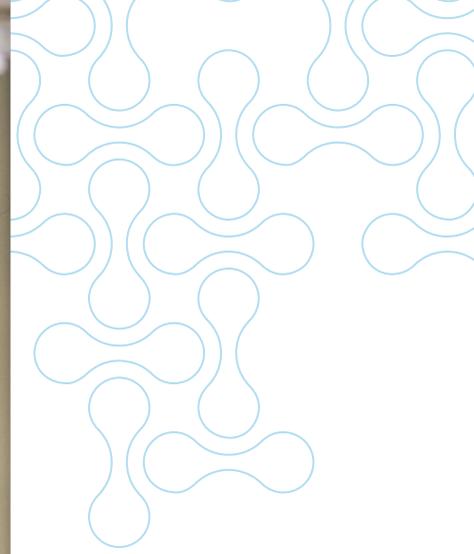




# 340B Playbook: A Guide to Understanding the Complex 340B Drug Pricing Program

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# Overview

## Demystifying 340B So Your Health System Can Thrive



### Did You Know?

340B touches not just pharmacy but every aspect of your organization, including information systems, legal and finance. That's why all health system C-suite leaders need to be involved in 340B decision making. Glean key insights and tips in a Q&A with McKesson's 340B experts.

The U.S. federal government created the 340B Drug Pricing Program in 1992 with a simple intention: to help health systems and other covered entities provide medications at a lower cost to underserved patients. Health systems have a lot to gain from participating in 340B, which can help them accrue significant savings that they can use to fund even more services and programs for vulnerable patients. Yet over the years, the 340B paradigm has grown increasingly complex to implement and manage. Compliance issues, operational hurdles and financial oversight tasks are just a few of the challenges that health systems face — and the ever-changing 340B landscape is anything but simple to navigate.

Designed to help you keep pace with the evolving world of 340B, this playbook can be a go-to resource — whether you're just beginning a 340B program for your organization, or you're looking to fine-tune and optimize the program that you already have. If you're new to 340B or need a refresher, start with our 340B Basics for Health Systems overview, which outlines a few of the ways the program has changed over the years as it has expanded to cover more sites of care. Then, turn to these pages for a deeper dive into three areas of special focus for 340B-covered entities right now:

- Implementing 340B in a specialty pharmacy or ambulatory care setting
- Developing a strong 340B contract pharmacy network
- Navigating 340B discounts for biosimilars

A nuanced understanding of these topics is indispensable for developing a successful 340B program that contributes to your organization's financial strength, while doing the most good for your patients and communities.

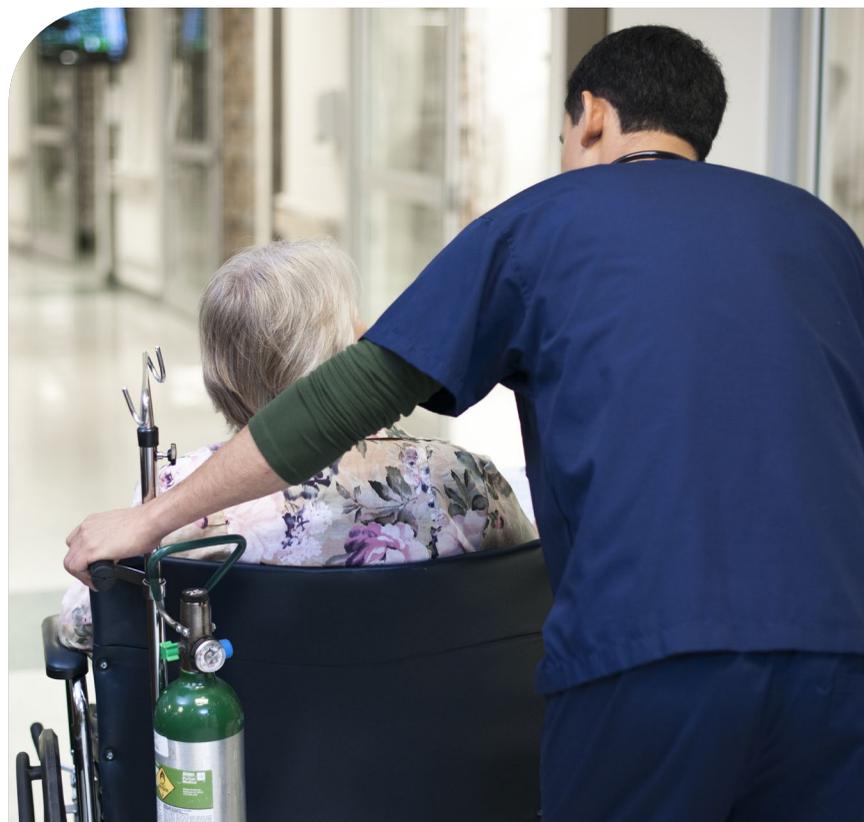
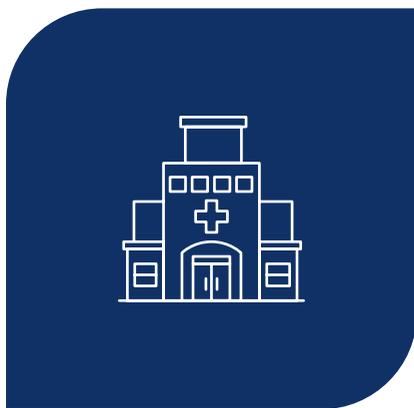
# Chapter 1

