

ACCELERATING THE ADOPTION OF BIOSIMILARS

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FIGURE 1. KEY DOMAINS IMPACTING BIOSIMILARS ADOPTION



POLICY



PAYER COLLABORATION AND ALIGNMENT



ORGANIZATION-WIDE ALIGNMENT



CUSTOMIZED APPROACH



PATIENT AND PHYSICIAN ENGAGEMENT

FORWARD

Despite the complexities within healthcare, all stakeholders strive to provide value and improve patient outcomes. The advent of biosimilars offers a significant opportunity to add value by reducing costs while increasing patient access to innovative biologic therapies. How can this opportunity be fully realized? What are the challenges for implementing a range of biosimilar medications—anticipated to grow in number, and how can access and affordability be expanded to all patients in all care settings? What lessons learned from early experiences can be translated to accelerate adoption in other therapeutic areas?

This report aims to explore these questions to enhance awareness, stimulate discussion, and support broader adoption of biosimilars. Throughout the report are participant examples of current barriers and opportunities (i.e., quotes and Case In Point), and strategies to accelerate adoption (e.g., Strategies in Practice) in five key domains (Figure 1). For those in the initial information gathering and evaluation phase, use this report as a starting point. For those who have experience in one therapeutic area and are looking to expand and accelerate the implementation of biosimilars, use this report to gain insights into successful strategies others have used in practice.

The report is part of an ASHP and ASHP Foundation project sponsored by Amgen exploring biosimilars' current and future adoption in the United States.

BACKGROUND

B iologics are large, complex molecules derived from living organisms and produced through biotechnological processes, unlike traditional small molecules created via chemical production processes.¹ Biologics have delivered advanced treatment options for various conditions, including neutropenia, cancer (e.g., chronic lymphocytic leukemia and breast cancer), auto-immune diseases (e.g., rheumatoid arthritis and Crohn's disease), diabetes, and macular degeneration. Biologics are approved and regulated by the Food and Drug Administration (FDA). The FDA defines a biosimilar as “a biologic that is highly similar to, and has no clinically meaningful differences from, another biologic that’s already FDA-approved (referred to as the reference product or original biologic).”² Biosimilars offer a way to increase treatment options and access to biologics while significantly lowering costs through competition. In 2009, through the Biologics Price Competition and Innovation Act, Congress created an abbreviated licensure pathway for biological products that are demonstrated to be biosimilar to or interchangeable with an FDA-approved biological product.³ The first biosimilar, filgrastim-sndz was approved in 2015; at the time of this report, there were 34

biosimilars approved by the FDA.⁴ Generally, biosimilars are administered by the same route (although delivery devices may differ from the reference product), have the same strength and dosage form, and, by extrapolation, should have a similar side-effect and efficacy profile. Nevertheless, uptake has been slow in the United States versus European market.⁵ While there is no “generic” equivalent for a biosimilar, biosimilars meeting additional requirements may be designated as “interchangeable” by the FDA.¹ The first interchangeable biosimilar, insulin glargine-yfgn, was approved in July 2021. The introduction of interchangeable biosimilars is anticipated to be a game-changer for accelerating adoption. One recent study indicated biosimilars are on track to save \$38.4 billion from 2021 to 2025; however, an alternative model that assumes accelerated approval and adoption predicts savings of as much as \$124.2 billion.⁶ A March 2022 report from the Office of the Inspector General also concluded that broader adoption of biosimilars would result in significant cost savings to Medicare Part D and its beneficiaries.⁷ It is important to understand and address barriers to adoption so that the maximum benefit from biosimilars can be achieved.

FDA'S BIOSIMILARS DEFINITIONS¹



BIOSIMILAR

A biosimilar is a biological product that is highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product.



BIOLOGIC

Biological products are a diverse category of products and are generally large, complex molecules.



INTERCHANGEABLE BIOSIMILAR

An interchangeable product is a biosimilar product that is expected to produce the same clinical result as the reference product in any given patient.

