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Biosimilars: What we can learn from early adopters

By Sonia T. Oskouei, PharmD, BCMAS, DPLA, Vice President of Biosimilars, Cardinal Health Specialty Solutions

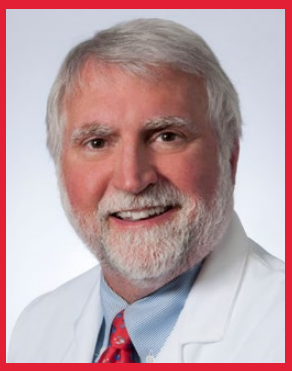
Three early adopters of biosimilars reveal insights to drive uptake in oncology

Six years ago, when the U.S. was on the cusp of approving its first biosimilar, many industry experts predicted that this new class of products, once commercially available, would be widely adopted and would drive a significant decrease in drug prices. However, with 20 biosimilars on the market today, the reality has not fully lived up to the early expectations. While some biosimilar products have experienced faster uptake than others, the overall product category has been challenged by complex payer dynamics and operational barriers, as well as clinical hesitancy and continued knowledge gaps among some healthcare providers (HCPs).

Perceptions about biosimilars among HCPs have evolved significantly over the past couple of years, specifically in oncology. Surveys of community-based oncologists, conducted by Cardinal Health, show that in 2017 only 28% expressed a willingness to prescribe a biosimilar to existing patients having success on a reference product, but by 2020 that percentage had grown to 70%. Yet in spite of their growing interest in biosimilars, many oncology practices still face challenges with adopting them.

To better understand how oncology practices can begin to overcome these obstacles, we spoke with three leaders in biosimilar adoption: Steven Yates, MD, Medical Director at Intermountain Healthcare in Las Vegas, Nevada; Josh Cox, PharmD, BCPS, Director of Pharmacy and Research at Dayton Physicians Network in Dayton, Ohio; and Matt Moser, PharmD, CPh, Lead Clinical Pharmacy Specialist at Health First Cancer Specialists in Florida. Their experiences and perspectives serve as the basis for the insights and best practices outlined below.

Meet the experts



Steven Yates, MD, serves as Medical Director at Intermountain Healthcare in Las Vegas, Nevada, which is ranked in the top five of U.S. health systems for quality, cost and innovation, and operates three oncology and hematology clinics. From a payer perspective, about 85% of Intermountain Healthcare's patients are on Medicare Advantage plans and the practice has its own health plan.

Joshua Cox, PharmD, BCPS, serves as Director of Pharmacy and Research at Dayton Physicians Network (DPN) in Dayton, Ohio, which is a multi-specialty network that provides comprehensive cancer care and urologic care to patients served at 12 locations. Approximately 59% of DPN's patients use Medicare, 33% use commercial insurance and about 8% are on Medicaid.

Matt Moser, PharmD, CPh, serves as Lead Clinical Pharmacy Specialist at Health First Cancer Specialists, an integrated delivery network comprised of four non-profit hospitals and five community-based infusion centers located on the east coast in Florida. Approximately 60% of their patients are covered by Medicare, 20% are covered by the HealthFirst's own health plan and 20% are covered by a mix of commercial payers.

1 Challenge 1: Building provider confidence

When it comes to patient care, clinicians first and foremost must have confidence in the efficacy, safety and outcomes associated with treatments they prescribe. With a high level of familiarity and comfort associated with reference biologics given their utilization for over a decade in cancer care, additional efforts are necessary for HCPs to develop equivalent trust in biosimilars.

Despite the first biosimilar being commercially available since 2015 in the U.S., market research studies reveal that some healthcare providers still lack familiarity with biosimilars and therefore lack confidence to prescribe them. Having a deep understanding of the FDA approval process and the scientific rigor behind biosimilar approvals, along with perspective on how they have been used in international markets, is critical to strengthening provider confidence in biosimilars. Proactive educational efforts driven by influential "champions" within organizations can serve as powerful strategies for overcoming clinical hesitation to prescribe biosimilars.

