharmacy consultant or a rebate aggregator; require full pass-through in contracts.
- ▶ Do not be lured into 340B pricing plans; if wage-band health plan differentials are being considered, only consider 340B pricing for those with incomes below the poverty line.
- ▶ Start over with a transparent or pass-through PBM, if necessary.



Pricing and Rebate Strategy

- ▶ **TODAY**
Using PBM-provided price and rebates.
- ▶ **TOMORROW**
Using a rebate aggregator or requiring full pass-through contracts.
- ▶ **FUTURE**
Taking a phased approach to reduce or eliminate pharmaceutical rebates or non-transparent credits and incentives.

Biosimilar Availability

Some employers have been told biosimilars/biologics are not always available in inventory and patients would encounter delays or lack of stock at the pharmacy or infusion center. In fact, the reason a biosimilar or biologic may not be available is that some PBMs are restricting access or not including them on the formulary, not because the supply chain or dispensing pharmacy lacks inventory.

Recommended Actions for Employers

- ▶ Include all biosimilars on formulary; when multiple biosimilars are available, providers might find it cost-prohibitive to inventory all of them; offer incentives for the use of all biosimilars in the same drug class over the reference product.
- ▶ Carve out specialty drugs and/or biosimilars.

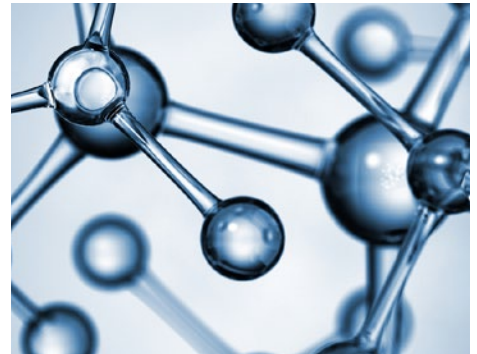
Site of Care and Drug Administration

In some discussions, employers highlighted their need to understand the actual total cost of care with biosimilars, as well as the costs related to drug administration, especially for infusible products. Employers currently lack a clear view of how they are being charged for provider and facility infusion fees, especially in clinic or hospital settings.

Some more advanced employers require home infusion as a primary means of lowering costs. Some large employers have installed infusion capabilities in their on-site or near-site clinics. While not every company can afford, or has the size to warrant, on-site clinics, one of the strategies discussed was creating a network carve out for specialty infusion and centers of excellence that agree to a fixed fee.

Recommended Actions for Employers

- ▶ Understand current health plan and PBM approaches to sites of care and drug administration, and consider preferred or tiered sites of care; for those with on-site/near-site/shared-site clinics, consider on-site infusion.
- ▶ Expect advances in drug delivery, such as infusion or ports replacing pills, and include those options in plan designs.
- ▶ Collaborate with local health systems to address sites of care as high-value and low-value care initiatives.



Biosimilar Availability

- ▶ **TODAY**
Generally excluded from PBM formularies.
- ▶ **TOMORROW**
Included in formulary by exception.
- ▶ **FUTURE**
Included on formulary at the time of market launch.



Sites of Care & Drug Administration

- ▶ **TODAY**
Administration at the discretion of the PBM.
- ▶ **TOMORROW**
Preferred/tiered site-of-care policy (e.g., home, outpatient pharmacy, outpatient infusion, etc.).
- ▶ **FUTURE**
Centers of excellence, sites of care/employer-owned clinics.

Top Priorities for Employers/Purchasers over the Next Two Years

Collecting objective information on biosimilars and the value of uptake — During the roundtable sessions, employers reported receiving conflicting information (e.g., biosimilars will be more expensive than the reference products if employers cover them) from health plans, PBMs, benefits consultants, providers, and pharmacists. This caused confusion, misinformation and a lack of biosimilar uptake. Employers want to better understand the rules/regulations, as well as the pipeline and related legislation.

Understanding the availability and interchangeability of biosimilars for biologics — Employers seek credible information about the 100% interchangeability of biosimilars with their reference products because they have been told patients could suffer side effects or have a worse response therapeutically. The FDA no longer requires a pharmacist to alert a physician when an interchangeable drug is switched, and this may present issues that need to be addressed if biosimilars are dispensed at retail pharmacies. Employers want up-to-date lists of biologics and biosimilars (including the availability of interchangeability) and regular updates as new biosimilar drugs are approved.

Determining improved drug-management approaches — Employers are considering the following strategies: custom formulary design (32%) and full case management for high-cost claims (36%); requiring full pass-through contracts (38%); implementing a phased approach to reduce or eliminate rebates (50%); including biosimilars on formulary at market launch (20%); preferred/tier site-of-care policy (50%); and limited site-of-care options for infused drugs (30%).