ABOUT THE PROJECT

The slow adoption of biosimilars in the U.S. has been attributed to various barriers, including awareness, prescriber and patient concerns, limited labeling allowances for some indications, and a lack of incentives to switch. To enhance the adoption of biosimilars in a range of therapeutic areas, ASHP and the ASHP Foundation (“ASHP”) engaged a group of stakeholders in a coordinated initiative designed to develop a deeper understanding of current trends, health-system challenges and opportunities, and to identify successful adoption strategies from early adopters of biosimilars. Furthermore, the project sought to explore pharmacists’ roles in stimulating the implementation of biosimilars in a range of practice settings and therapeutic areas. The findings and adoption strategies are presented in this report and will be part of a broader dissemination effort.

PARTICIPANTS AND METHODS

The project included three steps 1) Engagement of an expert steering committee, 2) Convening of a virtual research panel (VRP), and 3) Dissemination of findings and recommendations (see Figure 2). A ten-member steering committee was composed of experts representing diverse stakeholders, including health-system and specialty pharmacists, physicians, and payers (see Table 1). During its preliminary work, the steering committee identified key domains important for and believed to be impacting the adoption of biosimilars (see Figure 1). For each domain, the committee identified a series of questions to guide the VRP discussion (See Appendix 1). Sixteen participants were

FIGURE 2. PROJECT APPROACH



invited and participated in the VRP along with the steering committee members who served as facilitators (see Appendix 2). The VRP was conducted from Feb. 10-20, 2022. Activities of the virtual research panel included a moderated, 90-minute virtual meeting and a follow-up discussion board. Two questions were posted on eight of the ten days (to account for

weekends), with a window of two to three days to respond before the discussion was closed. Participant responses were aggregated and sorted by the established domains, barriers, recommendations, or best practices. The findings were then vetted with the steering committee.

Steering Committee

Russell D. Cohen, MD, FACG, AGAF

Professor of Medicine, Pritzker School of Medicine; Section of Gastroenterology; Director, Inflammatory Bowel Disease, The University of Chicago Medicine

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Sutter Health System-wide Clinical, Coordinator, Formulary and Clinical Programs. Sutter Health

Lisa Sivell, PharmD

Director, Medical Benefit Drug Management, Blue Cross Blue Shield of Michigan

KEY DOMAINS AND ADOPTION STRATEGIES



POLICY IMPACT

Despite the federal government's interest in the broader adoption of biosimilars, the uptake remains slow.⁵ The adoption in European markets has been much faster than in the United States and may be partly due to policy-related issues. These policies can be at the broader governmental (federal and state) or regional (payer) level. One factor delaying market entry and adoption of products is patent litigation by manufacturers of reference products. From a planning perspective, this uncertainty makes it difficult to predict when the products will hit the market, what the pricing will be, and whether payers will reimburse for them. Another factor affecting adoption is the limited number of designations by the FDA for product interchangeability and "skinny" labeling (i.e., approvals, but for limited indications). The impact of payer policies is addressed in more detail in several of the domains below; however, the misalignment of incentives and lack of transparency with costs and commensurate savings were predominant themes. For example, when a payer designates a preferred agent, pharmacists have to work with providers to get new orders, prior authorization for its use, and patients have to be educated (or re-educated). In some cases, patients may even experience higher copays because of copay assistance differences between the biosimilar and reference products causing delays and lack of engagement by providers and patients.

There are several payer-related issues (e.g., prior authorizations, site of care restrictions, and white bagging); it probably makes sense to have one holistic conversation and shift that conversation from cost to value.

—Health-System Pharmacist

Adoption Strategies

1. Develop and maintain an ongoing dialog with primary payers on their pending policy changes.
2. Advocate for the closure of loopholes such as "pay to delay" or for reference products that seek and obtain expanded indications late in the product life cycle to preserve patents.

Strategy in Practice

When oncology and supportive care biosimilars were initially introduced to the market, we (health plan) added them with reimbursement similar to the reference product. We monitored for uptake and cost over time and communicated with our key health systems to understand if they had biosimilar-preferred products. Using that information, we selected preferred products but have at least two preferred options for each reference product. We also removed the PA requirement for the preferred products.