## Putting 340B to Work in Ambulatory and Specialty Care

Top of mind for many health systems today is the fast-growing specialty drug market and its impact on everything from clinical operations to hospital bottom lines. Even though specialty drugs represent only a small fraction of prescriptions, the high price of these advanced therapies account for a massive chunk of consumer spending. The financial burden is only expected to snowball as more new therapies are developed — and as specialty medicine moves toward a projected \$118 billion market expansion through 2025.

Controlling costs for specialty patients has never been more of a concern than it is today, and 340B is a critical part of the equation. Many health systems now operate their own specialty pharmacies so they can lower costs, increase revenue and offer more services to their patients. And since these therapies can often be administered on an outpatient basis, caregivers are shifting to ambulatory care settings such as infusion clinics to treat patients for a range of conditions. Suddenly, health systems need to manage a complicated 340B paradigm across multiple sites of care.

If it sounds like a challenging proposition, it doesn't have to be. With the right tools and resources, you can successfully implement a 340B program across ambulatory and specialty care settings. Start by getting a big-picture view with our 340B specialty pharmacy white paper, which covers everything from tips for opening a new site of care, to obstacles and risks you might encounter along the way. Then, read on for a deeper understanding of how a meticulously managed 340B program can stretch federal resources to protect your bottom line and the health of your patients.





## Six Questions to Assess Your Ambulatory and Specialty 340B Program

Hospitals participating in the 340B Drug Pricing Program can reduce their costs for drug acquisition — an advantage that enhances business performance while supporting outreach and care for uninsured and underinsured patients. Although acquiring drugs at lower costs can provide a financial benefit to 340B hospitals, the complexities of the ambulatory pharmacy environment require thoughtful planning and adaptability to ensure success.

Here are six questions to help you effectively manage your ambulatory and specialty 340B program guidelines.

1. How does your hospital's plan align with your ambulatory and specialty pharmacy strategy?

340B can improve the financial performance of a solid proposal, but it can't save a poorly planned pharmacy strategy. Understanding the hospital's plan for continuing care, patient volumes and provider relationships — while aligning them with costs and services — is a key success factor. It is also important to examine provider relationships and competition in your service area. Some hospitals and health systems think that they "own" patients, but will the network of relationships within the integrated delivery network (IDN) ensure access to these patients in the future, and if so, under what terms? Health plans, employers and other providers also have substantial ongoing patient relationships. How will your patients select a provider, and under what rules and guidelines?

2. What do the terms "ambulatory" and "specialty" pharmacy mean to your organization?

Specialty, ambulatory and retail pharmacy are areas that blend together. Key attributes of specialty pharmacy include high-cost treatments for rare or uncommon diseases that have special development, handling, administrative and monitoring requirements. Retail pharmacy is generally the mix of brand and generic oral solid drugs dispensed in 30-, 60- and 90-day supplies. Ambulatory pharmacy commonly falls across the two categories and typically includes "in-clinic" and "in-office" administered drugs.

Because of these differences, payment rules and models vary. In the specialty space, competencies and certifications mean more potential revenue; whereas low cost and high efficiency are the greatest value in the retail environment.

### 3. Are you prepared for the competitive retail and specialty pharmacy environment?

The consolidation of, and competition between hospitals also affects retail and specialty pharmacy. For example, payers and manufacturers seek to narrow networks to contain administrative and patient care costs and to foster competition. Before entering the mature retail or specialty marketplace, determine whether your pharmacy is prepared to compete with national market leaders. Network size combined with key provider and network agreements, lower costs, and efficient operations makes them formidable competitors. In the [ASHP Foundation Pharmacy Forecast](#) for 2018, many surveyed pharmacy leaders predicted that 25% of health systems will abandon plans or discontinue current retail/specialty pharmacy services due to financial challenges associated with these service lines. This reinforces the value of solid business and strategic planning.