Exploring a precision-medicine model to help patients receive the right treatment the first time — Employers need to better understand the recent trend from a population-health model to a precision-medicine model. *For more on this model, see pages 15–17.*

Acknowledging the impact of rebates — Most employers want access to tools/resources to help them better assess the impact of rebates and hold drug price transparency discussions with their consultants, health plans, and PBMs. Tools such as playbooks from reputable organizations help them feel more empowered to act.

Understanding the impact of current policy legislation — Employers are interested in policy change at the federal level but require insight into how policy will affect the pricing and availability of drugs in both the pharmacy and the medical benefit.

Preparing for the future — With studies indicating drug spending could grow to become half of all medical spending within the decade, employers need strategies to help them prepare for the impact of high-cost drugs. Employers plan to focus on contracting for outcomes, not drugs, and determine if/how a specialty carve out should be put in place.

EMPLOYER PRE-ROUNDTABLE SURVEY RESULTS

The National Alliance conducted a baseline survey before each of the roundtable sessions to capture insights into specific themes related to pharmacy benefits. Below are the aggregate results.

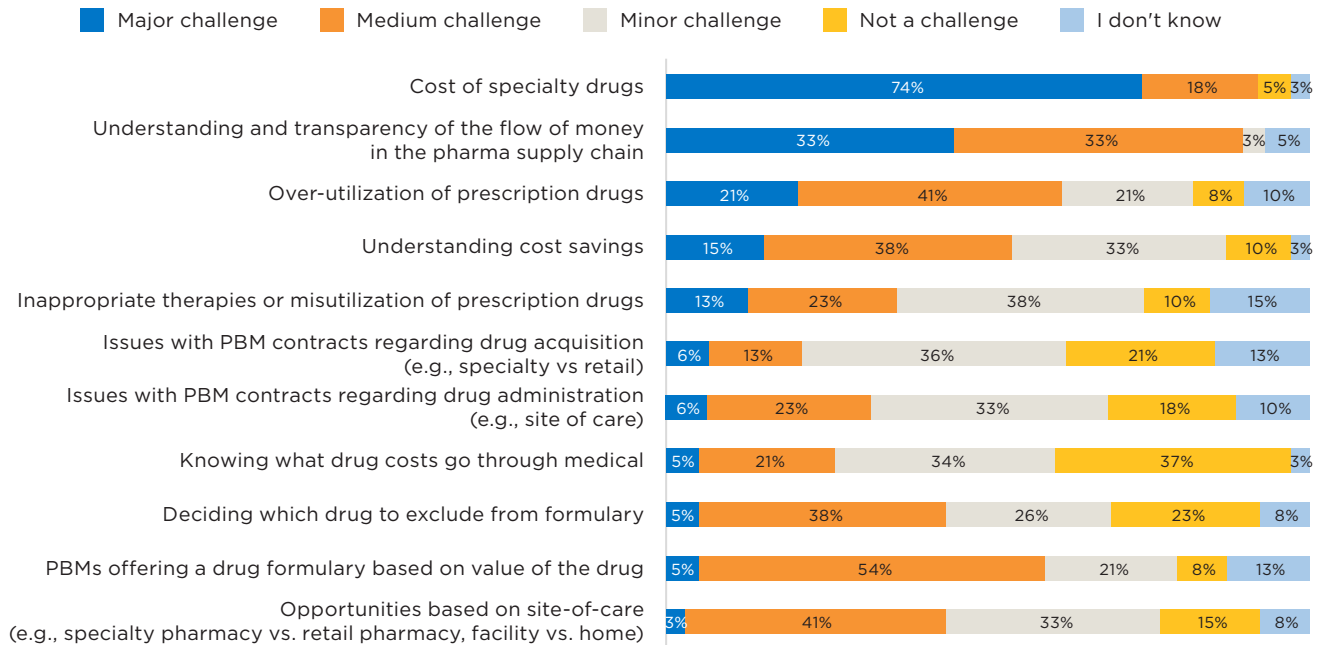
Participant Demographics

- ▶ 40 employers completed the survey.
- ▶ Company size (covered lives): 29%, over 20,000; 18%, 10,000–20,000; 8%, 5,000–10,000; 26%, 1,000–5,000; 16%, 500–1,000.
- ▶ Top three industries: 25%, Public Administration; 19%, Educational Services; 16%, Healthcare and Social Assistance.
- ▶ Percentage of total healthcare costs spent on drugs: 27%, above 25%; 37%, 20–25%; 18%, 15–20%; 12%, 10–15%; 6%, 5–10%.

