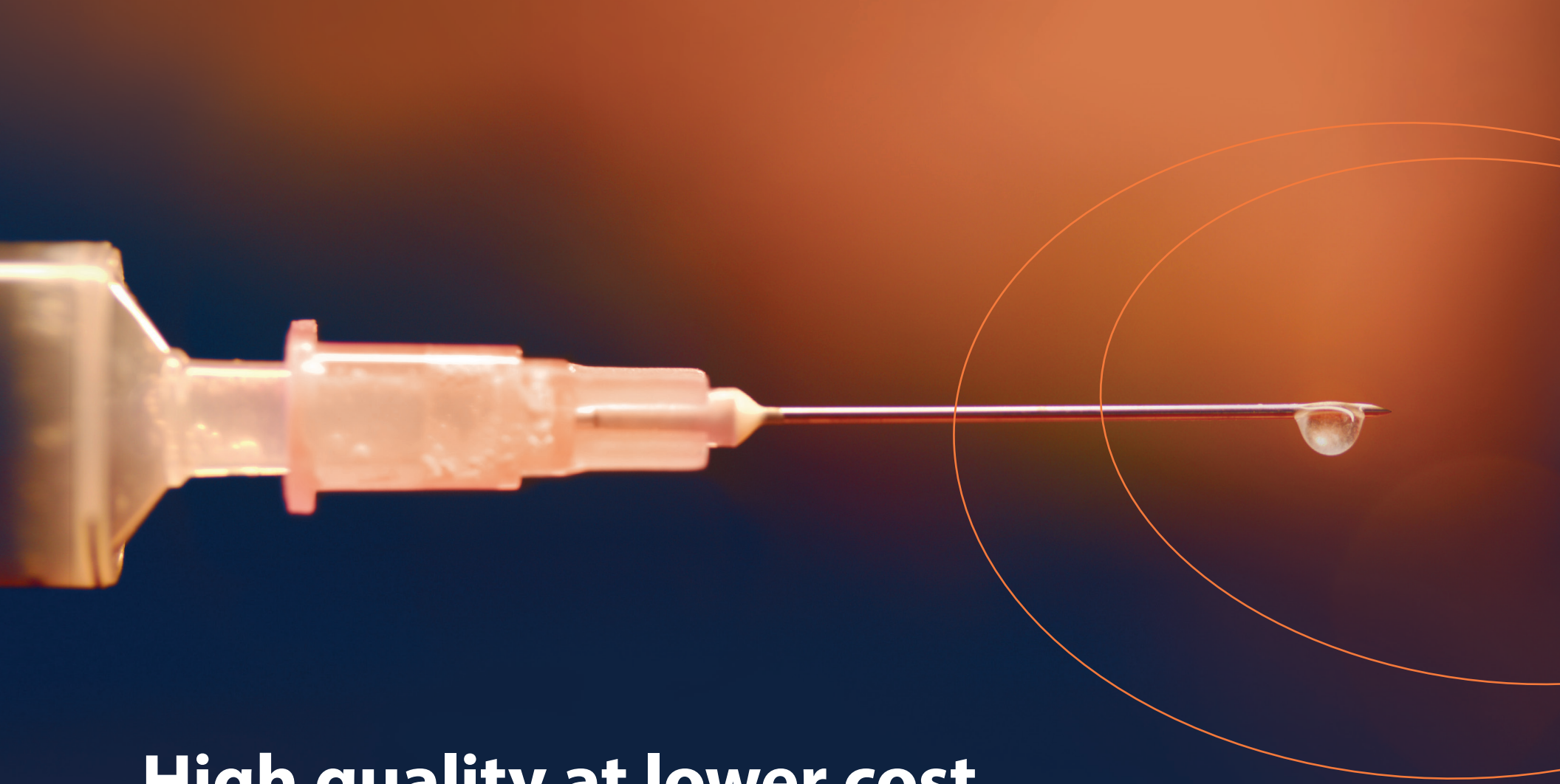


High quality at lower cost

Practical tips for adopting biosimilars in your health system

the craneware group™

Contents

Introduction

Spending on drugs is a huge driver of costs in hospitals, and these costs are only growing.