Although 340B provides a cost advantage in drug acquisition, how much of that savings will be consumed by the cost of operations? 340B discounts, while generous, are tied to the average manufacturer price (AMP) and are not consistent across therapies. Consider the impact of new therapies on your bottom line. For instance, recent advances in oral oncology therapy have had a positive impact on patient outcomes. However, high drug pricing has proven to be a challenge for the payer and reimbursement communities, making access and delivery of these specialty drugs difficult at times.

### 4. Will potential changes in 340B or prescription reimbursement rules affect your business?

Business plans that depend on 340B discounts should consider the potential risks and alternative outcomes associated with changes in 340B and reimbursement rules. Narrowed patient definition, 340B eligibility, or a changed business relationship with a key group of providers – all these factors and more can influence the 340B/non-340B patient mix. For hospitals subject to the GPO prohibition, non-340B drugs are purchased at full wholesale acquisition cost (WAC), which can result in a substantial premium.

5. Do you have the right tools and resources to be successful?

Hospital pharmacists typically comment on the key differences and new challenges in the ambulatory environment such as developing and securing talent, resources and competencies. However, it is also critical to assess payer and provider relationships, contracts, and software tools like retail pharmacy systems and 340B software.

Other things to consider:

- Do you have expertise in negotiating PBM contracts?
- Are regional payers reducing prescription reimbursements to 340B covered entities?
- Have you built resources to support prior authorization processes for specialty prescriptions?
- Have you considered prescription capture rates based on location, business model and network constraints?

6. Is a partnership or contract pharmacy right for your organization?

Financial planning can help set appropriate expectations and facilitate a full understanding of the likelihood for success — including 340B impact. Traditional and specialty pharmacies are in some key respects similar, but require separate considerations, particularly in services and support. Financial modeling should lead to a review of ramp-up periods, budgeting for capital assets and cash flow, and a frank discussion of alternatives. 340B provides a head start for financial and patient-care success, but only when built on sound strategies informed by targeted insights.



# Chapter 2

## Delivering for Your Patients with Contract Pharmacies

### Stay in the Know

If your organization works with contract pharmacies, here are two ways to keep abreast of industry happenings:

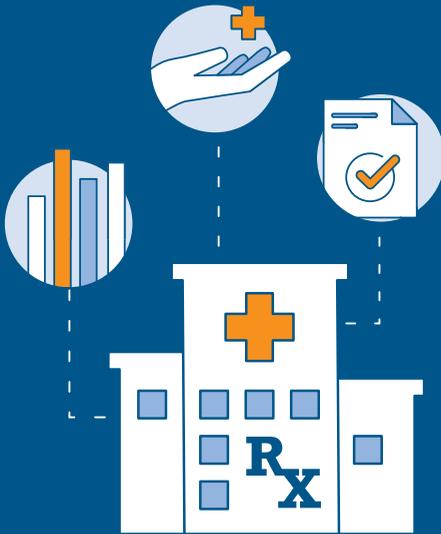
- Watch McKesson's on-demand [webinar](#) about the business impacts of manufacturer 340B contract pharmacy actions
- Check out our experts' [five key takeaways](#) to help you navigate this fast-evolving terrain

In recent years, increasing numbers of health systems and other covered entities have chosen to enter into contracts with outside pharmacies to provide their 340B-eligible patients with access to affordable medications. Partnering with one or more contract pharmacies can make it easier for health systems to participate in 340B if they're unable to offer on-site pharmacy services, or if they wish to supplement those services.

While using contract pharmacies can come with advantages — including lower overhead for hospitals that don't operate their own pharmacies — it can also introduce challenges. For starters, compliance issues tend to be more complicated with contract pharmacies, increasing the likelihood that the covered entity may be audited. And recently, some drug manufacturers have taken action on contract pharmacies, attempting to withdraw certain medications from 340B pricing. While covered entities and other stakeholders are pushing back with lobbying and legal actions, these factors have added a new layer of complexity to contract pharmacy arrangements.

All told, there's a lot to think about when you're partnering with contract pharmacies to secure affordable therapies for your patients. Read on to uncover best practices and practical insights about building contract pharmacy relationships that perform exceptionally well — even in a changing marketplace.