3. Advocate for legislation to increase the transparency in the cost of biosimilars, including rebates.

4. Advocate for increased affordability of all medications.
5. Prepare for more self-administered biosimilar products to be available, managed, and reimbursed under the pharmacy (versus medical) benefit.
6. Create a national clearinghouse for outcomes monitoring that can be used to collect real-world data over multiple sites and help to guide policy and coverage decisions.
7. Advocate for policies that ensure greater transparency and communication from regulators on the reasons behind “skinny” labeling.
 - Payers can be more flexible in their authorization for non-FDA-approved indications, when the biosimilar holds that indication in other countries.
 - Advocate for increasing the number of interchangeable biosimilars on the market to allow for seamless conversion between the biosimilar and the reference product.

I wish there would be real transparency in the cost of these drugs and the revenue trail including PBMs and their rebates, hospitals with 340b pricing, and facility fees.

—Physician

Prior Authorization and Care Coordination

Case in Point

A biologic was prescribed for a transplant patient that required a PA. The rejection just said “PA needed,” so we (specialty pharmacy) coordinated the PA paperwork with the clinic and ordered the drug preemptively (the pharmacy didn’t typically stock the dose). Then, the next day the PA was denied again, stating that the patient needed to try and fail the payer’s preferred product, which required a new PA. Pharmacy had to coordinate with the prescriber to obtain another PA urgently and obtain the product from our main specialty pharmacy 25 miles away. At this point, we had to ship to the patient same-day delivery at a significant expense (\$150) to the pharmacy to ensure the patient could get their drug ASAP.

Of all policies discussed, the virtual research panel expressed the most concerns about the prior authorization (PA) process and the desire for reform. Forecasting reimbursement and coverage with biosimilars is difficult when they are brought to market with a “skinny label” and lack one or more approvals that the reference product holds. Predicting reimbursement and coverage is particularly problematic with Medicare patients since it is impossible to do a PA predetermination for Medicare patients as with commercial payers. The prior authorization process can be time-consuming and can result in delays in therapy. The PA process has required health systems to invest in staff to navigate the process, and it is a significant burden on smaller practices that do not have those resources. Some barriers related to the PA process include:

- Pharmacy benefit manager (PBM) coverage information is often inconsistent and not easy to navigate, for example, the patient portal does not always contain information applicable to all scenarios.

- Sometimes, the clinical criteria that are put in place by some plans are not consistent with recognized practice guidelines.
- The process is primarily manual and based on a “trial and error” approach.

Adoption Strategies

1. Streamline and standardize the PA process, with more clear and rapid determinations.
2. Remove or reduce the PA requirements for preferred biosimilars.
3. Payers should provide automated, online submission of prescriptions that steers prescribers to preferred option(s) within the payer, clear prior authorization criteria, and notice of immediate approval if the criteria are met.
4. Utilize the pharmacy team to navigate the prior authorization process.



PAYER COLLABORATION AND ALIGNMENT

Case in Point

Copay cards from the manufacturers often help decrease the patient’s out-of-pocket expenses, but insurance companies don’t apply these copays to the patient deductibles. Some payers use a third-party vendor copay maximizer solutions. They use these companies to ensure (and often require) that patients use these vendors to set up their financial assistance. This arrangement seems reasonable on the surface; however, patients will max out the limits of the copay cards within a few months, and the amount paid won’t be applied to their deductibles, which many specialty pharmacy patients have relied on in the past.