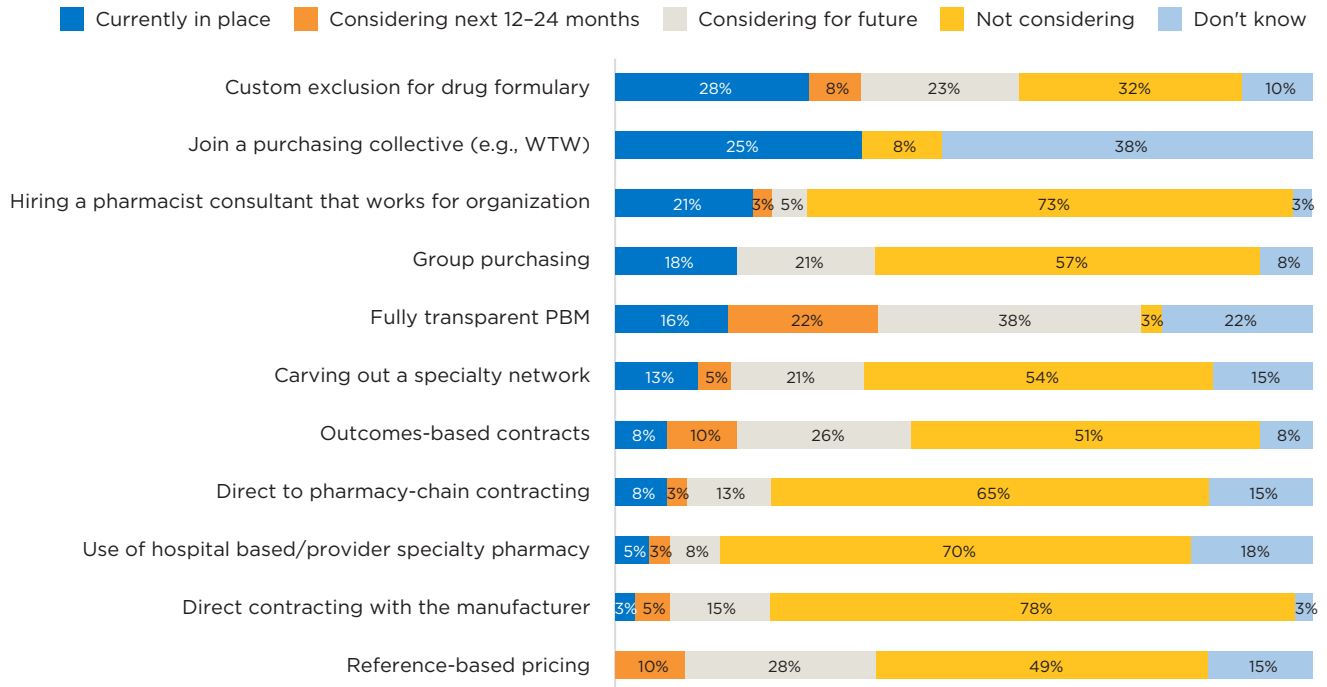
Key Observations

- ▶ 66% of participating employers find understanding the flow of money in the drug supply chain a challenge and 53% find understanding cost savings a major or medium challenge.
- ▶ 60% of employers are interested in a fully transparent PBM over the next two years or in the near future; 38% are interested in reference-based pricing over the next two years or in the future.

Key Challenges with Managing Drug Trends



Strategies to Address the High Cost of Drugs



EMPLOYER POST-ROUNDTABLE SURVEY RESULTS

Participating employers completed a follow-up survey about 90 days after the sessions to determine key focus areas for the next couple of years.

Participant Demographics

- ▶ 23 employers responded.
- ▶ Company size (covered lives): 27%, over 20,000; 18%, 10,000–20,000; 5%, 5,000–10,000; 27%, 1,000–5,000; 23%, 500–1,000.
- ▶ Top three industries: 17%, Educational Services; 17%, Healthcare and Social Assistance; 10%, Public Administration.

Key Observations

Employers are considering the following strategies:

- ▶ Custom formulary design (32%) and full case management for high-cost claims (36%).
- ▶ Requiring full pass-through contracts (38%); implementing a phased approach to reduce or eliminate rebates (50%).
- ▶ Including biosimilars on the formulary at time of their market launch (20%).
- ▶ Preferred/tier site-of-care policy (50%); and limited site-of-care options for infused drugs (30%).