# Three tips for developing a high-performance contract pharmacy network

Excerpts from “Practical Insights into 340B: Developing a High-Performance Contract Pharmacy Network” panel discussion\*

In recent years, we have seen a great deal of activity in the 340B contract pharmacy space. The number of covered entities with a contract pharmacy agreement has grown to over 5,000 with networks ranging in size from a single location to networks of 50 pharmacies or more.<sup>1,2</sup>

Data from the Office of Pharmacy Affairs (OPA) website indicates that during that same time period over 40% of contract pharmacy locations were terminated, indicating some material change in circumstances or expectations between the contracting parties over time.<sup>3</sup>

Covered entities currently participating in a contract pharmacy relationship or considering entering into a contract pharmacy relationship can benefit from strategies that enable them to react swiftly and capture revenue in a changing marketplace.

## Best practices from industry experts

To build a strong 340B contract pharmacy relationship, consider the following three tips from pharmacy directors and senior leaders at the Medical University of South Carolina, Meijer Pharmacy and McKesson’s 340B Consulting team.

### 1 Build strong relationships

One of the first steps for a 340B covered entity to take in building a productive contract pharmacy network is to establish clear organizational goals. Next, strategically evaluate and select contract pharmacy partners to ensure that 340B program expectations are aligned among the parties. After those initial steps are in place, focus on managing and strengthening those contract pharmacy relationships with both business performance and patient care in mind.

Fostering open, frequent communication will help minimize any surprises — especially during Human Resources and Services Administration (HRSA) audits. Having the support of the contract pharmacy partners along with the timely exchange of transaction data and reporting provides a tangible measure of performance and helps pharmacy partners manage expectations.



“Our retail pharmacy partnerships started out as numbers-based, but as we grew and evolved in this marketplace, **we realized that our strongest contract pharmacy providers were also the ones who were the most transparent and cooperative.**”

Heather Easterling,  
Director of Pharmacy Services, Medical University of South Carolina



**“Don’t be afraid to ask your contract pharmacy partners for what you need in an audit. We can help an entity significantly reduce the risk of a potential 340B program violation.”**

Jeff Romano,  
Hospital Programs, Meijer Pharmacy



**“If you are going to go talk to the CFO, have your house in order. It’s your responsibility to educate him/her on the contract pharmacy model – where the revenue comes from, how to understand the contract pharmacy numbers, and every element of expense, including infrastructure and headcount.”**

Gregg Niemiec,  
Senior Managing Consultant,  
McKesson Corporation

Visit [mckesson.com/340B](http://mckesson.com/340B) for more insights and news.

## 2 Enforce strict compliance

Covered entities know that contract pharmacy relationships can be complex and that compliance issues have the potential to jeopardize the covered entity’s 340B program status. Having a robust internal and external auditing process in place along with a well-utilized 340B management software package can help mitigate risks.

Best-in-class contract pharmacy networks understand the value of using a well-supported team of knowledgeable staff to oversee the organization’s 340B program. For example, a 500+ bed academic medical center may have three to five full-time employees dedicated to managing its contract pharmacy network, managing the internal auditing process, generating meaningful financial reports, and engaging with a third party to conduct annual audits. Managing compliance requires an ongoing investment in infrastructure.

## 3 Manage financial reporting and expectations

Other key elements in building a successful contract pharmacy network include understanding and managing the CFO’s expectations through regular and reliable financial reporting. For instance, developing financial controls and systems that help the 340B team track, manage and report revenue and expenses in detail will allow the team to provide store-level analysis upon request. The 340B team should be able to articulate any of the summary numbers that are presented within the organization. Robust reporting typically requires efforts beyond software-generated standard reports given the unique goals of 340B in each organization.

The reporting frequency should be regular, consistent and aligned with the organization. Frequency might be a monthly reconciliation report or quarterly report that highlights trends. Contract partners should work closely with the hospital finance team to develop a model that works for all parties and identify partners in the organization who can provide ongoing support. It may be someone from the finance or reimbursement department, or from a third-party software provider who can assist with developing insightful data.

## Summary

Contract pharmacy networks can be an important component of a covered entity’s 340B program. The complexity associated with 340B requires a deliberate, insightful approach to achieve the covered entity’s and partners’ goals. Asking the right questions and building the necessary infrastructure and relationships will facilitate the development of a risk/benefit profile that is appropriate for your covered entity.