Challenge 1: Building provider confidence (continued)

Below are some of the strategies early adopter practices used to build provider confidence.

- **Designate an individual or team of biosimilar champions.** Steven Yates, MD, Medical Director at Intermountain Healthcare in Las Vegas, Nevada, says that two and a half years ago, Intermountain Healthcare hired and empowered him with the leadership authority to champion the practice's adoption of biosimilars.

  He leads the necessary research into each product's efficacy and has the authority to make biosimilar formulary changes for his practice. He acknowledges that when a practice starts its initial stages of biosimilar adoption, provider education and stakeholder dialogue are critical to driving provider confidence and buy-in. However, Yates says that having a leadership champion with the authority to drive change is key to making significant headway.

  Josh Cox, PharmD, BCPS, who serves as Director of Pharmacy and Research at Dayton Physicians Network (DPN) in Dayton, Ohio, agrees. Cox says that at his practice, a 10-person, centralized Pharmacy and Therapeutics (P&T) Committee serves as the decision-making body responsible for standardizing the practice's formulary, similar to a health system model.

  Cox served as the champion of biosimilar adoption at his practice, and started educational efforts with the physician members of his practice's P&T Committee, to ensure they were comfortable with and understood the FDA approval process for biosimilars. Their initial approach was to evaluate the primary literature and adverse event profile for each agent and make a decision as a committee whether to adopt each one based on their findings.

  "When biosimilars first started coming to market a few years ago, there was a lot of interest in how they could impact cost of care," said Cox. "We worked quickly to develop a thorough understanding of what they were, how the FDA approved them and what the regulatory approval process looked like. Our practice leadership has always been progressive and interested in evaluating and adopting drug programs that can have a significant impact on healthcare spend."

- **Leverage data from both the U.S. and international markets to drive physician acceptance.** When U.S.-based clinical trials included a relatively small patient population, Cox said his practice's P&T Committee also reviewed European clinical trial data that included larger numbers of patients, and focused primarily on adverse events and infusion-related reactions.

  All three of the early adopters we interviewed agreed that using European clinical trial data has been helpful in solidifying an additional layer of physician confidence in biosimilars.

- **Consider gradual biosimilar adoption strategies to drive prescriber comfort level.** Matt Moser, PharmD, CPh, who serves as Lead Clinical Pharmacy Specialist at Health First Cancer Specialists, highlighted that when his IDN started incorporating biosimilars into patient regimens, their clinical team intentionally chose to initially prescribe them only with "new starts," and only when the physician and the patient felt comfortable.

  "We didn't push hard on converting patients to biosimilars until [some of our physicians had experience with them], more biosimilars were on the market and we had more confidence in the results," said Moser.

  Using this approach, within a month, Moser's IDN was able to convert 90% of one of its supportive care agents to the biosimilar.

Challenge 2: Analyzing costs and other decision variables

Once providers become comfortable prescribing biosimilars from a clinical standpoint, product decisions are primarily driven by financial considerations including costs and reimbursement. However, in situations where there are several biosimilar options for a single reference biologic (i.e., five trastuzumab biosimilars available as of February 2021), other variables may also play into the equation. Product costs, contracts, rebates and reimbursement rates (per commercial payer policies as well as Medicare payment limits) are all variables that need to be considered in evaluating product options. Many of these variables can change multiple times in a year, so product decisions require frequent re-evaluations.

When clinical and financial comparisons are similar among products, considerations such as the relationship and past experiences with the manufacturer can also contribute to product decisions. Supply reliability and patient support programs, for example, can influence prescribing decisions when all other factors are deemed equivalent. As with any new treatment adoption, there is always an associated "cost of change," so it is also important to ensure that the value of switching treatment exceeds any costs or burden associated with making a change in practice. Developing an organizational strategy and approach to evaluating biosimilars, including the cadence and variables for consideration, is key to ensuring treatment decisions are maximized for patients and the practice.