ADDITIONAL BACKGROUND

Defining Biosimilars

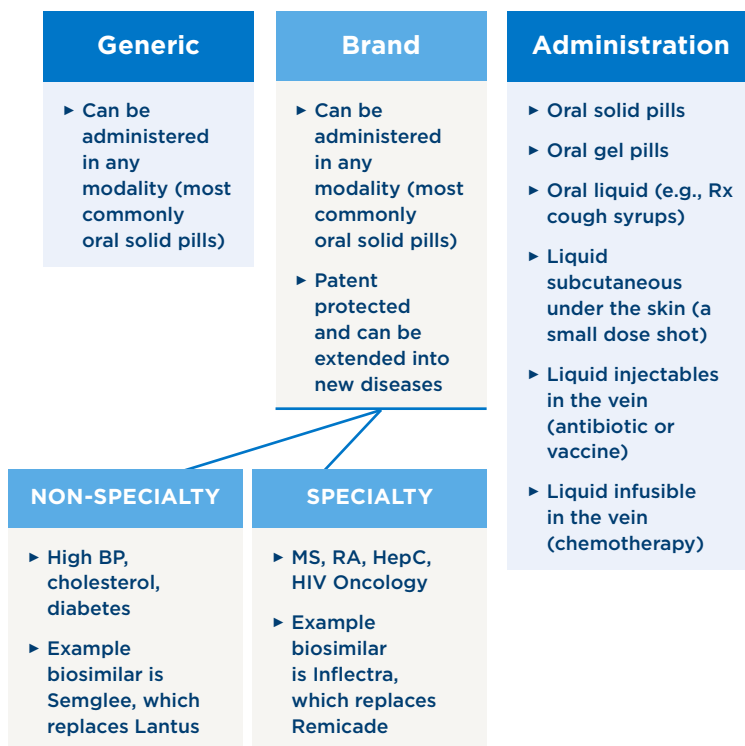
As stated above, biosimilars have garnered significant press over the past few years, with a primary focus on savings for employers. This savings is significant, as increased use of biosimilars will allow for a more competitive drug marketplace. Reduced barriers to biosimilar adoption could generate savings of about **\$25 billion over 10 years**, or roughly 0.5% of national spending on prescription drugs. However, other organizations, such as the Association for Accessible Medicines (AAM) indicate biosimilars savings could project upwards of **\$133 billion by 2025**, but only if policymakers encourage greater biosimilar adoption.

From the beginning of the roundtable discussions, significant misunderstandings about biosimilars and how they are characterized by various stakeholders were evident. PBMs currently treat biosimilars as “specialty” drugs, largely because biosimilar products that have been launched are replacing the higher-cost branded products generally priced in a “specialty drug” category. Drug companies see biosimilars quite differently, as they distinguish products based not on payment models, but on patent status.

The diagram below is a primer on how to view biosimilars without artificial payment characteristics. Drugs fall into two categories, those protected by patent (i.e., branded drugs) and those whose patent has expired (i.e., generics). Payment modality is usually correlated with administration modality because of the costs involved in more complex administration like liquid infusions.

Biosimilars also have a scientific definition: They are copies of biologic medicines. Biologic drugs are large, complex proteins made from living cells through highly complex manufacturing processes. Unlike generic drugs, which are copies of chemical drugs, a ***biosimilar*** is a copy of a ***biologic*** medicine that is similar, but not identical to, the original medicine.

Not all biosimilars replace specialty drugs. For example, the FDA approved the first *interchangeable* biosimilar insulin product for type 1 diabetes and type 2 diabetes mellitus. Semglee (insulin glargine-yfgn) is both biosimilar to, and interchangeable with (can be substituted for), its reference product Lantus (insulin glargine), a long-acting insulin analog. Semglee is the first interchangeable biosimilar product approved in the US for the treatment of diabetes.



Interchangeability is defined by US statute to mean that the product *may be substituted for the reference product without the intervention of the physician who prescribed the reference product*. The legal standard for interchangeability is an additional standard beyond the demonstration of “biosimilarity.”

