2022 Biosimilars Report:

The U.S. Journey and Path Ahead

CardinalHealth™

Welcome to our 2022 Biosimilars Report: The U.S. Journey and Path Ahead

Cardinal Health is fortunate to sit at the crossroads of the United States (U.S.) healthcare system, engaging with stakeholders from across the industry including healthcare providers, health systems, pharmaceutical and medical product manufacturers, pharmacists, payers and policy makers to support the delivery of essential care to the most important stakeholder – patients. This vantage point has given us a unique perspective on the important role of biosimilars in the U.S. healthcare landscape and the potential benefits they may deliver to patients and the healthcare system at large.

Since the first biosimilar was approved in the U.S. in 2015, we have taken an active role in supporting the use of these products – not only by distributing them to healthcare providers and working with manufacturers to bring new biosimilars to market, but also through extensive research and educational initiatives designed to build a better understanding of how biosimilars may contribute to high-quality, lower-cost care.

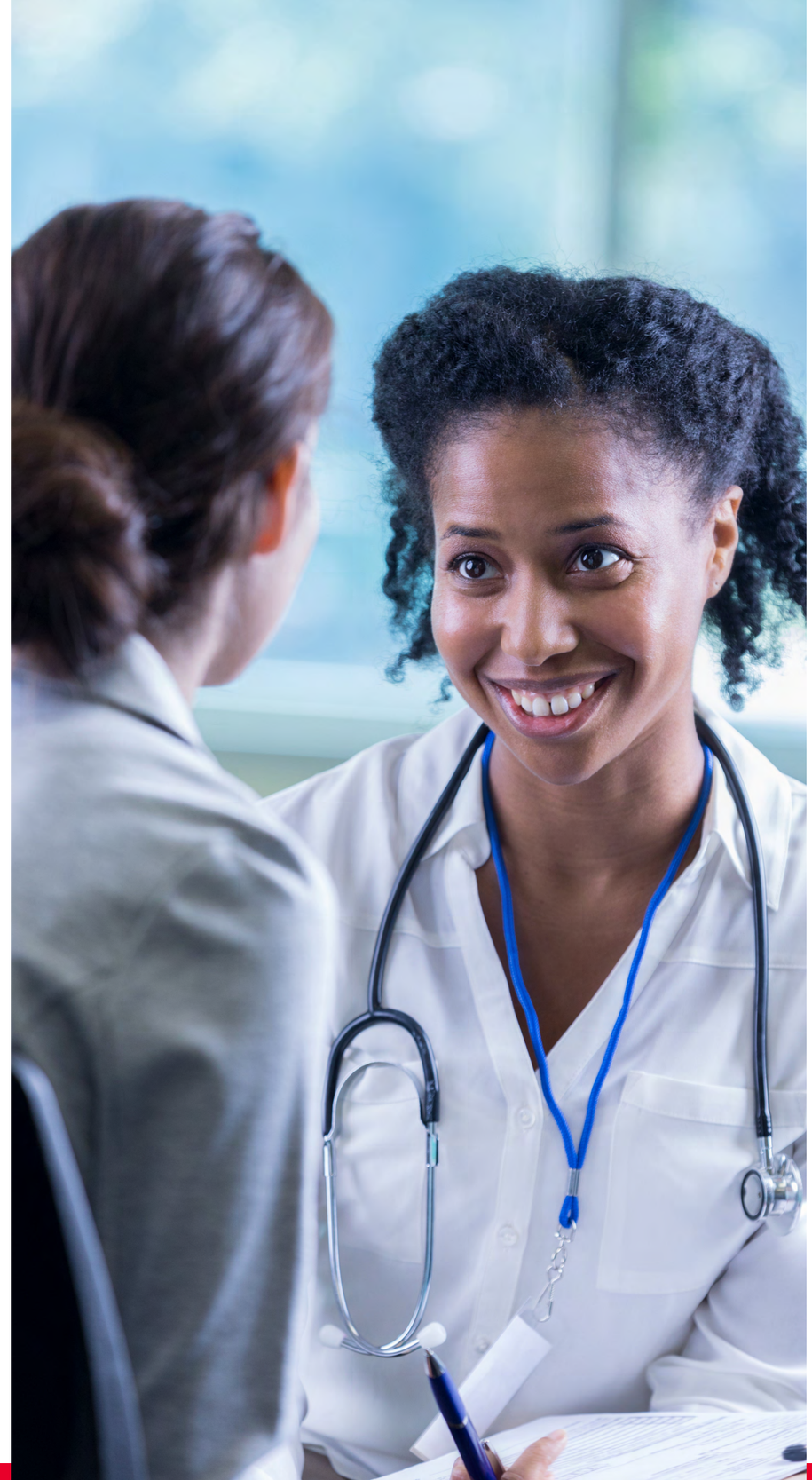
In this, our first-ever **Biosimilars Report: The U.S. Journey and Path Ahead**, we have aspired to bring together the latest industry data on utilization and payer coverage with our own research and perspectives from leading experts on where biosimilar adoption stands today in the U.S., and what we can expect in 2022 and beyond. We are pleased to include views from our internal experts and top physicians in key therapeutic areas where biosimilars are making an impact. The report also features results from our research with healthcare providers, which includes surveys with more than 320 oncologists, 100 rheumatologists, 100 retina specialists, 50 endocrinologists and primary care physicians treating diabetes, and 115 pharmacists.

The future of biosimilars in the U.S. is exciting – not only because of their potential to lower the costs of biologic medicines and to make care more accessible to patients, but also because they will create space for new innovations and scientific breakthroughs. As we move forward in 2022, enabling new advancements in care and better access for patients are goals that all healthcare stakeholders should be aligned on. We look forward to collaborating with our customers, partners and industry colleagues on these efforts.

Wishing you good health in 2022!

Sincerely,

Victor Crawford
CEO, Pharmaceutical Segment
Cardinal Health



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A Biosimilars Primer: Medications That Drive Competition, Lower Costs and Increase Accessibility

- Biosimilar treatment options are proven to be just as safe and effective as originator biologics.
- Biosimilars are approved through an abbreviated FDA pathway, with the goal of expanding patient access to high-quality, lower-cost care.
- As of January 2022, there are 33 FDA approved biosimilars in the U.S., 21 of which are commercially available on the market.

"Industry analysts say that biosimilars are on track to reduce U.S. drug expenditure by $133 billion by 2025."

Although the first biosimilar was approved by the U.S. Food and Drug Administration (FDA) nearly seven years ago, this class of products is still new to many who work in healthcare, particularly in therapeutic categories such as diabetes and ophthalmology where biosimilars have received approval only recently. The following is a primer of the key terms and facts related to biosimilars.

What is a biosimilar and how does it compare to a generic?

A biosimilar is a biologic treatment (i.e., made from living cells) that is just as safe and effective as an existing FDA-approved biologic, also referred to as the "reference product." Unlike generics, which are manufactured from small-molecule, chemical compounds and have the same active ingredients as brand name drugs, biologics are large, complex molecules that are manufactured from living cells, which results in inherent variability associated with them. Therefore, where a generic must demonstrate bioequivalence to the brand drug, biosimilars must demonstrate they are highly similar to the reference product — thus the term "biosimilar."

In the U.S., biosimilars are currently used to treat patients with cancers, kidney diseases, diabetes, and other autoimmune diseases such as rheumatoid arthritis and Crohn's disease.

How are biosimilars reviewed and approved by the FDA?

Biosimilar advancements in the U.S. began when the Biologics Price Competition and Innovation Act was enacted in 2010, which established an abbreviated pathway to FDA approval for biosimilars under section 351K, with the aim of enabling greater patient access to lower-cost, high-quality products.

The approval process requires biosimilar manufacturers to submit data that demonstrates there is no clinically meaningful difference from the reference biologic. Although the approval pathway for biosimilars is abbreviated, the FDA requires biosimilars to meet equally rigorous approval standards, which means patients and healthcare professionals can be assured of their safety, efficacy and quality – just as they would the reference products.

How many biosimilars are on the market in the U.S.?

As of January 2022, there are 33 FDA-approved biosimilars, 21 of which are available on the U.S. market. Ten of the 33 products have delayed launches primarily due to patent litigation between the reference biologic and biosimilars companies. Of the 21 biosimilars on the market, 17 are used for treatments associated with cancers, three are used to treat autoimmune conditions and one is used to treat diabetes (See Figure 1 for full details).

What does "interchangeability" mean and why is it important?

Interchangeability is a regulatory designation for biosimilars that is unique to the U.S. The designation allows "pharmacist-level substitution," meaning that a pharmacist can substitute the reference biologic with a biosimilar per state laws, without consulting with the prescribing physician. This is similar to how pharmacists routinely substitute generic drugs for brand name drugs today. For biosimilars dispensed at the retail pharmacy and/or covered under the patient's pharmacy benefit (such as insulin and Humira biosimilars), the interchangeability designation is important because it will enable pharmacists to help facilitate patient access to high-quality treatment options at the lowest cost.

A common misconception is that interchangeable biosimilars must meet higher standards for approval than non-interchangeable biosimilars. However, all biosimilars — whether interchangeable or not — undergo rigorous and thorough evaluations to ensure safety and effectiveness in order to meet the FDA's high standards for approval. Interchangeability designation is obtained through the submission of additional data, generally in the form of switching studies, to assess the safety of switching between a reference product and biosimilar multiple times.