- **Consider the hidden labor costs of switching from one biosimilar to another**. Conceptually, competition within the biosimilar market is driving product prices down — which, from providers' perspectives, is usually a good thing. New market entrants will often seek to compete on price, and established competitors often implement pricing changes to acquire new customers, too.

  However, Yates explains price drops alone are not the only factor he considers when determining whether to make a switch, and keeping up with constant pricing changes is its own challenge.

  "Switching from one biosimilar to another requires rebuilding each patient's entire care plan in our electronic health record (EHR)," said Yates. "That effort comes with a significant time and labor cost, and takes time away from patient care and other priorities."

  For that reason, Yates says that, assuming similar efficacy rates for competing products, the cost difference needs to be relatively significant for his practice to switch from one biosimilar to another. Yates says his practice has had success working with the manufacturers of biosimilars that are already on their formulary to request more competitive pricing. That strategy has led to reduced costs without having to endure the administrative time investment that comes with making changes in each patient's EHR.

- **Pre-screen biosimilars before they reach the market and negotiate early adopter pricing.** Pre-screening biosimilar options before they are available on the market has been an effective strategy for Intermountain Healthcare to lock in the most competitive prices for emerging biosimilars — which Yates says is an important component in driving down not just his own practice costs, but also in driving down the total costs of care.

  Yates recommends proactively initiating negotiations with the biosimilar manufacturers, because most have incentives for early adoption. These negotiations can be managed by your GPO or other contracting partners.

  "As soon as each therapy becomes available, we have our competitive pricing contracts already in place, and can begin immediate adoption," said Yates.

Challenge 2: Analyzing costs and other decision variables (continued)

- **When multiple biosimilars are available for the same indication, use financial comparison tools to help select the best option for your practice**. When multiple biosimilars are available for the same indication, DPN still conducts reviews of each product's performance in FDA trials, and of their efficacy and safety profiles. But more often than not, they find no meaningful differences. That's why DPN has built financial comparison tools to assess the economics of each biosimilar option. These models take into consideration the varied factors that determine the real costs of adopting a biosimilar, including reimbursement rates, contracts and rebates. DPN reviews this data quarterly since biosimilar options, pricing and payer formulary preferences change so frequently. He says that this process identifies at least one or two opportunities quarterly where switching to a new biosimilar would be financially advantageous to the patient, his practice, or both.

  "The biosimilar financial analysis tools that Cardinal Health provides through its VitalSource™ GPO practice consultant team have been very helpful to us when conducting our quarterly economic analyses," said Cox. "We've developed proprietary comparison tools for our practice, but the data I get from Cardinal Health validates the information I gather on my own. Cardinal Health data also helps us keep on top of the biosimilar pipeline and helps us evaluate where we should focus our biosimilar adoption efforts."

  Moser also utilizes Cardinal Health financial analysis tools and data to conduct financial comparisons of biosimilars in the same class, and said that having accurate data, which reflects his specific practice's wholesale pricing and rebates, has been particularly helpful in ensuring his comparisons are accurate.

- **Consider other manufacturer-related factors**. When there are multiple biosimilar options for the same indication, and all have similar efficacy and toxicity profiles, Yates says other factors, including the reliability of the manufacturer, help guide decisions on which option to adopt into patient care plans. Supply continuity, support services and past experiences can all influence product decisions.

"Some manufacturers have a much longer history of product production, and of being able to deliver product without interruptions," said Yates. "Those are factors we consider. We look at the price of each option, and the stability of each manufacturer's product production, as additional considerations to help us determine which product to include in our formulary."

"The adoption of biosimilars isn't just about practice-based economics, it's about driving down the total cost of care. In our practice, if we can reduce the total cost of care, we will. More often than not, when we've evaluated the opportunity to switch to a biosimilar, both the total cost of care and the practice economics have been favorable. For practices that haven't already started exploring biosimilar adoption, I highly recommend getting started."