According to guidance issued by the FDA in May 2019, for a biological product to be deemed interchangeable, the information submitted must be sufficient to show that:

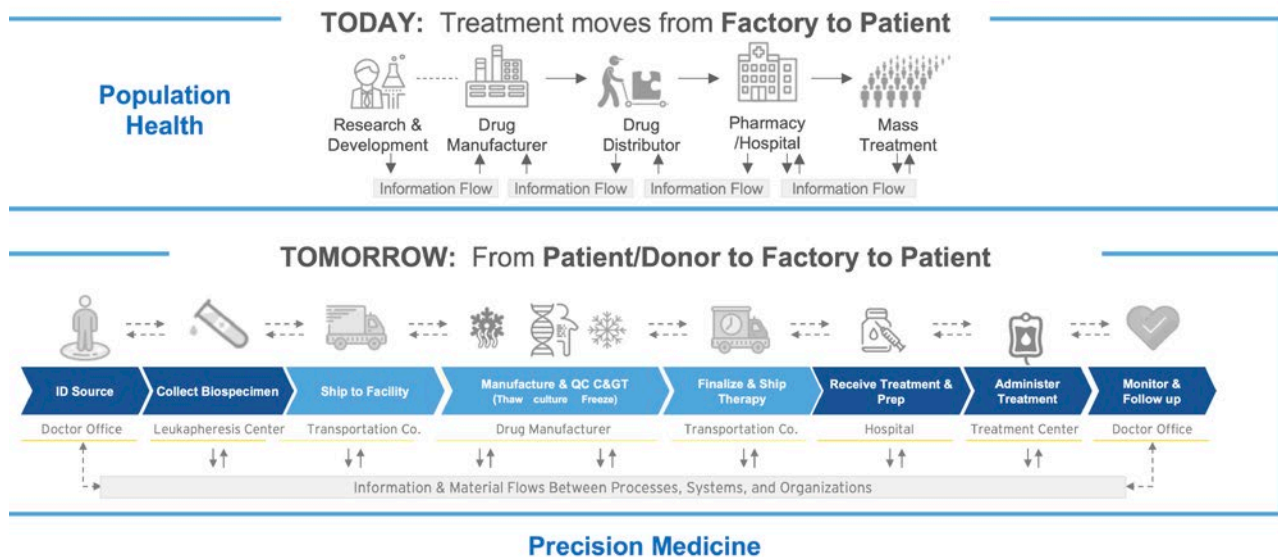
- ▶ The biological product is biosimilar to the reference product and can be expected to produce the same result as the reference product in any patient.
- ▶ For a biologic product that is administered more than once to an individual, the risk in terms of safety or diminished efficacy of alternating or switching between use of the biological product and the reference product is not greater than the risk of using the reference product without such alternation or switch.

Biosimilar products take approximately eight years to develop, at a cost of \$100–\$150 million. Typically, when launched, these products are priced at 15%–30% less than the reference product they replace. Compare that to a price reduction of 85%–90% on generic drugs that replace branded products. This price difference is because most biosimilars introduced to the market today are liquid injectable or infusible drugs, which cost more to compound, manufacture, transport and administer than pills.

Population Health and Precision Medicine

This evolution from “pills in a bottle” to “cells in a bag” signals a market moving from population health to precision medicine. The diagram below, developed by EY-Parthenon, depicts this paradigm shift.

The Move from Population Health to Precision Medicine



Source: EY-Parthenon; 2020

Today, most employers still employ a pharmacy approach founded on a population-health model. However, the market is already moving away from “standardized mass treatment,” with the patient as the end consumer, to a more personalized treatment model based on individual therapies. These therapies put the patient at the center and may often rely on the collection of a bio-specimen (e.g., DNA/cells/genes) to inform the manufacture of a medicine customized to treat a specific condition.

This precision-medicine model is already used in the treatment of conditions like rheumatoid arthritis, multiple sclerosis, cancer, and other diseases that may have genetic roots. To illustrate this, consider the example of reactive arthritis, a degenerative condition that creates inflammation in the joints and progresses over time, limiting mobility.

A biomarker has been found to identify the predisposition for reactive arthritis—a gene known as HLA-B27. Patients who test positive are typically diagnosed using a combination of ultrasound evaluations of inflammation and the prevalence of this biomarker. The condition can be treated using infusible drugs that help patients manage inflammation and flare-ups when the condition attacks the autoimmune system. This is the same approach most oncology treatments take and is the model that scientists increasingly adopt to tackle many conditions, with the goal of identifying the root cause and addressing the biology of the disease, not just managing the symptoms.

As the world of bioscience and medicine embraces genetics and develops more tests to identify and treat disease, the world responsible for the delivery and administration of these drugs needs to evolve. In the diagram above, the role of the lab becomes significantly more important. For example, the collection and evaluation of bio-specimens is critical to the creation of a personalized drug like a cell or gene therapy.