*This white paper was authorized by McKesson Corporation.*

*Note: The information provided here is for reference only and does not constitute legal advice. We make no representations with regard to the content’s comprehensiveness. You are solely responsible for investigating and complying with all applicable laws that govern the operation of your business.*

### Sources:

- \* “Practical Insights into 340B: Developing a High-Performance Contract Pharmacy Network” panel discussion held July 12, 2016, in Washington, D.C.
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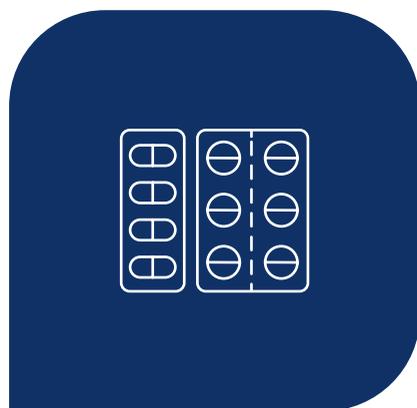
# Chapter 3

## Navigating 340B Savings for Biosimilars

A rapidly growing treatment option for patients with advanced or chronic diseases, biosimilars are biologic products that are highly similar to existing FDA-approved medications. Like generics, biosimilars are marketed as more affordable versions of costlier brand-name drugs, yet they are not generic equivalents. Biosimilars differ in chemical composition to their higher-priced counterparts, and they are subject to a rigorous FDA review process. The first biosimilar came to market in the U.S. in 2015, and after a slow start, this type of therapy is picking up steam. As of January 2022, over 30 approved biosimilars have come to market, with more on the way.

What does the influx of biosimilars mean for your 340B program? While they do offer cost savings, biosimilars do not fit neatly into one box, the way generics often do. Instead, biosimilars must be considered individually, rather than as one class of drugs. That means 340B-covered entities must review each biosimilar on a case-by-case basis to determine its economic value. Adding even more complexity to an already complex system, biosimilar adoption and reimbursement models will continue to change as these medications find footing in the marketplace.

If your organization is navigating the quickly-evolving world of 340B and biosimilars, it's key to stay informed about industry trends and developments. One place to start is by watching our on-demand [webinar](#) about overcoming 340B complications to optimize your supply chain in this area. Then, come back to these pages for the following white paper about biosimilar adoption rates, and discover insights to help your organization thrive in today's dynamic environment.



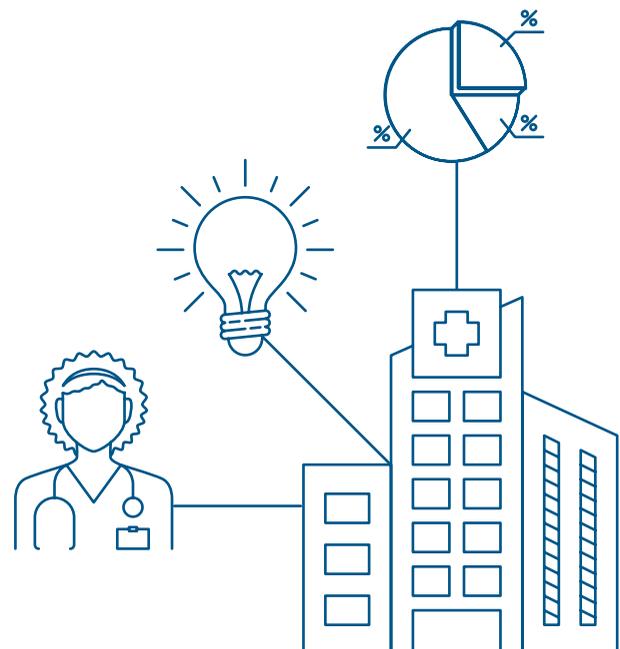
WHITE PAPER

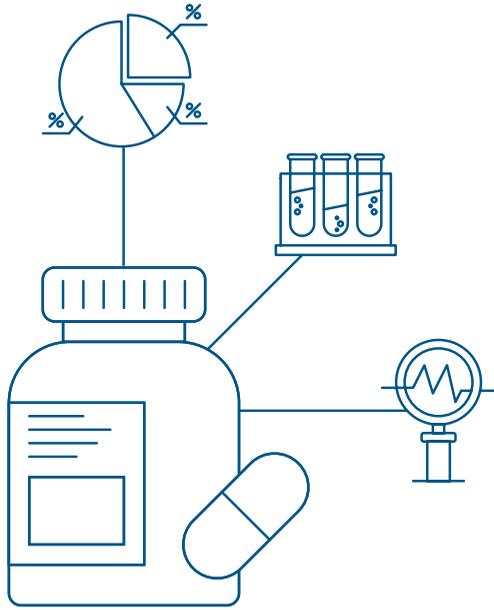
# Good News for Biosimilar Adoption Rates as Pharmacies Find Workable Strategies

Generic and biosimilar drugs both face challenges in terms of FDA approval, third-party payer pricing and physician/patient adoption. Yet biosimilars have unique complications as well. After a slow start — frequently the case with the introduction of new types of drugs — biosimilar adoption rates are trending upward in the United States.