There were several issues discussed by the VRP that indicated a lack of collaboration and alignment between the payer, health system, and providers related to biosimilar adoption. The conversation needs to move from costs to value and create a proposition that benefits everyone—manufacturers, payers, health systems, providers, and patients. From the health system perspective, a significant misalignment is a discordance in preferred biosimilars among payers, requiring health systems to stock multiple products and implement safeguards against dispensing errors. Having to carry multiple biosimilars in inventory is challenging. It is cost-prohibitive to keep multiple therapeutically equivalent products on a pharmacy shelf. Infrequently used products may expire, requiring that therapies be special ordered for a specific patient, which can result in delays. Delays in patient care may also occur when a payer restricts a patient from filling a certain product that is not readily available (even if there is another therapeutically equivalent option available in stock). In addition to the impact on inventory and delays, this also limits the ability of a health system or physician practice to gain any purchasing incentives, such as tiered pricing or rebates, based on market share. Another misalignment is that frequent, preferred product changes can be resource-intensive and result in payment denials; formularies may change as frequently as quarterly. As a result, a financial assessment is only accurate at that moment in time and then may be out of date in a few months. Finally, sometimes the lowest cost drug for a payer or health system may be the highest out-of-pocket cost for patients or the net revenue is less, creating little incentive to switch.

At this time, it seems that incentives are not aligned, and each player in the system is working towards a different goal. However, aligning incentives with the goal of measurably reduced costs for all parties involved, especially patients would go a long way in optimizing biosimilar adoption.

—Health-System Pharmacist

Adoption Strategies

1. Payers, health systems, and providers should work collaboratively to streamline biosimilar selection, adoption, and seamless conversion.
 - Remove barriers (e.g., eliminating prior authorization, reducing patient cost-sharing) when biosimilars are ordered rather than reference products. Reducing these barriers would also reduce the overall cost of delivering services.

Strategy in Practice

Our health system meets with one of our payers quarterly to discuss formularies (e.g., PA requirements and step therapies) to align policies with clinical practice. From the clinician's side, we can share real-world data and perspectives on why certain step therapies may be inappropriate or review new publications that impact place in therapy. It's a win-win. The payer benefits by having the opportunity to ask questions to gain insight into prescribing practices and trends, and we can share the rationale for our clinical approach.

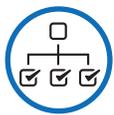
2. Payers should provide advance notice to health systems to allow time to coordinate implementation with the providers (e.g.,

change education materials, order sets, provide staff education, etc.).

3. Incorporate language into payer contracts to support the use of the institution's preferred biosimilars.
 - To align payer and health system policies, pharmacy should proactively reach out to their managed care/payer contracting department to discuss the importance of aligning biosimilar products between payers and health systems and get pharmacy input when negotiating contracts.
4. Health systems and specialty pharmacies should demonstrate to payers when they are charging less to plan beneficiaries by using lower-cost biosimilars, thus, reducing payer costs.
5. Payers should recognize and support pharmacists and prescribers for the time and resources spent educating patients when the insurance company benefits from the service.
6. Payers should utilize pharmacists on their team to educate providers and patients and provide input into policies, prior authorization guidelines and determinations; and be available to respond to questions.
7. Health systems should work with payers to align performance metrics.
 - Monitor and communicate market share changes for biosimilars versus reference products and related financials.
 - Compare results for commercially insured versus Medicare plans and evaluate differences.
 - Review prior authorization requests and denials for specific issues or trends (e.g., certain prescribers/facilities requesting the reference product, adverse events.)

We have successfully worked directly with our payers in our local market. There is no preference for a specific biosimilar and especially not a reference product. With the first few biosimilars, adoption was slow, and payers were more likely to enter agreements with rebates, but if providers went to them collectively to show that they are “100% in,” then payers wouldn’t be tied to these types of rebates.

—Oncology Specialty Pharmacist



CREATING ORGANIZATION-WIDE ALIGNMENT

Case in Point

Each new therapeutic space with new biosimilars has a unique impact on our organization. Ranibizumab, for example, is not routinely used in our hospital-based outpatient departments, and instead, is more heavily utilized in physician-based outpatient departments, which fall outside the purview of our P&T committee and medication policy structure.