According to a 2022 report from ASHP,[1] non-federal hospital drug spending rose 8.4% in 2021 to $39.6 billion, while clinics spent $105 billion, a 7.7% increase. From the onset of the pandemic in 2019 to 2021, drug-price inflation topped all other categories of hospital expenses at 36.9%.[2]

The spiraling costs have put hospital pharmacy departments on the hot seat as administrators demand answers.

Just as health systems have for years turned to generic drugs to lower costs, biosimilar versions of biologic drugs represent a growing opportunity for your organization to broaden access to high-quality care at lower costs while improving patient outcomes. One report found that the expanding availability and use of biosimilars was on track to deliver $100 billion in savings by 2024.[3]

But biosimilars remain underutilized in the U.S., and health systems need to balance concerns from providers, patients, and pharmacy staff about integrating them.

In this eBook, we'll outline some tips for adopting more biosimilars at your organization.

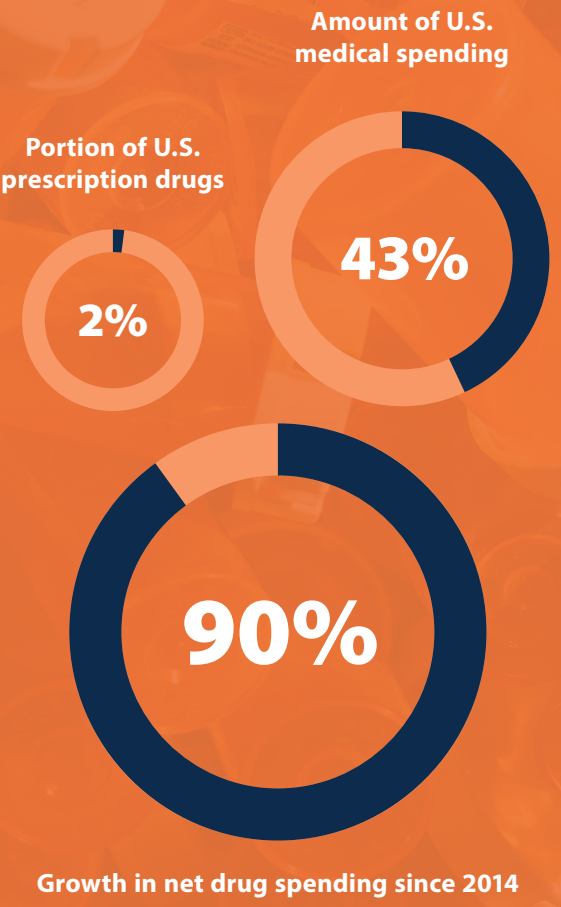
Getting started

Your first step should be to identify the use of biologics at your organization and look for opportunities to substitute biosimilars.

- A good starting point is to identify the biological drugs in highest use at your facility that have a biosimilar available on the market.
- Identify the service lines and prescribers using those biologic agents. You'll need to persuade these providers to move to biosimilars and educate them on their use, safety, and efficacy.
- Evaluate differences in the biosimilars available to determine which product makes sense for your facility.

Biologics by the numbers

Did you know? Biologics comprise only 2% of all prescription drugs in the U.S. but 43% of medical spending.[4] They account for more than 90% of the growth in net drug spending since 2014.[5]



How to adopt biosimilars

There are four steps to adopting biosimilars:[6]

1. Selecting the biosimilars you want to use
2. Review and approval from your hospital P&T committee
3. Implementation
4. Communication and education

We'll discuss each step in greater detail.

1. Biosimilar selection

You'll need to analyze your key services offered and patient populations treated — for example, oncology versus non-oncology, pediatrics, and whether you run any clinical trials using reference biologics, which would affect biosimilar usage.

While biosimilars must undergo a rigorous FDA approval process, you should evaluate clinical and safety data and cost, including institution savings.