Why are biosimilars important to the U.S. healthcare system?

Biologics are among the most expensive medicines in the U.S. — some with costs totaling tens of thousands of dollars each year per patient. Biosimilars are expected to be priced 15% to 30% lower than their reference products.[1] The market entrance of biosimilars leads to greater competition, thereby lowering costs and increasing accessibility and affordability of these critical treatments. Industry analysts say that biosimilars are on track to reduce U.S. drug expenditure by $133 billion by 2025.[2]

The U.S. is already seeing how biosimilars are reducing costs: In 2020 alone, biosimilars saved $7.9 billion (more than triple the $2.5 billion saved the previous year), with savings expected to grow significantly in the next few years as more biosimilars enter the market.[3]

If biosimilars are more affordable, why are they not more widely used?

The U.S. healthcare market is complex, particularly the payer dynamics that dictate how drugs are reimbursed. Although biosimilars are generally priced lower, stakeholder incentives are not always aligned to enable or support biosimilar adoption. In addition to the financial considerations, continued knowledge gaps among some key stakeholders (including providers and patients) regarding biosimilars can be a barrier to adoption. The lack of familiarity with biosimilars contributes to hesitancies with these products and is a key driver behind recent congressional and FDA activities, including the passage of the Advancing Education on Biosimilars Act of 2021, intended to increase education and awareness among providers.

What resources are available to provide further information on biosimilars?

Those who wish to learn more about biosimilars can explore the FDA's Biosimilars website, which includes a wealth of educational material, and the "Purple Book," which is the official database for all FDA-licensed biological products including reference biologics, biosimilars and interchangeable biosimilars. In addition, Cardinal Health has educational resources, thought leadership and a **full listing of available biosimilars**, as well as an interactive tool that can be used to look up **state laws related to interchangeability**.

BIOSIMILARS 101

"Biosimilars — whether interchangeable or not — undergo rigorous and thorough evaluations to ensure safety and effectiveness in order to meet the FDA's high standards for approval."

2021 Biosimilars Landscape

"By promoting negotiation, competition and innovation in the healthcare industry, we will ensure cost fairness and protect access to care."

- U.S. Department of Health and Human Services Secretary Xavier Becerra[4]

"The promise of biosimilars has started to become a reality, as greater competition ... is beginning to drive meaningful cost savings."

Sonia T. Oskouei, PharmD
Vice President, Biosimilars
Cardinal Health

2021: A Year of Milestones and Progress for Biosimilars in the U.S.

To begin a reflection of 2021 biosimilars activity, I cannot help but to think back to when I first began working in biosimilars and U.S. national strategies over five years ago. My passion for this space grew quickly as I saw how healthcare organizations, and more importantly patients, continued to grapple with the rising healthcare costs associated with critical biologics.

Fast forward to today, and I am deeply encouraged by the progress made in the U.S., especially this past year. Following the launch of the first biosimilar in 2015, we now have 33 FDA approved biosimilars with 21 available on the market as of January 2022. The U.S. biosimilars story that was initially described as sluggish and delayed has now transformed to one of progress and momentum. This past year, the promise of biosimilars has started to become a reality, as greater competition for some of the costliest biologic treatments on the market is beginning to drive meaningful cost savings.

2021 BIOSIMILARS LANDSCAPE

Significant progress has been made in the adoption of biosimilars in the U.S., particularly in oncology, where all three classes of therapeutic oncology biosimilars (i.e., rituximab, bevacizumab, and trastuzumab) have exceeded 60% market share (See Figure 2). Savings from biosimilars increased to approximately $8 billion in 2020 alone, more than tripling savings derived from previous years. In addition, for the first time in seven years, oncology expenditure growth fell below 10% due to the impact of biosimilars and new product launches.[5]

Although 2021 brought fewer market entrants than previous years, it was still one of the most eventful years in U.S. biosimilars history. Several key milestones were achieved this past year, and the following represent just a few worth highlighting:

The first interchangeable biosimilar was approved in the U.S.

In July 2021, the FDA made a landmark decision to approve the first interchangeable biosimilar in the U.S. for Viatris' Semglee (insulin glargine-yfgn), referencing the long-acting insulin, Lantus. The approval was significant for a multitude of reasons: Not only is Semglee the first interchangeable biosimilar, but the first biosimilar in diabetes care, and the first biosimilar that is primarily dispensed at retail pharmacies; therefore, it's billed under the pharmacy benefit.

Figure 1. **FDA approved biosimilars**

Reference Product (molecule) — Company	Biosimilar Product(s)	Biosimilar Company	(Estimated) Launch Date
Avastin (bevacizumab) — Genentech	Mvasi	Amgen	July 2019
	Zirabev	Pfizer	Jan. 2020
Epogen/Procrit (epoetin alfa) — Amgen/ Janssen	Retacrit	Pfizer	Nov. 2018
Enbrel (etanercept) — Amgen	Eticovo	Samsung	2029
	Erelzi	Sandoz	2029
Herceptin (trastuzumab) — Genentech	Kanjinti	Amgen	July 2019
	Ogrivi	Viatris	Dec. 2019
	Trazimera	Pfizer	Feb. 2020
	Herzuma	Teva	Mar. 2020
	Ontruzant	Organon	May 2020
Humira (adalimumab) — AbbVie	Amjevita	Amgen	Jan. 2023
	Hadlima	Organon	June 2023
	Cyltezo*	Boehringer Ingelheim	July 2023
	Yusimry	Coherus	July 2023
	Hulio	Viatris	July 2023
	Hyrimoz	Sandoz	Sept. 2023
	Abrilada	Pfizer	Nov. 2023
Lucentis (ranibizumab) — Genentech	Byooviz	Biogen	June 2022
Lantus (insulin glargine) — Sanofi	Basaglar	Eli Lilly	Dec. 2016
	Semglee*	Viatris	Aug. 2020
	Rezvoglar	Eli Lilly	TBD
Neulasta (pegfilgrastim) — Amgen	Fulphila	Viatris	July 2018
	Udenyca	Coherus	Jan. 2019
	Ziextenzo	Sandoz	Dec. 2019
	Nyvepria	Pfizer	Dec. 2020
Neupogen (filgrastim) — Amgen	Nivestym	Pfizer	Oct. 2018
	Granix	Teva	Nov. 2013
	Zarxio	Sandoz	Sept. 2015
Remicade (infliximab) — Janssen**	Inflectra	Pfizer	Nov. 2016
	Renflexis	Organon	July 2017
	Avsola	Amgen	July 2020
Rituxan (rituximab) — Genentech	Truxima	Teva	Nov. 2019
	Ruxience	Pfizer	Feb. 2020
	Riabni	Amgen	Jan. 2021

Biosimilars to be launched; all others are currently marketed.

Biologics that are not true biosimilars and were approved under either the 351(a) or 505(b)(2) pathways.

Source: U.S. Food & Drug Administration. Retrieved from: https://www.fda.gov/drugs/biosimilars/biosimilar-product-information.

*Semglee gained FDA approval as an interchangeable biosimilar on July 28, 2021, and Cyltezo gained an interchangeability designation in October 2021.
**Ixifi (Pfizer's other Remicade biosimilar) has no plans to launch in the U.S.

"Increasing competition through the introduction of biosimilars creates opportunity to decrease the financial burden associated with these products, which in turn could reduce the risk for negative outcomes due to medication nonadherence."

This approval has significant opportunity to expand lifesaving treatment options for the millions of insulin-dependent Americans living with diabetes. Despite its discovery a century ago, insulin continues to be among the costliest treatments for patients with diabetes, with studies showing nearly one in four patients ration insulin.[6] Between 2001 and 2018, the average list price of insulin products has increased around 11% annually.[7]

Increasing competition through the introduction of biosimilars creates opportunity to decrease the financial burden associated with these products, which in turn could reduce the risk for negative outcomes due to medication nonadherence. Furthermore, the introduction of an interchangeable insulin biosimilar may draw heightened attention to the healthcare delivery system and reimbursement model for pharmacy benefit products, fueling additional policy reform discussions.

Additionally, the entrance of interchangeable biosimilars into the retail pharmacy class of trade will empower retail pharmacists, some of the most trusted and accessible healthcare providers, to play a key role in influencing biosimilar adoption (with the ability to automatically substitute interchangeable products, per state laws) and to champion the education process in their communities.

The first biosimilar for ophthalmology was approved in the U.S.