Today, we manufacture products in a “factory” model and dispense them in retail pharmacies or send them to homes via mail-order pharmacy. This is possible because most medications today are “oral solids,” (i.e., pills). It is less expensive to mass-produce and mail pills than it is to collect lab specimens, transport them, and develop custom cell-based therapies.

Because biologics and biosimilars are cell-based, the need to develop a new infrastructure is acute. The market will need more lab capabilities, different shipment and delivery capabilities



(like cold storage trucks), and more specialized clinical labor to administer these products, most of which are injected or infused.

We already see the emergence of outpatient infusion centers and hospital-based pharmacies, as well as the repurposing of outpatient retail pharmacy footprints, to accommodate these emerging products. Hospitals, physicians, and other clinical providers strive to keep patients within their networks and are investing in real estate to accommodate patients who need infusions. Pharmacists are being certified to conduct injection training for self-injectables and even to administer specialty infusions.

The growth of specialty pharmacies occurs as payers recognize the need to pivot their business model to accommodate the growth in these products as replacements for pills. We have all heard the term “generic wave,” as branded products lost patent protection and were replaced by generics, but that wave is shifting again to branded cell-based products like biologics and biosimilars.

This trend is not new. In fact, the legalization of a biosimilars approval pathway occurred in 2010 with the enactment of the Biologics Price Competition and Innovation (BPCI) Act. By 2015, we had finalization of, and guidance for, three approved biosimilars and the approval and launch of the first biosimilar through BPCI Act: Sandoz’s Zarxio (filgrastim-sndz) launched in September 2015 at a 15% discount.

The Biosimilar Pipeline

Today there are 33 approvals and 21 launches in the US biosimilar market. As this market matures, its pipeline continues to grow and is estimated to have surpassed 100 as of December 2021. The European Union has 80% penetration of biosimilars, largely because national healthcare systems negotiate drug procurement directly, and the potential to save 30% on prices drove significant adoption. The US lags largely because of the unique and complex nature of its drug pricing and reliance on rebates.

The growth of biosimilars is only beginning, and there is a pipeline of drugs with patents due to expire over the next 5–7 years. These products will be replaced by biosimilars, so it will be critical for employers to have a robust strategy in place. The other issue employers must address is how credits and price incentives will work, since biosimilars don’t have rebates the way branded products do. The entire pricing model is likely to change.

Why is Europe Ahead of the US?

Biosimilars are available in more than 100 countries outside the US. There are more than 60 biosimilar products approved for use in the European Union, comprising **about 40%** of the total European biologics market. The primary driver for this level of availability is the money saved by the switch to biosimilars (which have a lower price) and the increased competition from new biosimilar products.

This uptake is driven by the European regulatory environment. The European Medicines Agency (EMA) developed a framework for the approval of biosimilars many years ago, while

the US relies on a patchwork of legislation like the Affordable Care Act and the Biologics Price Competition and Innovation (BPCI) Act.

Additionally, national health systems have centralized decision-making, which allows them to make these products available to prescribers and patients as soon as they are approved.

At a national level, governments create incentives for prescribing and taking biosimilars, since the payment/reimbursement is centrally controlled and consistent throughout the country.

According to a recent report by [ICON](#) (May 2020), the reasons for more robust biosimilar uptake are, in brief:

- ▶ The EU is several years ahead of the US, with many blockbuster biologics reaching the market sooner and subject to competition from multiple biosimilars, resulting in falling prices and high biosimilar uptake. This is due to a difference in the patent landscape, with some EU patents ending earlier and some originator companies generating more patent barriers in the US.
- ▶ In the US market, the FDA requires that biosimilars prove “interchangeability” with the originator before automatic pharmacy-level substitution is permitted. The EMA, on the other hand, does not have a specific “interchangeable” designation for biosimilars and has deferred all decisions on interchangeability, switching and substitution to member states.
- ▶ The EU has single-payer healthcare systems, in contrast to the fragmentation of the US market, and therefore has different acquisition practices and pricing. In the US, the key factor affecting biosimilar uptake is payers’ perception of safety and efficacy, as well as their management practices, which are driven by pricing and manufacturer rebates. In contrast, in the EU, biologics are often procured through [tenders](#), and biosimilars often win by offering the lowest prices.

US Employers and their Move toward Biosimilar Adoption

Although the full potential of biosimilars hasn’t been realized, employers can help spur adoption by becoming educated about biosimilars and advocating for them with their health plans and PBMs. Employers should communicate with workforces and families through company benefit packages and online education. Additionally, employers can provide access to resources and online tools that support access to appropriate biosimilars as available options.