Another critical step is gathering information on your institution's commercial and government payor coverage and payor mix. Coverage of biosimilars varies widely by payor, so you need to think strategically and pick biosimilars that will deliver the most reimbursement based on the payors you often work with at your organization.

Lastly, check whether there are patient assistance programs for biological reference products or biosimilars. The goal is for the patient to realize the benefit of switching to a biosimilar, so make sure the patient won't be penalized for switching.

As of September 2022, the FDA approved 38 biosimilars, with 22 available commercially.[7]

2. P&T Committee approval

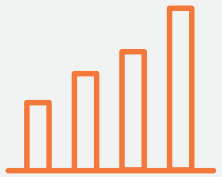
To gain approval from your hospital P&T committee, you'll need to delineate the populations for which the biosimilars will be used, including oncology versus non-oncology, adult or pediatric patients, and naïve or treatment-experienced patients who may already have been given a reference biologic but are eligible to be switched to a biosimilar for the next round.

It's imperative to involve and engage physician leaders to increase the uptake of biosimilars. Seek out physicians and other providers who work well with your pharmacy team to help you champion your plan.

Next, it's a good idea to establish a single preferred biosimilar product based on optimal payor coverage to limit inventory and overhead and keep your pharmacy director happy. Payor coverage can quickly change, such as when new biosimilars become available.

You'll also need to establish a therapeutic substitution process. Will there be automatic substitutions at your organization, or will physician permission be needed before each switch to a biosimilar?

Finally, you'll need to clearly define any exclusions, such as for ongoing clinical trials involving a biologic reference product or specific patient populations.



In 2018, biosimilars captured only 1% of the biologic market accessible to biosimilars in the U.S. By 2021, about 20% of biologic utilization was biosimilars, with savings of 30–40% off reference prices.[8]

3. Implementation

You'll need to involve several different teams as you prepare for implementation:

Involving your hospital IT department early is essential for adopting biosimilars. It will likely take months of work for all necessary order sets and protocols to be updated in the EMR before they are ready for providers to order available biosimilars.

The same holds for your revenue cycle team, which is heavily involved in negotiating with payors and manufacturers over acquisition costs and reimbursement.

Pre-certification or authorization teams are also critical. Let them know to expect to see biosimilars on the order sets so there is no confusion, and make sure they get back to you quickly about issues to minimize delays that could affect patient care. They'll also need to know which biosimilar is preferred by which payor to ensure the provider uses the right option for a given patient. Make a chart for your insurance verifiers, other pharmacists, and prescribers so they know which agent to use, and build it into the EHR, keeping it updated as coverage changes. The people verifying patients' insurance coverage can inform you in advance of any problems with using a specific biosimilar.

3. Implementation (cont.)

Prevent biosimilar medication errors stemming from having multiple options on your formulary. Biosimilars are named for the generic name of the reference product, plus four letters specific to that product. On EMR order sets, both the generic and brand names should be listed to ensure use of the correct product and decrease the risk of dispensing errors.

Inventory management is also critical. Selecting a single biosimilar is ideal for decreasing both the amount of physical storage needed and the financial burden of excess inventory. However, depending on payor coverage, you may need to stock more than one biosimilar.

Remember, those specific biosimilars may have to be drop-shipped, which can take a few days to arrive, rather than being available through your wholesaler, when it can generally arrive the next day.

As of September 2022, there are dozens of biosimilars in development that are expected to gain FDA approval and launch in the coming years. The pipeline suggests biosimilars poised to expand into new therapeutic areas such as ophthalmology, growth hormones, infertility, bone health, and immunosuppressants.[9]

4. Communication and education

To ensure success, good communication, advocacy efforts, and education should happen throughout the adoption process.

Stakeholder perceptions about biosimilars can vary widely, especially in a large hospital or health system. While biosimilars have been around for years, there are still pockets of resistance or misunderstanding. Enlist the help of clinicians who support biosimilars in persuading others who are less familiar with them.

It would help if you aimed to extend your outreach efforts to:

Prescribers

Physician leaders

Case managers

Pharmacists

Patients, of course, are central to the whole process, since the bottom line is to improve drug affordability and access. All your efforts will be in vain if you don't educate your patients about biosimilars, address their concerns, and obtain their buy-in.