In September, the FDA approved Biogen's Byooviz (ranibizumab-nuna), the first ophthalmology biosimilar for Lucentis (ranibizumab) to treat retinal conditions including neovascular (wet) age-related macular degeneration (AMD). This noteworthy approval is anticipated to expand treatment options with lower-cost, high-quality therapies for the approximately 11 million Americans diagnosed with AMD.[8] As Byooviz prepares to launch this year, retina specialists and ophthalmologists will have more treatment options than ever before to try to tackle the economic and treatment burdens associated with retinal conditions. However, findings from early market research with U.S. retina specialists indicate a lack of familiarity and comfort with biosimilars, which suggests a critical need for targeted educational efforts to help alleviate potential hesitancies and close knowledge gaps early on.[9]

2021 BIOSIMILARS LANDSCAPE

Figure 2. **Overall U.S. biosimilars market share**

Product	Category	1st Biosimilar Launch	Current Number of Biosimilar Competitors	Biosimilar Market Share (Sept. 2021)
Neupogen (filgrastim)	Supportive Care	2015	2*	89%
Remicade (infliximab)	Immunology	2016	3	32%
Epogen/Procrit (epoetin alfa)	Supportive Care	2018	1	52%
Neulasta (pegfilgrastim)	Supportive Care	2018	4	38%**
Avastin (bevacizumab)	Oncology	2019	2	74%
Herceptin (trastuzumab)	Oncology	2019	5	60%
Rituxan (rituximab)	Oncology	2019	3	64%
Lantus (insulin glargine)	Diabetes	2020***	1***	3%
8 Product Classes			**21**	

Source: IQVIA: Accessed via IQVIA National Sales Perspective (NSP) SMART Data. (October 2021).

*Excludes Granix.
**Neulasta Syr. only biosimilars market share is 75%.
***Excludes Basaglar. Includes Semglee, which transitioned to an interchangeable biosimilar in July 2021.

The first Humira (adalimumab) biosimilar achieved interchangeability designation, representing the second interchangeable biosimilar approved in the U.S.

In October 2021, Boehringer Ingelheim's Cyltezo (adalimumab-adbm) was granted interchangeability status, a long-awaited accomplishment for the biosimilar that was first approved in 2017. Cyltezo is currently one of seven FDA approved adalimumab biosimilars that are lined up to hit the market in 2023. With multiple other candidates in development, and various product attributes associated with each one, competition is expected to be fierce. (**Visit here** for a more detailed Humira biosimilar landscape overview). Although Cyltezo is the first adalimumab biosimilar to achieve interchangeability status, it is not expected to be the last. Alvotech/Teva, Pfizer, Amgen and Organon/Samsung Bioepis have all revealed that they are pursuing interchangeability designation for their adalimumab candidates as well.

It is no coincidence that the number one selling drug in the world, Humira, comes with the most extensive list of biosimilar candidates. With wide use in the management of autoimmune conditions including rheumatoid arthritis, psoriasis and Crohn's disease, the market entrance of adalimumab biosimilars will serve as one of the most significant events to impact U.S. healthcare costs in recent history.

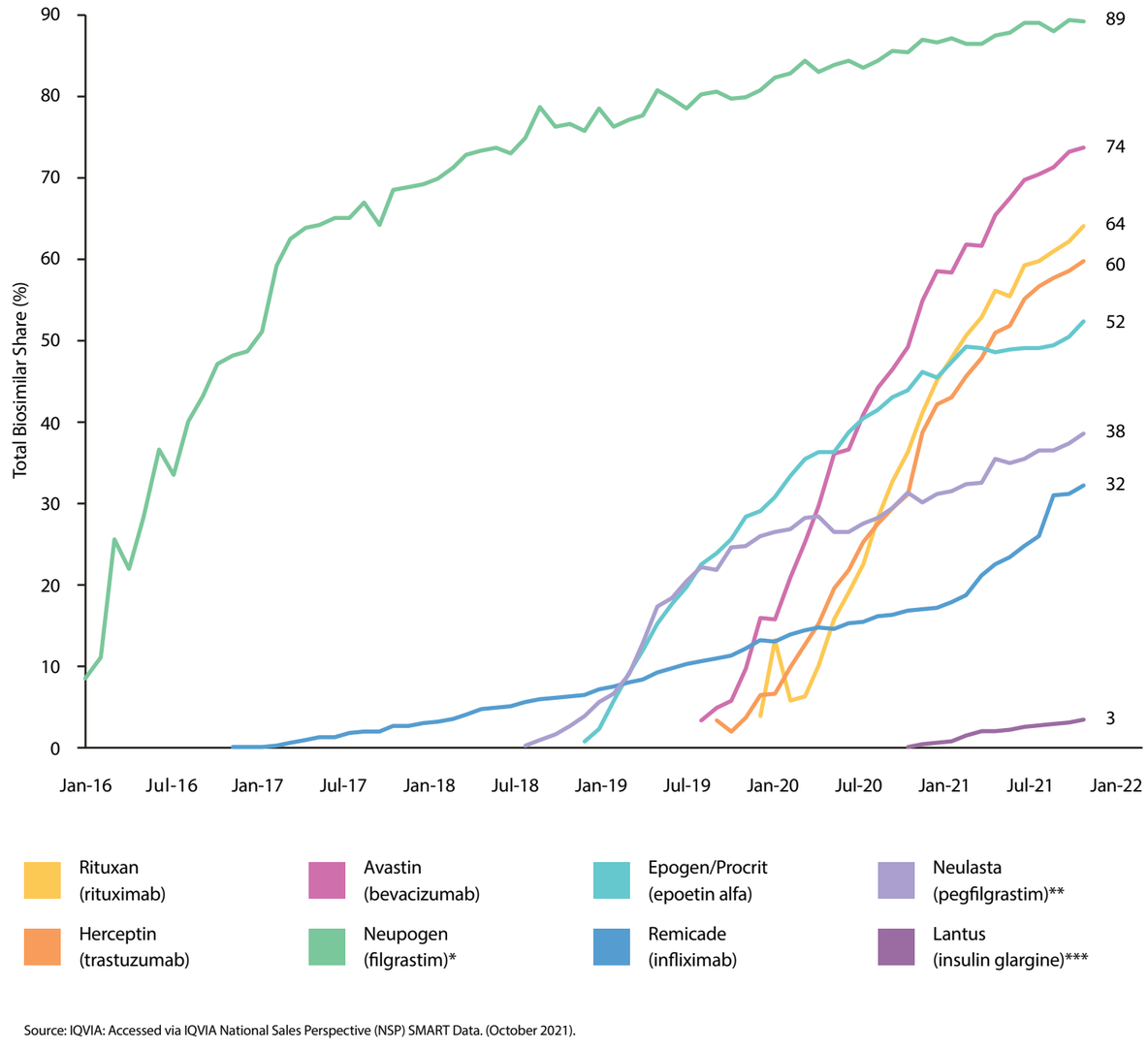
Regulatory activities drew heightened attention to biosimilars

As the U.S. continued to struggle with challenges related to the COVID-19 pandemic, congressional and government discussions around drug pricing and affordable care remained a top priority in 2021. In April, President Biden signed into law two bipartisan bills aimed at reducing prescription drug prices and addressing some key barriers to biosimilar adoption: The Advancing Education on Biosimilars Act and The Ensuring Innovation Act.[10] The former is intended to lower healthcare costs by strengthening provider and patient confidence in biosimilars through enhanced educational efforts, thereby increasing utilization, enabling greater competition in the market and lowering costs to the overall healthcare system. The latter is intended to limit the circumstances in which additional market exclusivity is granted to a reference product, ensuring any modification represents true innovation. The goal is to close potential loopholes that can delay competition and accessibility to lower-cost treatment alternatives, including biosimilars.

Additionally, in response to President Biden's Executive Order, the Department of Health and Human Services (HHS) released a comprehensive plan for addressing high drug prices this past September. The 29-page report, which outlines key principles for drug pricing reform through competition, innovation and transparency, mentions "biosimilars" over 90 times and "interchangeability" 25 times.[11]

"Savings from biosimilars increased to approximately $8 billion in 2020 alone, more than tripling savings derived from previous years."