Joshua Cox, PharmD, BCPS, Director of Pharmacy and Research at Dayton Physicians Network

Challenge 3: Navigating complex payer dynamics

One of the most persistent challenges to biosimilar adoption is managing the payer landscape. With the vast majority of biosimilars available as infused therapies in the outpatient setting, product utilization is heavily influenced by payer coverage. Many commercial insurers utilize formulary management tools to control costs and product utilization. Payer policies can vary by region, patient and product, even depending on the time of year. As a result, providers are challenged with keeping up with payer formulary decisions based on their specific payer mix, while also making treatment decisions that result in optimal clinical and financial outcomes. Additionally, quarterly changes in average sales price (ASP) and Medicare Part B payment rates, as well as potential delays in Healthcare Common Procedure Coding System (HCPCS) assignments from CMS for newly launched biosimilars, can influence prescribing decisions and require frequent and constant monitoring.

- **Providers prefer parity payer coverage for biosimilars**. The payer landscape that Cox and his colleagues at DPN have to contend with is considerably varied: 59% of patients use Medicare, 33% use commercial insurance and about 8% are on Medicaid. Now that physicians at DPN are comfortable prescribing biosimilars, his practice is focused on how to efficiently and quickly switch patients to new biosimilar products as they become clinically available. He says varying payer biosimilar policies make that a considerable challenge.

  "Payers are picking and choosing the biosimilars that they want to have on their formularies, and those payer-to-payer formulary differences create many challenges, making it very difficult, if not impossible, to maximize the single use of any biosimilar agent across our practice," said Cox. "These payer-to-payer differences also place a huge time burden on our physicians, who sometimes have to touch a medication order multiple times, because a payer preference has changed multiple times within a span of a year."

  Moser says that Health First experiences some of the same challenges.

  "We take all insurances, and it's challenging to stay on top of which biosimilar is preferred by each payer," said Moser.

  Moser says that when payers make frequent changes to biosimilar formulary decisions, lack of clear and immediate communication about those changes can cause delays in patient treatment.

  All three of our early adopters indicated that if practices could be freed to prescribe the biosimilar that they felt was clinically best for patients, at the best price for the patient and the practice, biosimilar adoption would be far more straightforward. The labyrinth of payer biosimilar formularies, changes and reimbursement structures adds untold levels of complexity that they believe is slowing adoption of new therapies that truly have the potential to significantly drive down the total costs of care.

- **Work with payers to reinforce your practice's need for consistency and be persistent in requests for reimbursement policies that facilitate/enable biosimilar adoption**. Moser says his practice has had success working with payers to negotiate reimbursement for biosimilars.

  "Your business management team has to be proactive in discussing biosimilars with payers, and you have to be willing to push back if payers are onerous," said Moser. "You've got to be able to run your practice with a certain level of consistency in your work product. If you have a high level of variability [in the products you include in patient regimens], you have more opportunity for errors and mistakes. So ideally, you try to get away from a high degree of variability."

  Moser said that early on, health plans were not as proactive as he initially hoped, but after payers saw an increase in new biosimilar products and more interest in prescribing them, they began to be more open to discussions.

Challenge 3: Navigating complex payer dynamics (continued)

He said that payer strategies, like removing prior authorization requirements from biosimilar products and instead requiring prior authorization to prescribe the reference product, make it far easier for physicians to adopt biosimilars into practice.

- **Practices like Intermountain Health, which serve a high proportion of Medicare Advantage patients, tend to face fewer obstacles to biosimilar adoption**. Encouraged by the adoption of biosimilars in Europe, Intermountain Healthcare has been using biosimilars since 2018. Yates says that because his practice's oncology and hematology clinics primarily serve Medicare Advantage patients, the health system is, in effect, its own payer. That means it has significant control over its own formulary. His practice doesn't generally need to worry about pre-authorization hurdles, or about multiple payers having varied processes and price structures for adding biosimilars to their formularies. However, this model puts heightened importance on cost containment strategies to ensure organizational viability, which further supports biosimilar utilization.