**Heather Easterling**

PharmD, MBA  
Senior Managing Consultant  
McKesson





## Biosimilars vs. generics

Both biosimilars and generic drugs are alternatives to brand name drugs and may be more affordable. But important differences set them apart from each other.

A generic drug contains the same active ingredients as the brand name and is a proven equivalent — an identical copy of the original drug.

Biosimilars must be highly similar to the reference product (the single biological product approved by the FDA) with no clinically meaningful differences. However, they are not completely identical to the original medicine. The biosimilar must be proven in clinical studies to be as safe, pure and effective as the reference product.<sup>4,5</sup>

Healthcare system pharmacies are often driven by drug costs, choosing formulary drugs that support maximum reimbursement and lower patient copays. Innovative, relatively new treatments such as biosimilars may receive little consideration as alternatives since hospital pharmacies rarely have the time or resources to explore these options.

### Navigating the use of biosimilars with the 340B Pricing Program

The 340B drug pricing program, a section of the Public Health Act, was passed by Congress in 1992 to provide discounted outpatient drugs to eligible healthcare providers. Over the years, however, the program has proven more and more difficult to navigate as treatments evolve and specialty drug costs keep rising. Biosimilars further complicate these critical discounts since they don't fit neatly into the same boxes as traditional generics.

### Defying categories

Perhaps the only place where generic and biosimilar drugs overlap is in their ability to help lower costs. Prescription formularies divide drugs into categories such as treatment for asthma or arthritis, listing covered medications in each category. Programs like McKesson's 340B Impact<sup>1</sup> optimize generic purchasing by providing insight into historical prices and comparing them with similar drugs. Biosimilar drugs are, by nature, not interchangeable,<sup>2</sup> and are therefore not part of an existing class of drugs to treat a condition. The single exception, which received FDA approval in the summer of 2021 as the first interchangeable biosimilar product approved in the United States, is Semglee insulin.<sup>3</sup> While pharmacists are accustomed to considering drugs as part of a class, biosimilars must be considered individually.

### Rising adoption rates

Biosimilar approval and adoption are on the rise in the U.S. among 340B-eligible entities as well as non-covered entities, despite naysayers' reports to the contrary.<sup>6</sup> As of November 2021, 31 biosimilars were approved for use in the United States, compared to 65 in the European Union and 27 in Canada, both of which have a different payer mix that can play a key role in adoption.

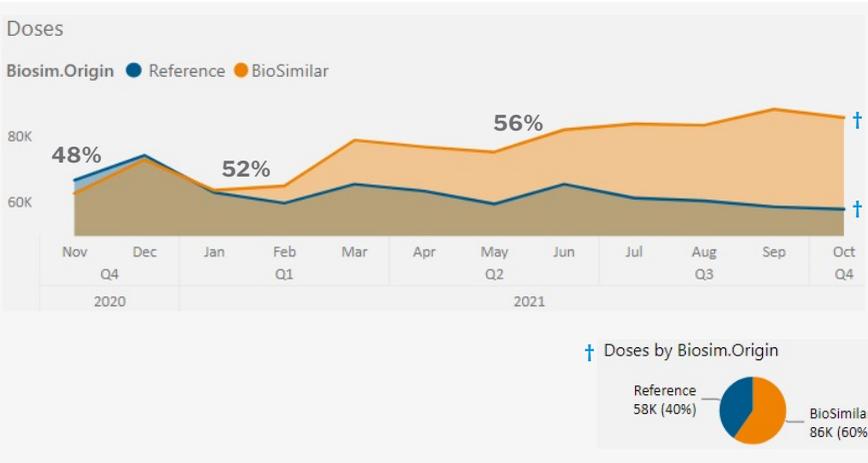
Drug Name	Therapeutic Area	Approved Biosimilars	Launches	Originator/Manufacturer
<b>Adalimumab</b>	RA, plaque psoriasis, ankylosing spondylitis, Crohn's disease, UC	6	0	Humira/AbbVie
<b>Bevacizumab</b>	Colorectal cancer, NSC lung cancer, glioblastoma, kidney, cervical, renal cell carcinoma	2	2	Avastin/Genentech
<b>Epoetin alfa</b>	Anemia	1	1	Procrit, Epogen/Amgen
<b>Etanercept</b>	RA, plaque psoriasis, psoriatic arthritis, ankylosing spondylitis, polyarticular juvenile idiopathic arthritis	2	0	Enbrel/Amgen
<b>Filgrastim</b>	Neutropenia	2	2	Neupogen/Amgen
<b>Infliximab</b>	Crohn's disease, UC, RA, ankylosing spondylitis, psoriatic arthritis, plaque psoriasis	4	3	Remicade/Janssen Biotech
<b>Insulin Glargine</b>	Diabetes mellitus	1	1	Lantus/Sanofi
<b>Pegfilgrastim</b>	Febrile neutropenia, acute myelosuppressive radiation exposure	4	4	Neulasta/Amgen
<b>Ranibizumab</b>	Neovascular age-related macular degeneration, macular edema, mopic choroidal neovascularization	1	0	Lucentis/Novartis
<b>Rituximab</b>	NH lymphoma, chronic lymphocytic leukemia, RA, granulomatosis with polyangiitis	3	3	Rituxan/Biogen-Genentech
<b>Trastuzumab</b>	Breast and gastric cancer	5	5	Herceptin/Genentech