Large employers can also advocate for the expansion and implementation of health policies, such as Medicare Part B and D, which will help speed biosimilar uptake. One of the best ways employers can learn about biosimilars is through the sharing of best practices; the roundtable discussions provided a forum for constructive dialogue and allowed employers to see they are not alone in their challenges. As employers hold discussions with health plans, PBMs, specialty pharmacies, and consultant partners, they need to communicate their expectations and ensure these will be met. As advocates and educators, large employers and health plan decision-makers can boost biosimilar adoption so that the savings potential of these medicines can be more fully realized. In turn, this will reduce overall healthcare spending, out-of-pocket costs, and monthly premiums for employees.

APPENDIX: APPROVED BIOSIMILARS

REFERENCE PRODUCT	FDA APPROVAL	COMPANY	DATE
Semglee (insulin glargine-yfgn)	Lantus	Mylan Pharmaceuticals Inc.	7/28/21
Riabni (rituximab-arrx)	Rituxan	Amgen Inc.	12/17/20
Hulio (adalimumab-fkjp)	Humira	Mylan Pharmaceuticals Inc.	7/6/20
Nyvepria (pegfilgrastim-apgf)	Neulasta	Pfizer Inc.	6/10/20
Avsola (infliximab-axxq)	Remicade	Amgen Inc.	12/6/19
Abrilada (adalimumab-afzb)	Humira	Pfizer Inc.	11/15/19
Ziextenzo (pegfilgrastim-bmez)	Neulasta	Sandoz Inc.	11/4/19
Hadlima (adalimumab-bwwd)	Humira	Samsung Bioepis Co., Ltd.	7/23/19
Ruxience (rituximab-pvvr)	Rituxan	Pfizer Inc.	7/23/19
Zirabev (bevacizumab-bvzr)	Avastin	Pfizer Inc.	6/27/19
Kanjinti (trastuzumab-anns)	Herceptin	Amgen Inc.	6/13/19
Eticovo (etanercept-ykro)	Enbrel	Samsung Bioepis Co., Ltd.	4/25/19
Trazimera (trastuzumab-qyyp)	Herceptin	Pfizer Inc.	3/11/19
Ontruzant (trastuzumab-dttb)	Herceptin	Samsung Bioepis Co., Ltd.	1/18/19
Herzuma (trastuzumab-pkrb)	Herceptin	Celltrion, Inc.	12/14/18
Truxima (rituximab-abbs)	Rituxan	Celltrion, Inc.	11/28/18
Udenyca (pegfilgrastim-cbqv)	Neulasta	Coherus BioSciences, Inc.	11/2/18
Hyrimoz (adalimumab-adaz)	Humira	Sandoz Inc.	10/30/18
Nivestym (filgrastim-aafi)	Neupogen	Pfizer Inc.	7/20/18
Fulphila (pegfilgrastim-jmdb)	Neulasta	Mylan N.V.	6/4/18
Retacrit (epoetin alfa-epbx)	Epogen/Procrit	Hospira Inc.	5/15/18
Ixifi (infliximab-qbtx)	Remicade	Pfizer Inc.	12/13/17
Ogivri (trastuzumab-dkst)	Herceptin	Mylan GmbH	12/1/17

REFERENCE PRODUCT	FDA APPROVAL	COMPANY	DATE
Mvasi (bevacizumab-awwb)	Avastin	Amgen Inc.	9/14/17
Cyltezo (adalimumab-adbm)	Humira	Boehringer Ingelheim Pharmaceuticals, Inc.	8/25/17
Renflexis (infliximab-abda)	Remicade	Samsung Bioepis Co., Ltd.	4/21/17
Amjevita (adalimumab-atto)	Humira	Amgen Inc.	9/23/16
Erelzi (etanercept-szsz)	Enbrel	Sandoz Inc.	8/30/16
Inflectra (infliximab-dyyb)	Remicade	Celltrion, Inc.	4/5/16
Zarxio (filgrastim-sndz)	Neupogen	Sandoz Inc.	3/6/15

PROJECT TEAM

Margaret Rehayem, *Project Lead*



Margaret Rehayem is vice president of the National Alliance and provides leadership for national initiatives that support member collaboration, helping coalitions leverage their regional efforts at the national level to drive innovation, health and value for organizations and communities across the country. Her focus has been on health and well-being, continuous improvement frameworks, multi-stakeholder collaboratives, and the development of strategies that support system and delivery reform. With over 20 years of experience working with employers in various areas, including overall healthcare strategic planning, Margaret oversees several grant activities in conjunction with national funding organizations such as the CDC Foundation and PCORI. She helps drive the direction of the organization's National Health Leadership Council and engages with employers through the National Purchaser Leadership Council (NPLC). Margaret is a national speaker on healthcare topics, including business performance and leadership, health benefits, medical and pharmacy drugs, biosimilars, employee engagement, organizational culture, and the impact of health and well-being in organizations.