While it is ideal for health systems to be able to align biosimilars strategy with payers, it is also critical to optimize benefits to the organization, its providers and patients despite external challenges. A well-aligned organization and biosimilars strategy leveraged by physician champions can create a strong service line that payers will be more inclined to collaborate with and build win-win contracts and policies. There is also an opportunity to leverage technology

and the electronic health record (EHR), particularly in health systems that can manage patients across the entire care continuum. Doing so can assist providers with prescribing biosimilars, provide a way to track patient response and outcomes, and supports quality improvement activities. Some health systems provide patient portals with educational information and online prior authorization guidance. Providers note inconsistencies between what is available in electronic prior authorization tools and insurance benefit information which can cause confusion, rework, and delays. The pharmacy enterprise can advance adoption through a variety of roles (Figure 4). Payers will see the value in partnering with a high-performing health system with a track record of shifting product market share while delivering high-quality outcomes to satisfied patients.

We have a primary product for inpatient use and are currently working to carry all products for outpatient use due to the payer dictating which agent they will reimburse, thus limiting our ability to contract using a market share or volume commitment which could greatly reduce the price of procurement and financial burden to our health care system.

—Health-System Pharmacy Executive

Adoption Strategies

1. Use a systematic approach: identify and engage providers and stakeholders; complete an analysis of the opportunities; develop proactive processes and systems (e.g., ordering/referral process and order sets); provide training for pharmacists,

providers, and nurses; and evaluate the outcomes.

2. Establish a biosimilars committee or subcommittee.
 - In addition to clinicians include representatives from finance, payer contracting, pharmacy operations, and information technology.
3. Identify physician champion(s) to support the work and deliver the message.

While pharmacy may take ownership, we have found that it GREATLY helps to have a provider champion for each market to assist with outlier (aka, slow adopter) providers.

—Health-System Pharmacy Executive

4. Share information with key stakeholders throughout the organization:
 - Present successes and lessons learned to all of the departments impacted by conversions (e.g., gastroenterology, rheumatology, and ophthalmology).
 - Report performance to the Pharmacy and Therapeutics (P&T) Committee, and if appropriate, the Medication Safety and Quality Committees.
5. Pharmacists should lead the biosimilar adoption process within health systems and engage with all stakeholders, such as physicians, nurses, and payers.
6. Develop and integrate technology to support implementation and monitor outcomes.
 - Create a biosimilar adoption dashboard to track and report progress at planned

FIGURE 3. EXAMPLES OF BIOSIMILARS METRICS



FINANCIAL PERFORMANCE

(e.g., costs, revenue and denials)



MARKET SHARE

(e.g., % adoption)



ADVERSE EVENTS

(e.g., the incidence of hypersensitivity reactions, switches back, discontinuation rates)



PURCHASING PATTERNS

(e.g., wholesaler, GPO, WAC, 340B accounts)



FINANCIAL OPPORTUNITY

(e.g., preferred contracts, risk contracts)



CLINICAL OUTCOMES

(e.g., patient satisfaction and provider assessment of disease control)



FIGURE 4. PHARMACIST ROLES

- ✓ **Lead formulary management initiatives of the P&T committee**
 - Shape policies
 - Guide review and dissemination of scientific, clinical, and economic analyses
- ✓ **Support drug ordering and approval**
 - Coordinate order set development and updating
 - Coordinate product conversions or convert, as allowed by policy
 - Clarify indications and evidence to support the use of each product
 - Interpret payer policies for administrative staff
- ✓ **Serve as a central resource for questions**
 - Answer questions from healthcare professionals and patients
 - Conduct provider in-services
- ✓ **Ensure patient access to medication**
 - Complete prior authorizations and assist with appeals
 - Identify and enroll patients in copay assistance programs
- ✓ **Monitor and communicate outcomes**
 - Collect performance metrics and report to key stakeholders
 - Monitor, evaluate, and report adverse events

intervals (e.g., on a monthly and then quarterly or annual basis).

- Develop therapy-specific plans and order sets in the EHR for each biosimilar based on preferred therapies.
- Develop order sets by “generic” name (e.g., filgrastim, rituximab) to allow more flexibility in product selection.
- Integrate payer information into the EHR that follows the tiered structure at the point of prescribing as is done for other drugs and includes requirements (e.g., failure or intolerance of other therapy, laboratory parameters, etc.)