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> **Matthew Moser, PharmD, CPh, Lead Clinical Pharmacy Specialist, Health First Cancer Specialists**

Without having to worry about biosimilar-related payer reimbursement challenges, Yates and his colleagues have been able to exclusively focus on researching the efficacy profiles for each biosimilar option, and on analyzing the degree to which each biosimilar could positively impact the costs of care for the patient, the practice and the overall health system.

When a new biosimilar comes to market, Yates said his practice runs a report on all patients on that branded or current biosimilar medication.

"If they're a Medicare Managed Care patient, we can and will easily switch them," said Yates. "For patients with commercial insurance that requires prior authorization to make a switch, we wait and request the new biosimilar upon renewal."

Challenge 4: Managing operational challenges

As previously discussed, many of the operational barriers to biosimilar adoption are the result of varying payer policies that require the use of one particular biologic/biosimilar over another. This dynamic can force practices to carry multiple, if not all, product options for a single reference biologic. Management of multiple products creates operational challenges including inventory management, EHR maintenance, and expanded administrative duties including increased prior authorizations. To protect the financial health of a practice and to avoid any potential delays in delivering patient care, it's critical for practices to implement strategies to manage the operational considerations associated with biosimilar adoption.

Challenge 4: Managing operational challenges (continued)

- **As more biosimilars come to market, consider the real impact of EHR fatigue on physicians**. One of the biggest challenges DPN faces when introducing new biosimilars to its formulary is that each of its physicians must go into the practice EHR and manually discontinue one treatment and create a new regimen with the new biosimilar for the next round of treatment. The process is very time consuming and the administrative burden can be frustrating for physicians, who usually prefer to focus their time on patient care activities.

  "Because of the ways the payer landscape is unfolding, and because of the frequency of new biosimilar product launches, we have opportunities to switch to new biosimilars multiple times per year," said Cox. "However, we're finding now that when we switch biosimilars too frequently, our doctors are less engaged in helping us with the switches. They're just tired of hearing about it, tired of dealing with payers, tired of having to input new orders — because it's time consuming and administrative. So now, when we consider introducing a new biosimilar to the formulary, we take a close look to ensure that the financial benefit for the change is large enough to justify it. We also strongly consider whether our doctors will be receptive, or if we should delay the change for a while, to avoid fatigue and drive greater adoption, later."

  Moser agreed.

  "It's challenging to switch from one biosimilar to another, because our hospital system has a P&T formulary and each health plan has its own formulary. That makes switching regimens a lot of time and work."

  He recommends that practices refrain from switching to one biosimilar to another, within the same class, within the same year, and says that his practice has been able to negotiate additional discounts by sticking with one biosimilar for an extended period of time.

> "Some manufacturers have a much longer history of product production, and of being able to deliver product without interruptions. Those are factors we consider. We look at the price of each option, and the stability of each manufacturer's product production, as additional considerations to help us determine which product to include in our formulary."
>
> **Steven Yates, MD, Medical Director at Intermountain Healthcare**

- **Limit your inventory to a two-day supply to expedite the process of introducing new biosimilars to your formulary**. Cox says that DPN's buyer places pharmaceutical orders based on the next two days' worth of therapy needs, reflective of the patient schedule. DPN stores very small quantities of product in-house, with only a couple of extra doses to allow for a patient add-on or breakage. Having a "just-in-time" amount of inventory on hand ensures that product switches aren't slowed down by waiting on the depletion of in-house inventory levels before a new product can be introduced.

Challenge 5: Helping patients become comfortable with biosimilars

The most important stakeholder in any prescribing decision is the patient. When it comes to biosimilars, patient education is instrumental to ensuring patient comfort and confidence when initiating or transitioning treatments. The oncologist-patient relationship is a sacred one, and oncologists play a significant role in ensuring patients feel comfortable with biosimilars. When providers are confident and able to educate patients on biosimilars in a way that is easy to understand, patient confidence is enhanced as well.