A clear plan can help your health system navigate the process smoothly — particularly important given the increasing number of biosimilars available on the market.

Common hurdles to adopting biosimilars:[10]

Availability
Payor denials
Different payor formularies
Adding biosimilars to EMR
Lack of provider awareness

Considerations for a solid communications strategy

Perception is everything. To ensure success, good communication, advocacy efforts, and education should happen throughout the adoption process. The following pages include some aspects to consider for your communications strategy.

Clinical use

- **Changing processes is difficult in any large organization,** so it's essential to gain buy-in from the different service lines that will be affected by adopting biosimilars — oncology, rheumatology, gastroenterology, nephrology, etc. — and identify physician champions within each to build support.
- **Create multi-stakeholder teams.** If everyone has input, they are more likely to buy into the process.
- **Think about the approved indications for biosimilars.** Many biosimilars are FDA-approved for some, but not all, of the indications approved for the reference product. Will you use a biosimilar for a labeled indication for the reference product even when it's not approved for the biosimilar? That's a question for the institution, prescriber, and payor, since you'll need to ensure they reimburse for non-approved indications.
- **Optimize biosimilar utilization by setting.** Evaluate purchase cost and reimbursement by the site of care — inpatient versus outpatient. Ideally, high-cost biologics are being used in outpatient settings.
- **Create options for preferred and non-preferred biosimilars,** or establish a therapeutic interchange process. For example, you can make the preferred product the default with alternative options available if needed.

  If state law allows it, your hospital's therapeutic interchange policy will allow you to change biosimilars without input from a provider if a payor demands a product other than the institution's preferred agent.

Pharmacy & health system operations

Keep your staff up-to-date on your biosimilars, including differences between agents. Their safety profiles are generally the same as those of the reference product.

Revenue cycle

Know your reimbursement amounts for biosimilars. Try to get financial information from your business office or talk with your pharmacy director, who knows which drugs you use that lose money. Keep track of the financials and ensure you're being reimbursed appropriately because what you're paying for drugs and receiving for reimbursement are often very different.

Patient-centered concerns

Keep patients apprised of the safety and efficacy of biosimilars. This goes hand in hand with perception. Some patients may want brand-name drugs, so it's essential to educate them on the benefits of biosimilars — that they cost less while being just as safe and effective.

Conclusion

Implementing biosimilars might seem like a lot of work, but it's worth it. In an analysis of real-world patient data presented at the American College of Clinical Pharmacy spring 2022 meeting, The Craneware Group projected annual cost savings for the three biosimilars available for rituximab based on the averaged 2020 wholesale acquisition cost for a typical dose of 700 mg. With a 20% shift from the reference product to any of the biosimilars, the projected annual cost savings were:

$1.6 million
for oncology indications

$2.2 million
for non-oncology indications

Biosimilars represent an excellent opportunity to lower your drug spending and improve your margins, leaving more money in your budget for new staff, new services or equipment, or other upgrades, improving the care you can provide for your patients.

Contact us today to learn how The Craneware Group can help you implement biosimilars or find other opportunities to strengthen your margins.

CONTACT US

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About The Craneware Group

Founded in May 1999, Craneware has spent more than 20 years as the leading provider of revenue integrity solutions improving financial performance in U.S. hospital and health systems. In July 2021, Craneware announced the acquisition of Sentry Data Systems and Agilum Healthcare Intelligence — optimizing an already-robust catalog of solutions with industry-leading 340B solutions and expertise.

As ***The Craneware Group***, Craneware, Sentry Data Systems, and Agilum collaborate with U.S. healthcare providers to plan, execute, and monitor operational and financial performance, so they can continue to deliver quality care and services to their communities. The Craneware Group's Trisus platform combines revenue integrity, cost management, 340B, and decision enablement into a single, SaaS-based platform, connecting actionable insights to deliver sustainable margin and operational efficiency — something no other single partner can provide.

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