Strategy In Practice

Our (health system) patient consent form generally references the generic product name, including all biosimilars. Patients are made aware before initiation of treatment that they may receive the reference product or any biosimilars on the market, depending on the P&T-preferred product at that time.

7. Work with physicians to identify the most meaningful outcomes and align with EHR documentation so data can be extracted to evaluate clinical outcomes.
 - Measures should include conversion rates, insurance metrics, adverse drug reaction reports, financial metrics including revenue and denials, and working with physicians to track patient outcomes. (See Figure 3.)
8. Health systems should have a centralized authorization team focused on obtaining and facilitating authorizations for facility-administered biosimilars.
9. Specialty pharmacies should have a dedicated clinical team to facilitate authorizations for self-administered specialty drugs.

10. Integrate clinic-based pharmacists to assist in managing the biosimilars process, including order set development, providing physician and patient education, prior authorization processing, and patient assistance support.
11. Utilize pharmacy technicians to facilitate access by completing prior authorizations and coordinating copay assistance programs.

SHARING PERSPECTIVES AND APPROACHES

Health-System Pharmacy

Executive: Our approach is to add a single biosimilar and remove or restrict the branded product. The restriction allows active patients to remain on current therapy or a payer-mandated product. Health system P&T policy allows for interchangeability for new starts through its formulary management.

Physician: We have a great deal of respect for our pharmacy colleagues. They often know more about a great variety of drugs—specialists typically have more therapeutic insight into why they may have chosen a particular agent for a specific patient. Each patient is an individual with a unique history, comorbidities, and other issues which make a difference. Timely prescriber notification and the option to override with an explanation are important.

Health-System Pharmacy

Executive: We have reviewed it as a system and recommend switching to a biosimilar agent for infliximab, bevacizumab, rituximab, and epoetin for inpatients and outpatients (if covered and preferred by the payer). It is not an automatic conversion, so pharmacists have to work with a provider to get the order updated for every single patient.





APPLYING EVIDENCE AND EXPERIENCE TO A CUSTOMIZED APPROACH

Case in Point

One of the differences with Humira (and subsequently other patient-administered injectibles) that had not arisen with infliximab (infusion) is that the device is proprietary. There may be differences from the reference product pen.

There is a lack of available clinical data on outcomes for converted patients and few studies for off-label indications. While, by definition, biosimilars are expected to have the same efficacy and side effect profile as the reference product, physicians' and patients' concerns can be barriers to adoption. Oncology has the most penetration of biosimilars, primarily because evidence from Europe supported their use and, for some therapies such as filgrastim, the clinical response can be objectively measured. However, for other biosimilars, this evidence is currently limited.

Physicians are less likely to convert patients to biosimilars that are well-established in long-term therapy with a reference product for chronic conditions (e.g., Crohn's disease and rheumatoid arthritis) due to concerns with efficacy and lack of significant cost savings for patients.⁸ For self-injected biosimilars, delivery device differences add complexities to the conversions. Health systems and providers can customize their approach to adoption by building and applying available evidence on the safety and efficacy of conversion to a biosimilar.

Adoption Strategies

1. Ease in new biosimilars by requiring them only for new starts to increase exposure and experience with the new product, then consider the potential for expanded conversions.
 - Support medications, such as filgrastim, can be easier to switch since they are short-term therapy and the clinical response can be objectively monitored.
2. Adopt biosimilars when their use is supported by national guidelines and for acute indications (e.g., oncology).
3. Recognize that each patient will have different educational needs and require different educational approaches.
 - Engage the patient where they are, then fill in the gaps.
 - Customize education that recognizes differences for new starts versus switching from a reference product.
 - Connect patients with outside informational resources, like patient-facing organizations and patient champions already on a biosimilar.

Pharmacy has been the catalyst for biosimilar conversion and is involved at every level of the implementation process.