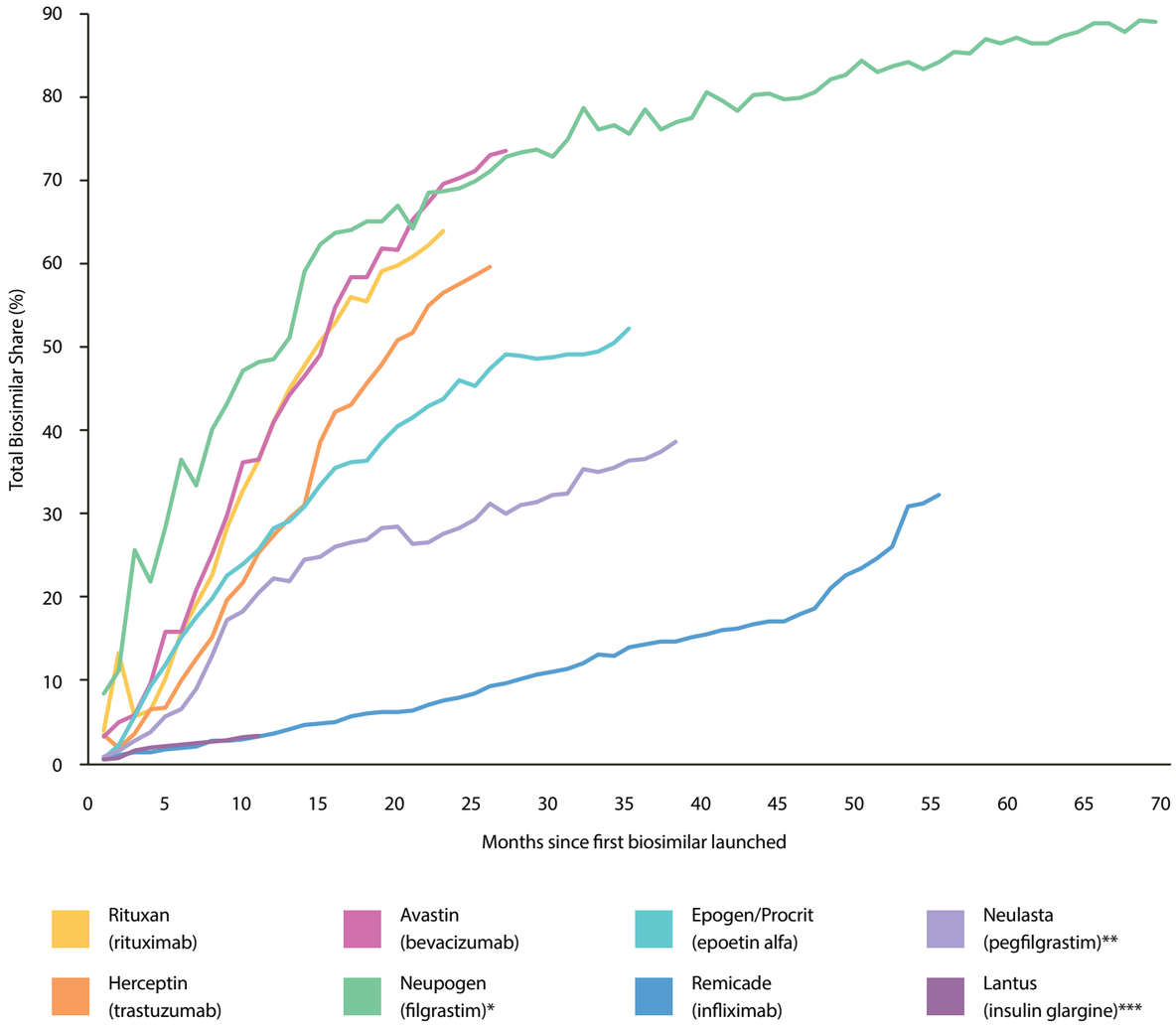
Figure 3. **Use of biosimilars has grown significantly since 2015.**



Source: IQVIA: Accessed via IQVIA National Sales Perspective (NSP) SMART Data. (October 2021).

*Filgrastim excludes Granix.
****Neulasta Syr. only biosimilars market share is 75%
***Insulin glargine excludes Basaglar.

Figure 4. **Adoption of biosimilars typically accelerates quickly after market introduction.**



Source: IQVIA: Accessed via IQVIA National Sales Perspective (NSP) SMART Data. (October 2021).

*Filgrastim excludes Granix.
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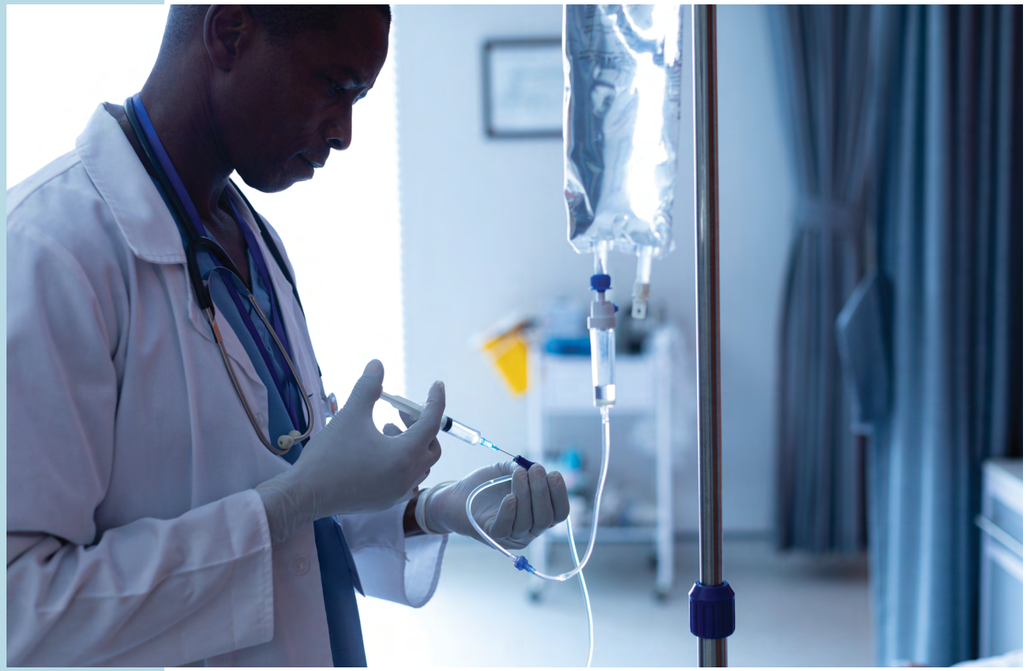
***Insulin glargine excludes Basaglar.

2021 BIOSIMILARS LANDSCAPE

"Although there has been stronger use of biosimilars in oncology, progress in other specialty areas such as rheumatology has continued to be slow."

While these noteworthy events signal that the tide is starting to turn toward greater biosimilar adoption, this past year also proved that significant barriers and challenges still exist. Although there has been stronger use of biosimilars in oncology (17 of the 21 biosimilars on the market have oncology indications), progress in other areas such as rheumatology has continued to be slow. On the payer front, the landscape continues to be complex, with formulary decisions that have challenged the uptake and management of biosimilars and policies varying across plans. And as market research continues to indicate, clinical barriers and knowledge gaps remain in the market, with increased desire for data and evidence around switching between reference biologics and biosimilars, as well as between biosimilars. Collaboration among all healthcare stakeholders will be needed to overcome many of these barriers and to ensure a viable biosimilars market in the U.S.

Our 2022 Biosimilars Report will take a deeper examination of many of these issues and what steps the industry will need to take to ensure patients have access to these high-quality, lower-cost treatment options.



Provider Trends

The success of biosimilars in the U.S. is dependent on many different stakeholders, but the healthcare provider remains central to every treatment decision. As data from Europe and the U.S. over the past 15 years has demonstrated, when providers gain clinical confidence with biosimilars, adoption increases exponentially.[12]

With this knowledge in mind, Cardinal Health began conducting research about biosimilars with oncologists starting in 2015 to assess their familiarity and understanding of biosimilars, and to identify concerns and barriers that might impede adoption. Over the years, as new biosimilars have received FDA approval, we have expanded our provider research to include rheumatologists and ophthalmologists. Most recently, we broadened our provider surveys into diabetes care and included both prescribers (endocrinologists and primary care physicians) and pharmacists, who are now empowered to make decisions about substituting insulin biosimilars for reference biologics at the time of dispensing.

Our research has provided valuable perspective into the views of each provider group, enabling us to better understand their similarities and differences. The next section of this report highlights key findings from our most recent healthcare provider surveys (conducted in 2020 – 2021), along with insights from leading physicians in each therapeutic area.

The majority of participating physicians are familiar with biosimilars, but prescribing patterns vary by specialty.

Oncology (Prescribers) N = 323 | **Rheumatology (Prescribers)** N = 102 | **Ophthalmology (Prescribers)** N = 102 | **Diabetes (Prescribers)** N = 54

Figure 5.
How would you describe your familiarity with biosimilars?
(Surveys conducted 2020-2021)

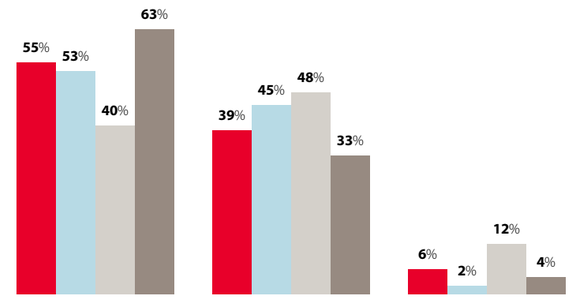
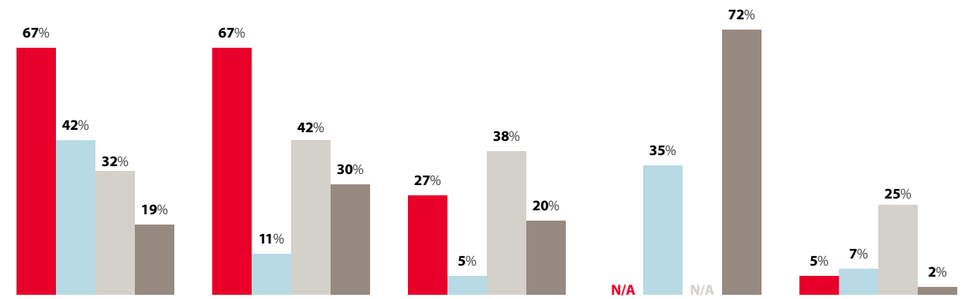


Figure 6.
For which patients are you most likely to prescribe a biosimilar?
(Select all that apply.)
(Surveys conducted 2020-2021)



Note: This answer choice was not included in oncology and ophthalmology surveys.