Since biosimilars tend to be cheaper than reference products, using dollars to analyze biosimilar adoption is difficult. Yet we can see an upward trend using a metric of Equivalent Doses Sold of reference products and biosimilars gleaned from McKesson analytics over time. For each group of biosimilar and reference product, we assumed an equivalent dose and used this normalizing metric to measure adoption rate. We excluded Semglee® from this analysis but anticipate that it will become part of our biosimilar basket in the future.

# Adoption of Biosimilars All Health Systems, October 2021

For all health systems, adoption of biosimilars\* is moving in a positive direction over time. Of note, 340B covered entities have a lower biosimilar adoption rate in comparison to non-covered entities and it has taken longer. This lag for covered entity hospitals may be due to difficulty navigating the various pricing files and reimbursement differences which make the determination of economic value more complex for these health systems.

\*Biosimilars include bevacizumab, epoetin, filgrastim, infliximab, pegfilgrastim, rituximab, trastuzumab



## Working with winners

Looking at specific drugs reveals that some products have been readily adopted, while others have not broken through. The differences can be explained by considering, among other things, whether the products are for chronic or acute care, along with factors such as reference product use of innovative delivery devices as with Neulasta® Onpro®.

## Adoption Winners, October 2021

### Trastuzumab



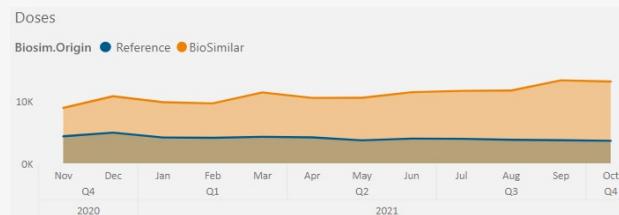
### Bevacizumab



### Filgrastim



### Epoetin



### Rituximab



## Adoption Losers, October 2021

### Trastuzumab



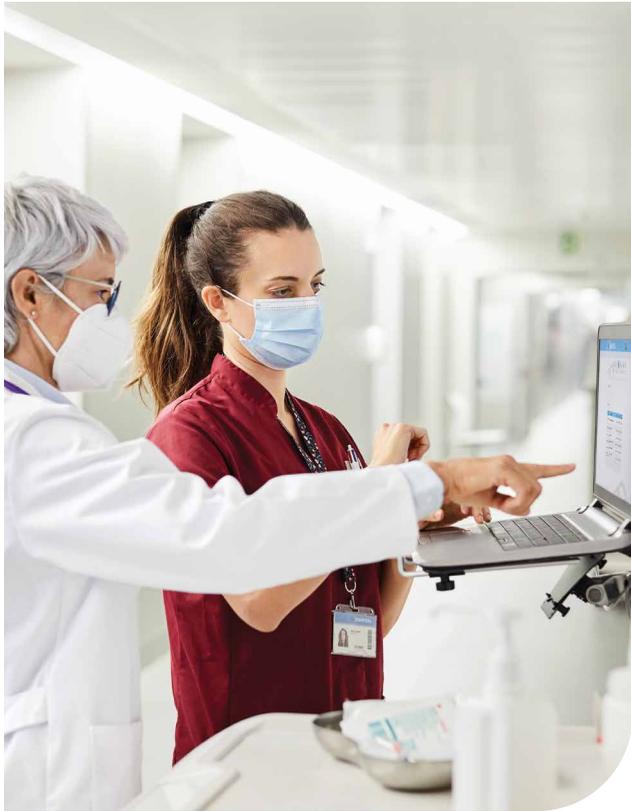
### Bevacizumab



Most of the “winners” are acute care or episodic drugs such as epoetin for anemia or trastuzumab for breast and gastric cancers, respectively. Yet chronic care drugs such as infliximab for Crohn’s disease have not been as widely adopted in favor of reference products. The reason may be as simple as staying with what works. If a patient has Crohn’s disease and is stable on the reference product for Infliximab, changing to the biosimilar may not be a pragmatic choice in the minds of physicians and their patients. Rituximab is seeing a favorable biosimilar adoption; however, it has lagged behind others. For episodic diseases like breast cancer, patients have never been on the reference product, so initiating therapy with a biosimilar is an easier decision. Biosimilars for disease states that rely on subjective evidence of improvement, unlike others that have measurable objective evidence (radiologic scans, laboratory tests), may also have lower adoption rates.

What is clear is that varying adoption rates are seen for biosimilars according to disease state, patient and physician preference, and economics. Aggregating all biosimilars into one “class” of drugs as is typical of articles on the subject does not give a clear picture. The trend for biosimilar adoption is moving directionally toward increased adoption albeit at different rates and with different barriers to address.