—Health-System Pharmacy Analyst

4. Recognize that biosimilars may have different delivery devices from reference product.
5. Create a comprehensive clearinghouse of evidence in different patient populations from Europe and publications from centers in the United States.

- Incentivize or provide a mechanism for early adopters to collect and publish real-world data showing safety and efficacy, particularly experience with disease states with reference product indications.

Strategy in Practice

We (health system oncology service) tracked clinical performance with our first conversion (filgrastim) in a non-inferiority study (healthcare resource utilization patterns, time to neutrophil recovery, duration of neutropenia, etc.). As expected, we didn't find any clinical difference.

6. Support collaborative research to collect key data (Figure 3) on biosimilars and when switching between biosimilars.
7. Map out a timeline and strategy for each biosimilar implementation that considers factors affecting adoption. (See Figure 5.)



PATIENT AND PROVIDER ENGAGEMENT

Patient and provider education is critical to the adoption of biosimilars. Providers must feel confident that the therapy will be safe and effective for their patients and, as the patient's advocate, ensure the patient can access indicated therapies at the lowest out-of-pocket cost. Unfortunately, the provider has no incentive to switch therapy for stable patients, resulting in an administrative burden (costs, time, and resources) with no return. It is particularly challenging for smaller practices with limited resources to create educational materials, navigate copay assistance programs, and process prior authorizations. Furthermore, there is often little incentive (e.g., reduction in their copay or premiums) for patients to switch therapy, but some perceived risk, if they are stable and tolerating their therapy well. In some cases, biosimilars can even be more costly to the patient because copay cards are

FIGURE 5. ACCELERATING ADOPTION



EARLY ADOPTERS

- Gather a team of key stakeholders
- Understand drivers of adoption and incentives
- Identify a physician champion
- Create a biosimilars subcommittee
- Implement biosimilar where outcomes are easily monitored, new starts, good evidence



SEASONED ADOPTERS

- Share successes with other providers
- Utilize pharmacy support to assist with prior authorizations
- Create a performance dashboard
- Expand to more biosimilars, consider conversions



INNOVATORS

- Share successes with payers
- Consider the risk contract with the payer
- Expand to all therapeutic categories
- Publish real-world evidence

not available to reduce patient costs. Additional barriers identified were:

- Self-injected biosimilars having different key features from the originator, such as injection device (e.g., preloaded syringe versus auto-injector) for patient acceptance.
- The naming of some biosimilars causes confusion and implies a difference between the available biosimilar and the given reference product.
- Some copay cards are available for a biosimilar or branded drug, but only for certain indications resulting in a negative incentive—higher copays—for patients.
- Providers and patients have concerns about the risk of relapse and flares, especially when they could lead to hospitalizations.
- Communication and education about changes are sent to the patient from the payers; however, pharmacists or physicians aren't always aware of that until they hear from the patient, who is confused.
- There does not always seem to be a consistently applied rationale to payer policies; step therapy does not always align with the evidence-based guidelines, or logic is inconsistently applied. For example, sometimes, there are denials when an indication is off-label for a particular drug. However, an off-label drug is required as the first choice of therapy in other situations.

Even if one provider is not on board, it can cause confusion or derail the strategy.

—Health-System Executive, Oncology

Case in Point

Time is definitely a limited resource but essential in addressing the many patient concerns associated with switching therapies, especially those with chronic diseases, such as irritable bowel disease or rheumatoid arthritis, where the patient may have been on the product for a long time, controlled, and stable—the worry of the switch will require time spent with the patient.

Adoption Strategies

1. Build upon existing relationships and trust between patients and providers.
2. Ensure adequate time is allowed for the prescriber and patient conversation; this is key to effectively engaging patients in their chronic disease management, including the use of a biosimilar.
3. Proactive outreach to patients is essential (e.g., via the patient portal in their electronic health record or mailings) to inform them of their options (assuming they have one) and to come prepared with questions for their physician or pharmacist.
 - There should be significant lead time when requiring changes (e.g., no less than six months in advance).
4. Equip clinical pharmacists and physicians with talking points (e.g., similar to generic switches, reassure them there was a rigorous FDA review process).
 - Create standardized, foundational information about the biosimilar, and customize it to the indication or situation (e.g., established therapy versus new starts).
 - Use generic terminology versus brand names in communications.