Oncologists are comfortable with biosimilars, but changes in value-based care may impact utilization

Bruce Feinberg, DO
Vice President/Chief Medical Officer for Cardinal Health Specialty Solutions

The approval of the first biosimilar in the U.S., Zarxio (filgastrim-sndz), in March 2015 represented a sea change in the biologic drug marketplace with broad impact for all stakeholders. Recognizing this new class of medicine would bring significant change to oncology care, our team at Cardinal Health began conducting research with oncologists in 2015 to gauge their understanding and desire to use biosimilars, and we have maintained these studies over the past seven years. Over the course of this time, we have measured how physician views and utilization rates have changed and tracked the relationship between utilization and payer benefit design.

One of our early conclusions about biosimilar adoption, as cited in our 2018 *JAMA Oncology* publication, was that the rate and depth of biosimilar adoption was more likely to depend on payer programs and value-based care models than on the inclusion of biosimilars in clinical guidelines.[13] This conclusion proved prescient. Value-based care (VBC) initiatives like the Oncology Care Model (OCM), in which physicians assume greater financial risk for administered healthcare, have been shown to have the most effective influence on driving biosimilar adoption by oncologists in an unrestricted oncology marketplace.[14] Conversely, commercial payers and pharmacy benefit managers (PBMs) initially impeded biosimilar adoption in oncology in the early years of biosimilar availability, but as coverage has improved in recent years, market uptake of oncology biosimilars has similarly increased (as shown in Figure 3).

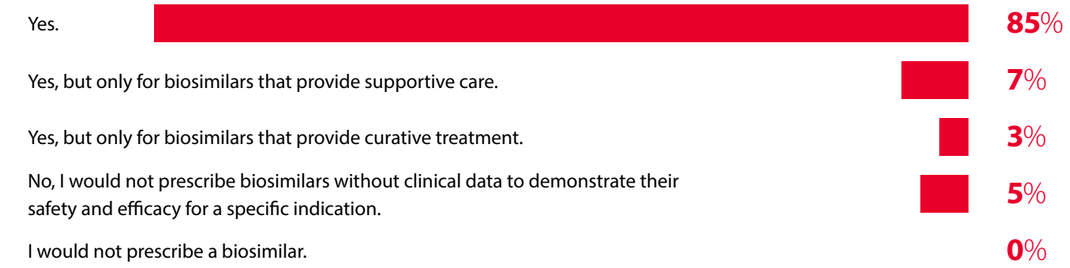
Provider perceptions of biosimilars over this time period have evolved from a 22% acceptance of interchangeability in 2017 to a near 100% for some indications in 2021. In this same time period, oncologists have grown comfortable using biosimilars in all clinical categories in oncology: supportive care, palliative care and curative intent – and a strong majority are comfortable with "non-medical switching."

Despite oncologists' positive perceptions of biosimilars, uncertainty for oncology biosimilars lies ahead due to the changing value-based care landscape. The OCM will expire in 2022, and with no replacement VBC reimbursement model yet announced, oncology practices may see a gap for as long as 18 months, which could result in prescribing patterns reverting to prior brand preferences. Oncology biosimilars may also face greater competition from the improved efficacy of second and third generation iterations of reference therapies that are rapidly entering the market, as well as innovative new targeted therapies, which are continuing to change the oncology treatment landscape. In spite of these uncertainties about the future, in the near term, we anticipate oncologists will continue to adopt biosimilars – and their experiences may serve as a model for other therapeutic areas where biosimilars will launch in 2022, such as vascular endothelial growth factor (VEGF) inhibitors for retinal diseases.

ONCOLOGY TRENDS

More than nine in 10 participating oncologists are comfortable prescribing a biosimilar with an FDA approval based on extrapolation.

Figure 7. **Would you prescribe a biosimilar in indications that have been granted FDA approval based on extrapolation?** (Surveys conducted in 2020 - 2021) N = 323

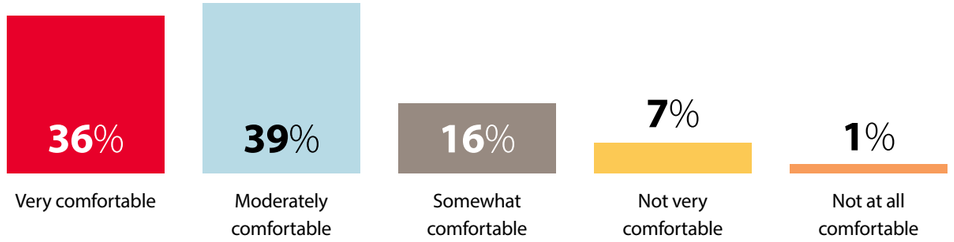


Only **5%** of participating oncologists said they **would not prescribe biosimilars for indications without clinical trial data.**

More than seven in 10 participating oncologists said they are "very" or "moderately" comfortable with automatic substitution of biosimilars.

Figure 8. **What is your comfort level with automatic substitution of a biosimilar for its reference product by a pharmacy or an insurance company?**

(Surveys conducted in 2020 - 2021) N = 323



Oncologists say they feel comfortable switching patients to biosimilars for both curative and palliative intent.

Figure 9. **Which of the following best aligns with your perspective on biosimilars administered for curative intent?** (Surveys conducted in 2020 - 2021) N = 323

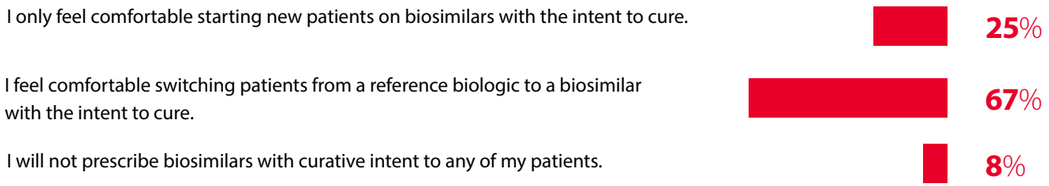
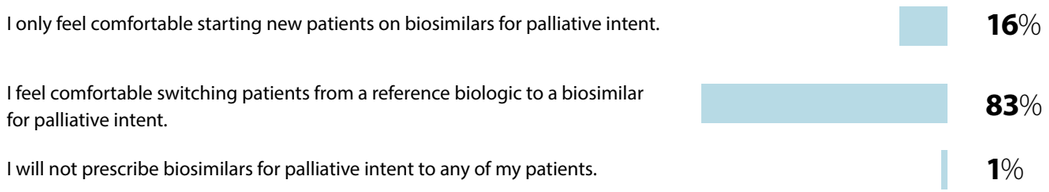
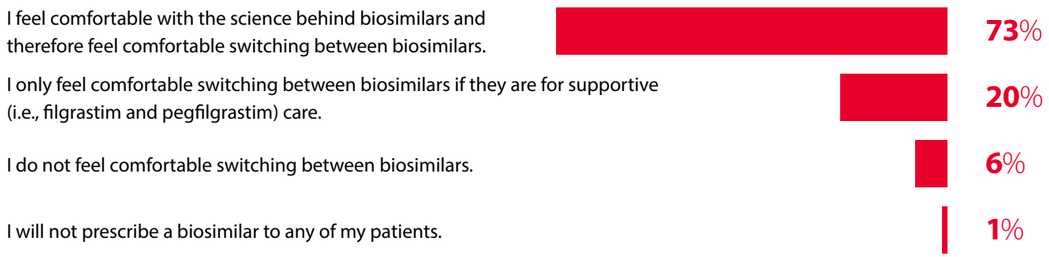


Figure 9-1. **Which of the following best aligns with your perspective on biosimilars administered for palliative intent?** (Surveys conducted in 2020 - 2021) N = 323



More than 90% of participating oncologists said they are comfortable switching between biosimilars in at least some cases.

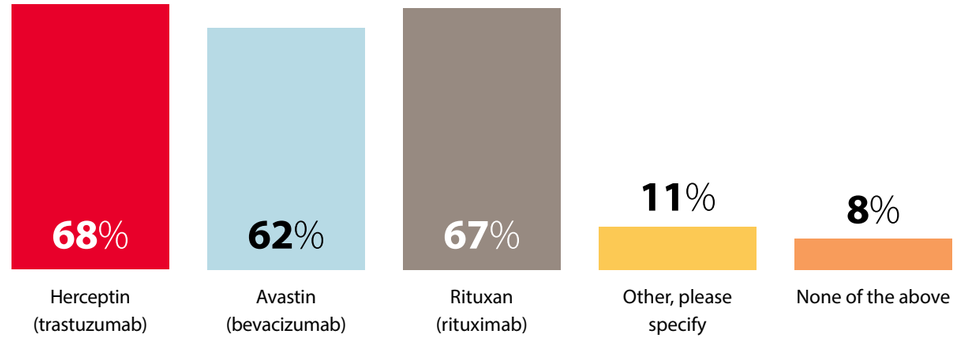
Figure 10. **Which of the following best aligns with your perspective on switching from one biosimilar to another biosimilar?** (Surveys conducted in 2020 - 2021) N = 323



The majority of oncologists have prescribed biosimilars to Avastin, Herceptin and Rituxan in the past year.

Figure 11. **Which therapeutic biosimilars have you prescribed in the past year?** (Select all that apply.)