### **Educating patients and physicians**

The innovative nature of biosimilars may cause both physicians and patients to be skeptical. Plus biosimilars go through the same rigorous testing and clinical trials required for other drugs. Patients who rely on their physician’s guidance for treatment may be uncomfortable with this uncertainty. Education about biosimilars<sup>7</sup> can provide clarity in adoption decisions. While much remains to be studied, clinical questions can be addressed with confidence.

### **Considering the costs and reimbursement**

Financial concerns also play a big role in biosimilar adoption. Cost to buy the biosimilar product is less for health systems; however, rebates and reimbursement concerns can lead to confusing economics. For third-party payers, hospital-based clinics – specifically those that are 340B eligible – and patients, the cost of biosimilars is often a deciding factor. Medicare has changed its reimbursement formula, giving most biosimilars pass-through status – reimbursement at average sales price (ASP) plus 20% of the reference product price. The reference products are reimbursed at ASP minus 6% for 340B hospitals. Biosimilars now have an advantage that will drive adoption.<sup>8</sup> Pass-through status can expire in time and biosimilars within a group lose pass through status at different times; furthering the difficult math gymnastics for covered entities to calculate. Commercial payers have thus far not followed Medicare’s lead. Health system pharmacies must maintain access to multiple products to meet different payer requirements.



### **Adapting to the unknown**

Biosimilar adoption and reimbursement models will continue to change. Health systems, which are already strained for resources, must make a concerted effort to stay informed and, in turn, help providers keep up with evidence that supports brand, generic and biosimilar decision making. This may involve designating a group to study reimbursement practices, market influences, third-party payers and alternative payment models such as Medicare’s. In the long run, strategies to take advantage of increased competition in the growing biosimilar market will create better access for patients and financial benefits for hospital pharmacies.

This white paper was authorized by McKesson Corporation.

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# Closing

## Your Partner on the 340B Journey

In the world of 340B, change is inevitable as the healthcare ecosystem continues to evolve around it. The rise in specialty care, changes to the contract pharmacy model and the prevalence of biosimilars are just a few of the variables that add complexity to an already complicated federal drug pricing system. As new issues arise, McKesson is here for you with expert resources and tips, as well as third-party administrator guidance and software to help your 340B program run smoothly and achieve optimal savings for your organization and patients.

### Next Steps

Ready to explore how your organization can build a 340B program that works for everyone? Contact us at [healthsystems@mckesson.com](mailto:healthsystems@mckesson.com). We're excited to connect with you and explore the possibilities.



### A Cutting-Edge New 340B Solution

McKesson Health System's 340B advisors and Macro Helix's technology experts have been hard at work developing an innovative technology solution designed to help you optimize your 340B performance. 340B Impact uses advanced analytics to take your 340B program to the next level. [Learn more](#) about this cutting-edge business intelligence platform.

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