- Provide a hotline/helpdesk number in the letter so patients can speak with a pharmacist for any questions.
5. Payers, health systems, patient advocacy groups, and professional associations should collaborate to create and provide patient and provider education to deliver a consistent message.

Tailoring patient education around specific needs and common confusion points was a great way to more deeply understand how to tailor our educational materials so they could have as much impact as possible.

—Executive, Health Plan

6. Processes across care settings should ensure minimal treatment disruption and follow-up to assess the patient experience.
 - Proactively determine which product the patient should receive and discuss

options with the patient in advance. Doing so would eliminate denials, improve patient satisfaction, improve provider satisfaction, and prevent delays in treatment.

- Remove administrative burden on physicians when prescribing biosimilars (e.g., remove the PA requirement).
 - Follow-up with patients after treatment to close the loop and address any concerns.
7. Identify a physician champion(s) to assist with provider education; providers are more likely to embrace an idea for change from trusted peers.
 8. Patients need to see the direct benefits of using a biosimilar, with a reduction of their out-of-pocket costs.
 - Ideally, copays are minimal or waived, but if there is a need for copay assistance programs, they should be comparable to the assistance available with a reference product.

SUMMARY

This report provides insights from a diverse group of healthcare leaders who engaged in a virtual discussion to share their experiences implementing biosimilars, challenges with their adoption, and strategies they believe can accelerate adoption to the benefit of the key stakeholders, including patients. The discussion identified key challenges such as the complexity of the delivery system, the lack of cost transparency,

the paucity of real-world evidence, and concerns about affordability. Successful implementation strategies currently in practice and shared by project participants build on existing, trusting relationships between the healthcare team, patients, and payers; alignment of incentives; a coordinated organizational approach; and an adoption plan customized to the therapeutic area.

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APPENDIX 1

VRP QUESTIONS POSTED FOR DISCUSSION

- What barriers discussed during the live call resonated with you? What new strategies did you learn about and may incorporate into your strategy?
- What resonated with you about the live discussion on therapeutic areas where adoption may be easier or more difficult to stimulate?
- How have you evaluated and addressed reimbursement challenges and the impact of payer policies (e.g., payer preferred biosimilars)? Have you done a financial analysis, and, if so, what challenges did you encounter?
- If you could change one thing in the world of biosimilars that you believe would optimize adoption, what would it be?
- How have you tracked the performance of your biosimilars strategy (e.g., market penetration, clinical outcomes, adverse events)?
- What role has pharmacy/pharmacist played in adopting biosimilars and access to patients? Is there an opportunity to expand the role of pharmacists?
- What strategies do you recommend to educate patients about biosimilars?
- How do you approach the patient's copay and evaluate the patient's best choice?
- How have you worked to increase collaboration and alignment of incentives between payers and health systems/providers? What do you see as a best practice or effective strategy?
- How have you worked to align with patients? What do you see as a best practice or effective strategy?
- How have you utilized technology to support adoption and evaluate outcomes of biosimilars?
- How has your organization managed discordance between formulary preferred biosimilars with different payer plans?
- How are you preparing for/handling the difference between interchangeability for medical and non-medical switches?
- What legislative or payer policy changes do you believe would have the greatest impact on the adoption of biosimilars?

APPENDIX 2

VIRTUAL RESEARCH PANEL ROSTER

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The ASHP Foundation was established in 1968 by ASHP as a nonprofit, tax-exempt organization. As the philanthropic arm of ASHP, the Foundation shares ASHP's vision that medication use will be optimal, safe, and effective for all people all of the time. Our mission is to support ASHP by advancing the professional practice of pharmacists and the pharmacy workforce by funding research and education that improves health outcomes through optimal, safe, and effective medication use. To learn more about the Foundation's programs, visit ashpfoundation.org.

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