(Surveys conducted in 2020 - 2021) N = 323



The promise of biosimilars remains unfulfilled in rheumatology

Gordon Lam, MD
Medical Director of Clinical Research at Arthritis & Osteoporosis Consultants of the Carolinas

In early 2020, Cardinal Health surveyed more than 100 rheumatologists to understand their attitudes about biosimilars. The findings showed that despite an overwhelming familiarity (98% were somewhat or very familiar) and comfort level with biosimilars (88% expressed comfort with the FDA approval process, and 90% were comfortable with prescribing biosimilars), the majority were reluctant to use biosimilar products. Sixty-five percent of respondents felt that the economic climate was unfavorable to switch to biosimilars, and less than half said they were likely to prescribe a biosimilar to a new patient.

This reluctance was based on a variety of concerns including skepticism of their efficacy and lack of meaningful cost savings to patients and practices. These concerns are not surprising considering that real-world evidence (RWE) of the cost-effectiveness of biosimilars in the U.S. has been scant, and presently, the most heavily used rheumatology biosimilars are priced at only 20%-35% below the reference product's list price.[15] In addition, many providers fear that the majority of the economic benefit will go to PBMs and payers, not to patients and practices.

Lack of payer adoption was also cited as a key concern, with 66% of physicians stating they are unlikely to switch their patients from reference products to biosimilars until there is greater adoption among payers. Paradoxically, uncertainty and lack of payer adoption may limit utilization and hence impede accumulation of RWE, but RWE is often needed to alleviate uncertainty and increase payer adoption.

However, since the survey was conducted, there are signs that the landscape is beginning to shift. Concerted efforts at physician and patient education have reduced skepticism about the efficacy and safety of these agents. Legislation has been proposed to increase transparency of biologic patents, which may curb litigation that delays entry of biosimilar competitors once they're approved. Regulations that target anti-competitive practices of exclusionary contracts may free the forces of supply and demand, thereby increasing access and lowering costs.

Also, despite the sluggish sales of biosimilars to date, the net price of some reference products has fallen over the past few years, impacting the cost of healthcare in a different way. For example, the sale price of Janssen's Remicade has fallen by an average of 19% annually since January 2018.[16] The market share of rheumatology biosimilars is also growing slowly but steadily to 32%.[17]

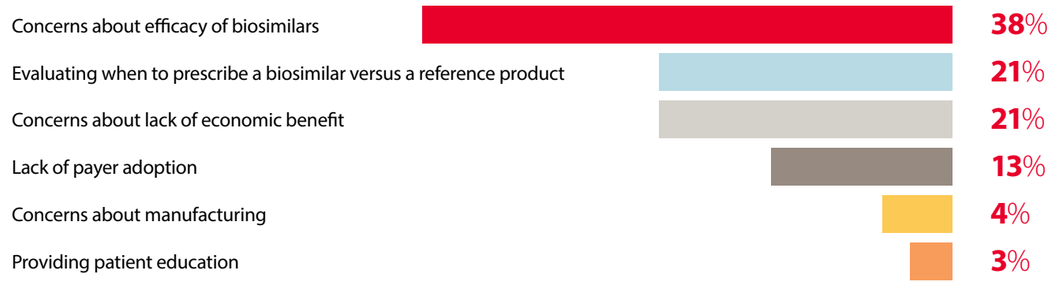
While slower than expected, the needle is gradually starting to move. It will take time to overcome these obstacles, but as it does, the value of biosimilars may be appreciated beyond that of mere price reduction. In doing so, utilization will increase, and the promise of biosimilars may be fulfilled.

RHEUMATOLOGY TRENDS

Four out of 10 rheumatologists felt very comfortable prescribing biosimilars, but efficacy remains the primary concern.

Figure 12. **How comfortable do you feel prescribing biosimilars to your patients?**
(Surveys conducted in 2020) N = 102

Figure 13. **What is your top concern about prescribing biosimilars?**
(Surveys conducted in 2020) N = 102



More than 60% of **rheumatologists say they are unlikely to switch patients to biosimilars** until there is greater payer adoption.

Most rheumatologists view cost savings to their patients as very important.

Figure 14. **When considering biosimilars as a treatment option, the importance of cost saving for my patients is:** (Surveys conducted in 2020) N = 102

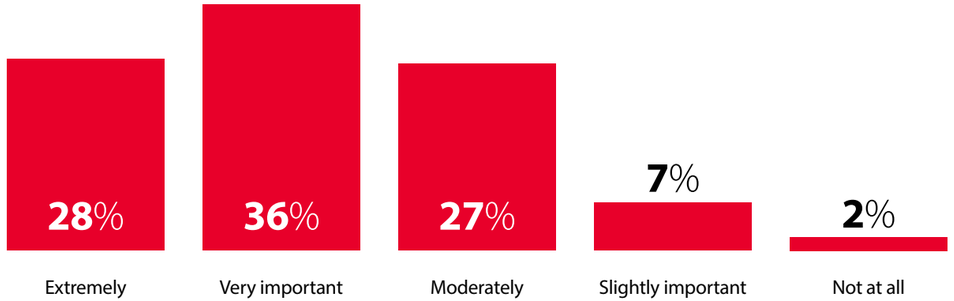
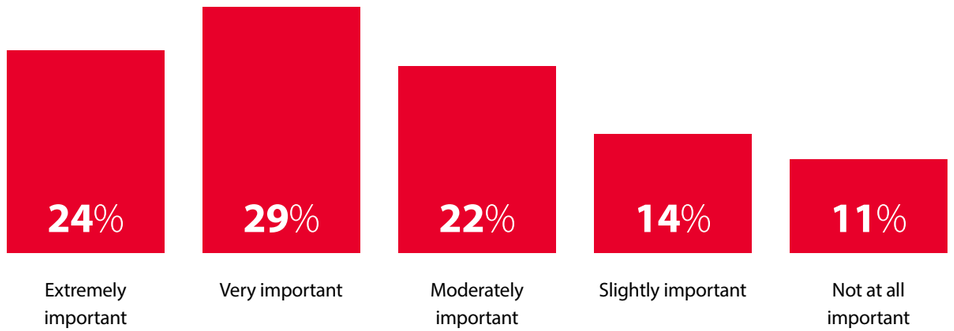


Figure 15. **When considering biosimilars as a treatment option, the importance of favorable economics for my practice is:** (Surveys conducted in 2020) N = 102



Nearly seven in 10 rheumatologists said cost savings for patients is "extremely" or "very" important.

About two-thirds of participating rheumatologists said the economics of biosimilars are a barrier to adopting biosimilars.

Figure 16. To what extent do you agree with the following statement? **Today, the economics of biosimilars are not favorable enough to motivate me to switch from the reference products.** (Surveys conducted in 2020) N = 102

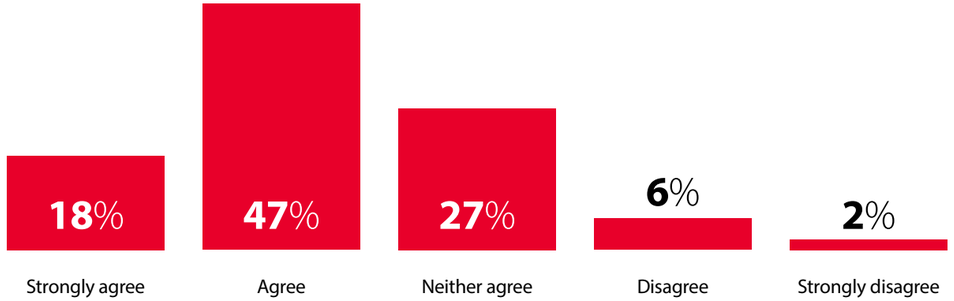
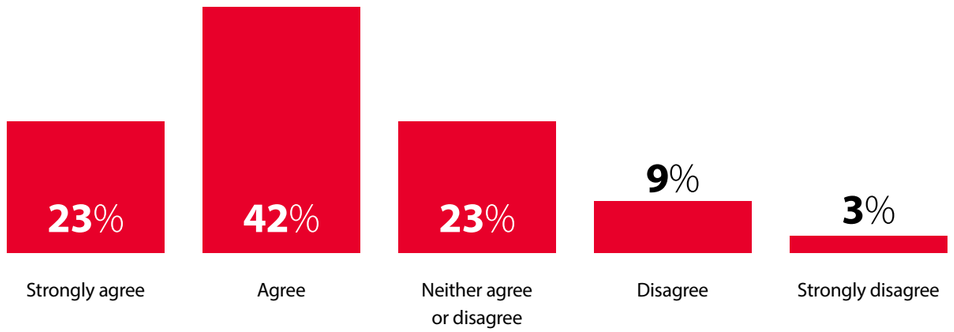


Figure 17. To what extent do you agree with the following statement? **I am unlikely to switch my patients from reference products to biosimilars until there is a greater adoption of biosimilars among payers.** (Surveys conducted in 2020) N = 102



Adoption of biosimilars among retina specialists will depend on education, price and payer influence

Nancy M. Holekamp, MD
Director of Retina Services at the Pepose Vision Institute

With the first ophthalmology biosimilar expected to launch in 2022, Cardinal Health saw an opportunity to survey ophthalmologists to better understand how prepared they feel to use this new class of medicines. The results of the survey confirm that biosimilars are an emerging treatment option for retina specialists in the U.S. Of the more than 100 respondents in the survey, only a minority (40%) agreed with the statement, "I am very familiar with biosimilars. I understand how the FDA defines and evaluates biosimilars." That means the majority of retina specialists surveyed are not adequately familiar with biosimilars. In fact, when queried, 82% of respondents requested additional educational information about the safety, efficacy and performance of biosimilars. If we consider this survey to be representative of retina specialists in general, there is an identifiable gap in knowledge surrounding biosimilars. This is the first important teaching point of the survey.