Alex Jung, *Facilitator*



Alex Jung is a former partner at EY Parthenon and is known as an expert in business strategy and economic modeling. She has over 30 years of experience with strategic growth and risk mitigation and has developed corporate and growth strategies for several Fortune 500 companies, including the top healthcare payers, PBMs, pharmaceutical companies, and pharmacies. Additionally, she has worked with major private equity firms on their portfolio M&A strategy and commercial due diligence. She is a regular speaker at events such as the JPMorgan Annual Healthcare Conference, BIO and BIO International, ASCO, AHIP, Assembia, OPPM of India, World Healthcare Congress, Crain's Annual Health Care Conference, and Northwestern and Yale Universities' Annual Healthcare Conference. She has been quoted in numerous articles in Kennedy Research, Forrester, *Forbes*, *The Chicago Tribune*, *Business Insurance*, *Workforce*, *Crain's Chicago Business* and other industry publications.

PARTICIPATING COALITIONS



Economic Alliance for Michigan: EAM comprises businesses and labor organizations representing more than 900,000 covered lives working together and serving as a trusted source for employers and health benefit professionals who are searching for solutions to better manage the costs of benefits and provide access to quality care to their covered populations.

Contact: Bret Jackson, president; website: eamonline.org



Florida Alliance for Healthcare Value: The Florida Alliance is an employer-led research and education organization that brings together benefits leaders and healthcare stakeholders to develop and implement innovative improvements in healthcare cost, quality, transparency and safety in Florida.

Contact: Karen van Caulil, president & CEO, Ashley Tait-Dinger, director of analytics, alternative payment models (APM) & finance; website: flhealthvalue.org



HealthCare 21 Business Coalition: Participating members have a clearer understanding of the healthcare market and are better equipped to improve healthcare in their regions. A diverse group of members have a common design to transform healthcare delivery and payment.

Contact: Jeff Townsend, vice president, purchaser services; Phil Belcher, chief operating officer; website: hc21.org



Houston Business Coalition on Health: As an employer-centric healthcare purchaser coalition, HBCCH uses a set of key foundational pillars to focus efforts and provide tangible value to members. These pillars include “build smart data,” “promote transparency,” “drive innovation,” and “advance population health best practices.”

Contact: Chris Skisak, executive director; website: houstonbch.org



Lehigh Valley Business Coalition on Healthcare: LVBCH has been serving the needs of employers by leading the way in the development of affordable, cost-effective employee benefits. Forward-looking business leaders discuss and recommend actions to address the rapidly rising cost of medical care and the impact it has on providing employees with quality, affordable medical benefits.

Contact: Carl Seitz, president; Amanda Green, director of operations; website: lvbch.com



Memphis Business Group on Health: MBGH is a coalition of member employers sharing solutions, providing connections, and offering tools to members so they can better manage the cost and quality of employee health benefits in an ever-changing environment. Key initiatives include providing access to critical market data, facilitating best practice sharing among the market’s leading employers, and offering practical tools for successfully managing health benefits and creating worksite cultures of health.

Contact: Cristie Travis, president & CEO; website: memphisbusinessgroup.org



Washington Health Alliance: The Washington Health Alliance leads health system improvement, bringing together those who get, give and pay for healthcare to create a high-quality, affordable system for the people of Washington state.

Contact: Nancy Guinto, resident & CEO; website: wahealthalliance.org



National Alliance of Healthcare Purchaser Coalitions

1015 18th Street, NW, Suite 705

Washington, DC 20036

(202) 775-9300 (phone)

(202) 775-1569 (fax)

nationalalliancehealth.org

twitter.com/ntlalliancehlth

<https://www.linkedin.com/company/national-alliance/>



National Alliance
of Healthcare Purchaser Coalitions
Driving Health, Equity and Value

The National Alliance of Healthcare Purchaser Coalitions (National Alliance) is the only nonprofit, purchaser-led organization with a national and regional structure dedicated to driving health and healthcare value across the country. Its members represent private and public sector, nonprofit, and Taft-Hartley organizations, and more than 45 million Americans spending over \$300 billion annually on healthcare. Visit nationalalliancehealth.org, and connect with us on Twitter and LinkedIn. ©National Alliance of Healthcare Purchaser Coalitions. May be copied and distributed with attribution to the National Alliance.