Notably, patient comfort with biosimilars is not solely determined by oncologist interactions. Nurses, pharmacists, administrators and other healthcare professionals who interact with patients along their care journey all play a role in ensuring education and consistent messaging are delivered. In fact, studies have revealed that gaps in healthcare provider awareness, understanding and perception in biosimilars can even contribute to the "nocebo effect," whereby a patient may experience new or worsening symptoms based on negative expectations versus the pharmacologic treatment itself. Patient engagement strategies are key to reducing any potential impact on clinical outcomes that may be the result of lack of patient comfort with biosimilars.

- **Implement nurse- and physician-led patient education to quickly earn patient confidence**. Yates says his practice has engaged nurses to explain to patients the efficacy and toxicity standards that biosimilars are required to meet before they're commercialized. In his experience, once patients understand that the main difference between biosimilars and their branded counterparts is price, they rarely receive pushback.

  Moser agrees that helping patients to understand that making the switch may result in lower costs for them is important.

  Moser said that Health First's nurse educators created simple tools to estimate the patient cost savings that a given biosimilar would provide, extrapolated for the year. These patient cost projections were particularly well received by patients at the beginning of each calendar year, before patients had exceeded their out-of-pocket insurance maximums.

  "We haven't experienced any patient push back regarding biosimilars, due, I think in large part to the conversations our medical oncologists and nurses are having with patients," said Moser. "We explain to our patients that we're switching them to a biosimilar, what a biosimilar is and how it compares to the branded version. There's a very trusting relationship between medical oncologist and a patient, and between our nurses and our patients. When the practice does a good job providing information, the trust level is there."

  Yates agrees and says that trust level extends even as patients are converted from one biosimilar to another.

  "We have never had a patient request to go back to a biologic, [or to go back to a prior biosimilar, in cases when we've moved from one biosimilar product to another]," said Yates. "In the tightly regulated pharmaceutical space, with all the industry's measures focused on quality, I wouldn't expect patients to see or feel a difference."

Closing thoughts

While biosimilar adoption has been challenged by complex payer dynamics, operational barriers and knowledge gaps among some healthcare providers, the experiences and insights of Yates, Cox and Moser demonstrate that some forward-thinking practices are already leveraging this new class of therapies to reduce costs, without sacrificing patient outcomes.

As just a single proofpoint, Moser shared that Health First was able to reduce its total medication costs by more than $3 million in one year, thanks specifically to its biosimilar adoption efforts. Yates says his practice saved approximately $1.5 million due to biosimilar adoption last year.

Importantly, the early adopters with whom we spoke reinforced that their embrace of biosimilars isn't just about practice-based economics, it's about driving down the total cost of care.

"In our practice, if we can reduce the total cost of care, we will," said Cox. "More often than not, when we've evaluated the opportunity to switch to a biosimilar, both the total cost of care and the practice economics have been favorable. For practices that haven't already started exploring biosimilar adoption, I highly recommend getting started."

As more practices share their experiences with biosimilars and their successful strategies for adoption and cost savings metrics, we believe that biosimilars will continue to serve as valuable tools for oncology practices in their continued quest to deliver high-quality care to more patients at a lower cost.

About the author

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Sonia T. Oskouei, PharmD, BCMAS, DPLA, is Vice President of Biosimilars for Cardinal Health, responsible for leading the biosimilars strategy across the organization. In her role, she leverages an enterprise perspective to maximize the value of biosimilars to enhance patient access to critical therapies and improve outcomes, while lowering the costs of high-quality care. She previously led Premier Inc.'s national biosimilars strategy on behalf of 4,000 hospitals and 175,000 other provider types. She is a frequent speaker and author on biosimilars and serves on the Advisory Board for the Center for Biosimilars.

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Whether you have already begun using biosimilars or you are still evaluating the role that biosimilars could play in your formulary, Cardinal Health and our VitalSource™ GPO team of practice consultants can help. Contact us at:

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