To drive this point further, 34% of retina specialists surveyed admitted very limited knowledge of clinical trial design for biosimilars. Additionally, 46% of respondents cited, "I have little knowledge on the FDA approval pathway for biologics." When it comes to the concept of extrapolation, only a small minority (18%) of those surveyed said they were fully aware of extrapolation and had no concerns about it, and nearly half (46%) of those surveyed stated they would not prescribe a biosimilar for indications that have been granted approval based on extrapolation. Thus, there is a suggestion that current impressions and answers in this survey are based on limited understanding and could possibly change over time with additional information and education.

As biosimilars are introduced into the field of retina, the existence of an inexpensive, off-label treatment option, bevacizumab, which has been comfortably utilized by 100% of respondents in this survey, looms large. Further, 97% do not have safety concerns, or believe the cost-effectiveness outweighs any concerns, with off-label compounded bevacizumab use. These two statistics represent the highest degree of agreement for any question in the survey.

While 80% of retina specialists surveyed agree that ranibizumab/aflibercept biosimilars could reduce the use of off-label bevacizumab "if price discounts are significant enough," in reality, achieving meaningful price discounts might be a tall order. In a related question, more than one third (37%) of those surveyed said a greater than 40% discount from the reference product would be necessary to prescribe a biosimilar. Yet today, bevacizumab can be purchased from compounding pharmacies for as little as $20 per syringe in most U.S. markets, meaning biosimilars may be hard pressed to compete on price.[18]

The final teaching point from this survey regarding biosimilar use is the growing realization among retina specialists that choice in prescribing behavior may no longer be only in the hands of the doctor. When asked, "Who ultimately has the greatest influence on which anti-VEGF biologics/biosimilars are utilized in your practice?" nearly half (48%) answered the prescriber, but close behind, 40% of respondents answered the payer. Then, when asked, "To what extent are you able to influence payer formularies and therefore treatment strategies for patients?" 76% of retina specialists replied, "I have little influence or no influence on payer formulary decisions." This may be the biggest battle facing physicians across all pharmacologic therapeutic areas. There are forces larger than retina specialists at play that may alter the prescribing landscape, and as biosimilars continue to emerge, I believe the results of surveys such as this one will evolve and over time change dramatically.

OPHTHALMOLOGY TRENDS

Participating retina specialists were mixed in their understanding of clinical trial design for biosimilars.

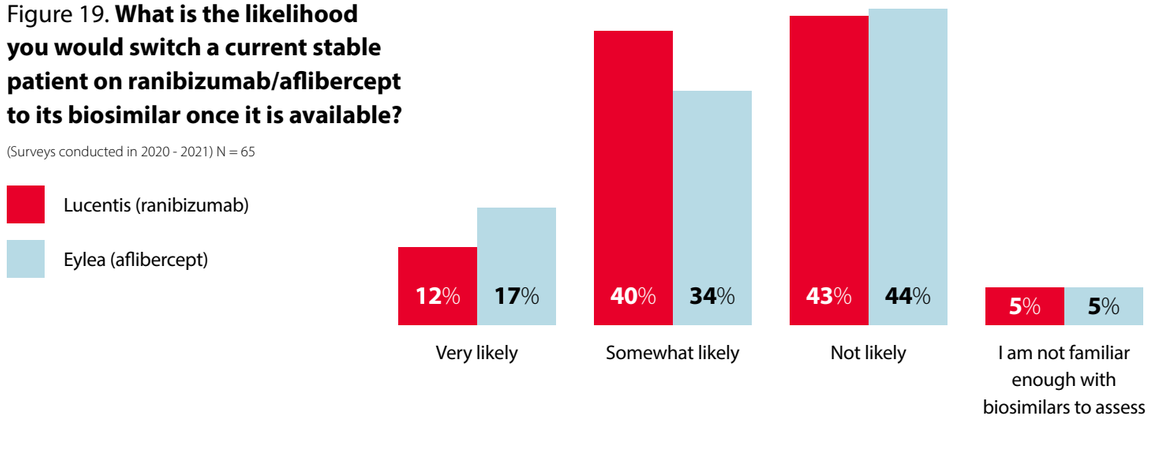
Figure 18. **Which of these statements best reflects your understanding of clinical trial design in biosimilar development?** (Surveys conducted in 2020 - 2021) N = 93

61% of retina specialists reported that they **were aware of ophthalmic biosimilars in development.**

Retina specialists had mixed views on switching stable patients on reference products to biosimilars.

Figure 19. **What is the likelihood you would switch a current stable patient on ranibizumab/aflibercept to its biosimilar once it is available?**

(Surveys conducted in 2020 - 2021) N = 65



For their patients with nAMD, **respondents said they would be most likely to prescribe a biosimilar to existing patients having either success (40%) or limited success (36%) on a reference biologic.**

Over two-thirds of participating retina specialists do not have safety concerns with off-label, compounded bevacizumab use.

Figure 20. **Which statement below best aligns with your perspective regarding compounding/repackaging bevacizumab?** (Surveys conducted in 2020 - 2021) N = 65

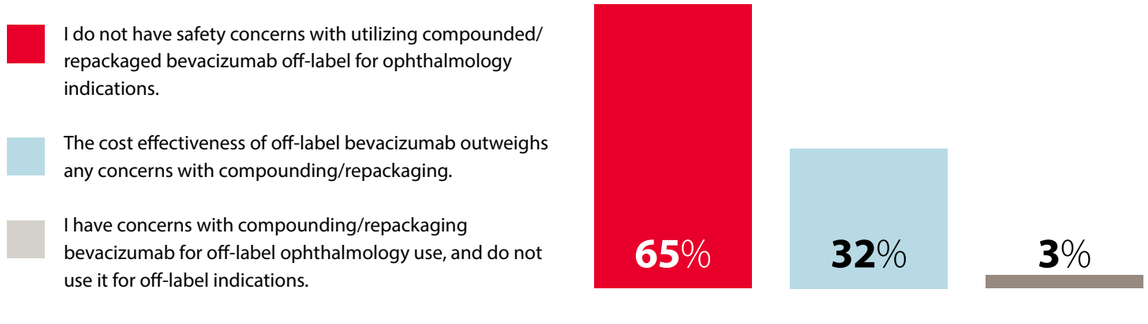
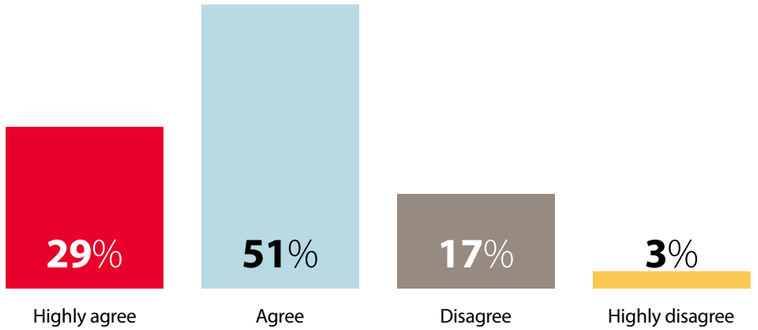


Figure 21. **To what extent do you agree with this statement? The availability of ranibizumab or aflibercept biosimilars will shift utilization away from off-label bevacizumab if price discounts are significant enough.**

(Surveys conducted in 2020 - 2021) N = 65



Key influences in future utilization of biosimilars in ophthalmology include cost, payer coverage and clinical data.

Figure 22. **What will be key decision criteria for using an anti-VEGF biosimilar?**
(Please select all that apply.)
(Surveys conducted in 2020 - 2021) N = 65

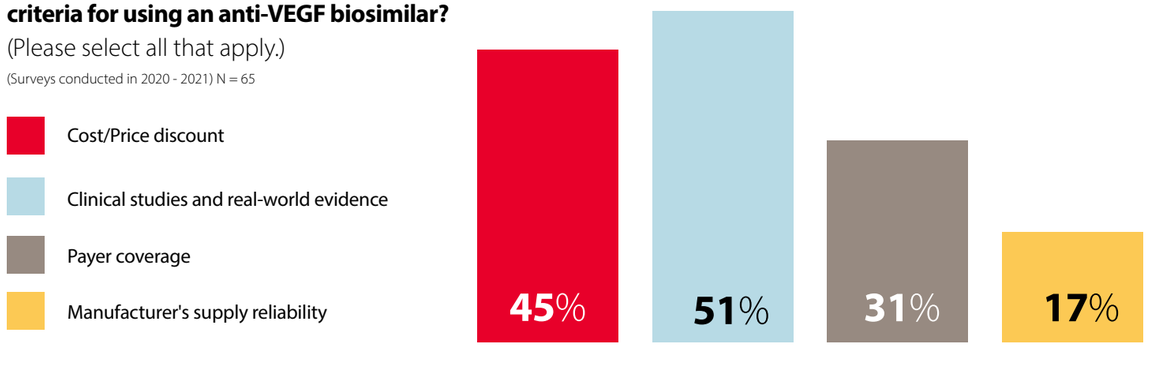


Figure 23. **What would be your primary concern with prescribing biosimilars once they become available?** (Surveys conducted in 2020 - 2021) N = 102

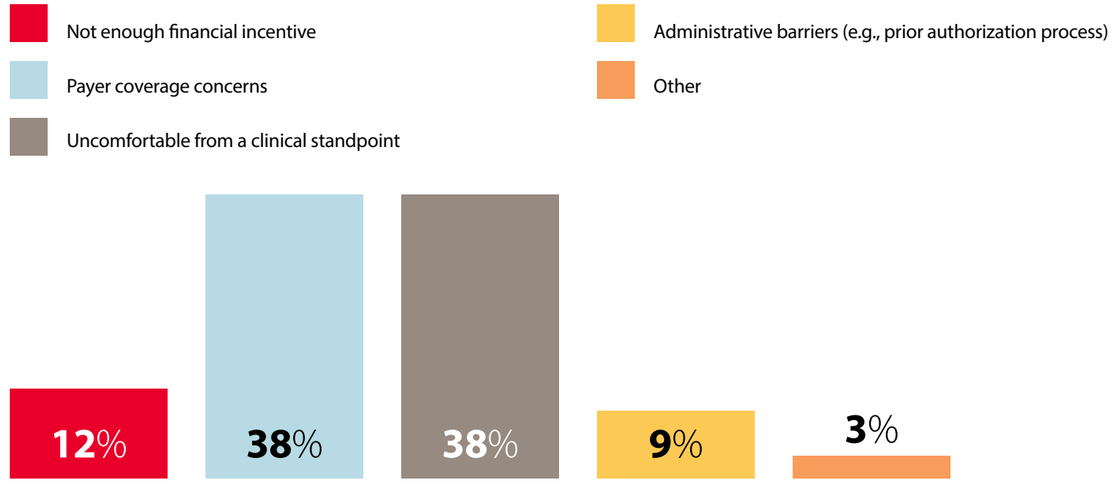
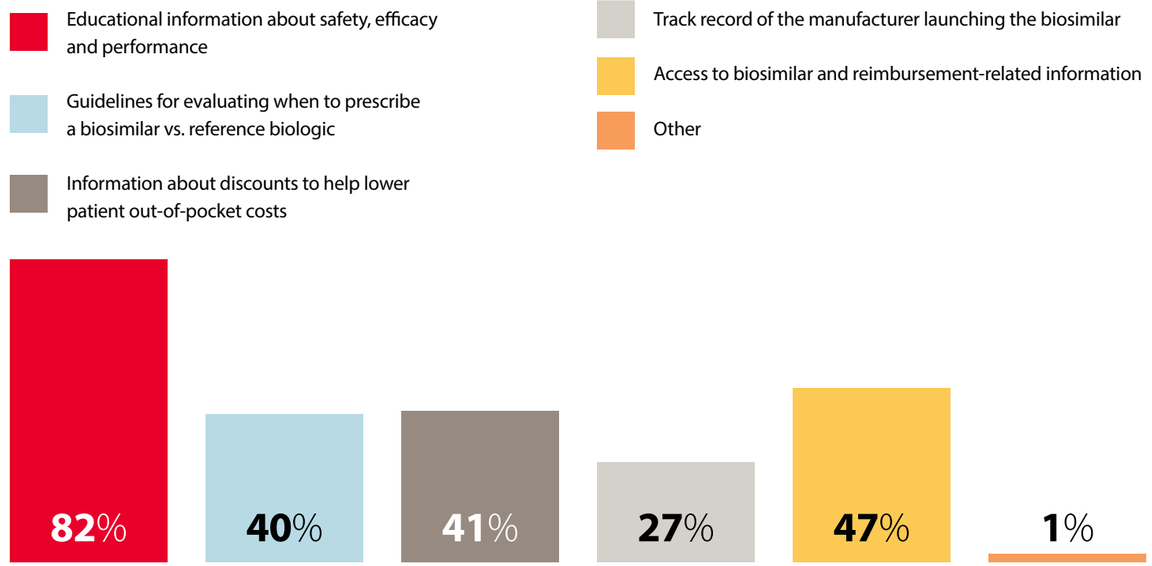


Figure 24. **Which of the following would help you achieve a greater understanding of biosimilars?**
(Please select up to three.) (Surveys conducted in 2020 - 2021) N = 102



Physicians and pharmacists see potential for insulin biosimilars to increase access and lower the cost of diabetes care

Chevon Rariy, MD
Vice President and Chair of Virtual Health at Cancer Treatment Centers of America and Medical Director of Endocrinology

To assess perceptions about the recently approved insulin biosimilars, Cardinal Health conducted a survey of 54 diabetes care providers and 115 pharmacists. The results of this study show that providers (endocrinologists and primary care physicians) agree that they view the introduction of insulin biosimilars as a likely mechanism to help lower the cost of care for patients with diabetes and that availability of insulin biosimilars is expected to shift utilization away from reference products if price discounts are significant enough. But how much is "significant enough" and whom a price discount would benefit remain to be seen. In our survey, for providers to prescribe a biosimilar versus the reference product, a discounted amount of more than 20% would be necessary.

Approximately 10% of the U.S. population has a diagnosis of diabetes, type 1 or type 2, and as of 2018, diabetes ranked as the seventh leading cause of death in the U.S.[19] To date, over eight million people use insulin daily to effectively manage their diabetes. However, the list price of insulin has continued to rise, nearly tripling since 2001, forcing many patients who face affordability and other access barriers to self-ration their insulin.[20] Uncontrolled blood glucose levels can lead to worsening health complications or even death while at the same time increasing the burden on the health system with costly, otherwise unnecessary hospitalizations.[20]

In 2021, the FDA approved the first insulin biosimilar, insulin glargine-yfgn, under the name Semglee, with an interchangeable designation. The introduction of insulin biosimilars is expected to help cut the cost of insulin, improve access to the medication, and create a win-win-win situation for the patient, care team and overall healthcare economics. In fact, insulin cost has been a top priority for the Endocrine Society, which recently recommended that the FDA ensure the safety of insulin biosimilars while allowing for approval in an expedited manner.

In our study, we saw nearly 40% of physicians expressed discomfort with pharmacists' ability to substitute interchangeable biosimilars in place of reference products without first seeking approval from the prescriber. However, pharmacists' ability to provide insulin to a patient without delays in therapy and facilitate greater patient adherence in a cost-effective way is in direct alignment with the goal of increasing access to insulin. In fact, this was the principal reasoning behind the Biosimilar Insulin Access Act of 2020, which focused on the need for insulin biosimilars to be interchangeable with their reference product and, in turn, streamlined the approval process.

In our survey, most pharmacists were comfortable substituting a biosimilar for a reference product if it would deliver lower out-of-pocket costs for the patient, but they expressed concern about both the efficacy of biosimilars and a lack of payer adoption in this substitution.

While it is true that interchangeable biosimilar insulin products like Semglee could potentially provide cost-effective, safe treatment options for patients with diabetes, providers agreed that payers and PBMs have the most influence in shifting utilization to insulin biosimilars.

As insulin interchangeable biosimilar products hit the market, only time will tell if they deliver on their promise of driving costs down. The hope is that they will pave the way for those diabetic patients who have been rationing their insulin to offset high cost and obtain more affordable insulin, thus improving adherence. This would in turn lead to improved glycemic control, better health outcomes and lower total cost of care for diabetic patients.

Moving forward, it is important that we work with patients, caregivers, providers, payers and pharmacists to provide education around insulin biosimilars and interchangeability, including its efficacy and safety, to overcome hesitancy, increase awareness and improve acceptability.

DIABETES TRENDS

Participating pharmacists are slightly more likely to substitute biosimilars for new diabetes patients than for existing patients.

Figure 25. **For which patients are you most likely to substitute an insulin reference product with a biosimilar?** (Please select all that apply.)
(Surveys conducted in 2021) N = 115

Nearly 60% of participating pharmacists said they **fill prescriptions daily or weekly for insulin** to be used in an insulin pump.

Less than half of participating pharmacists said they are "very" prepared for discussing biosimilars with patients.

Figure 26. **How prepared do you feel to have conversations with patients on their options for insulin biosimilars?**
(Surveys conducted in 2021) N = 115

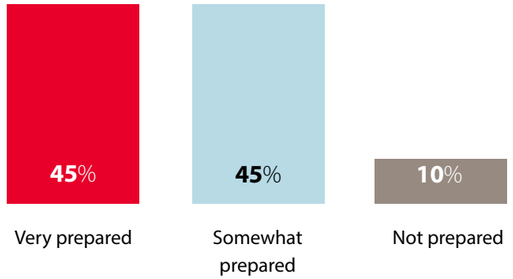
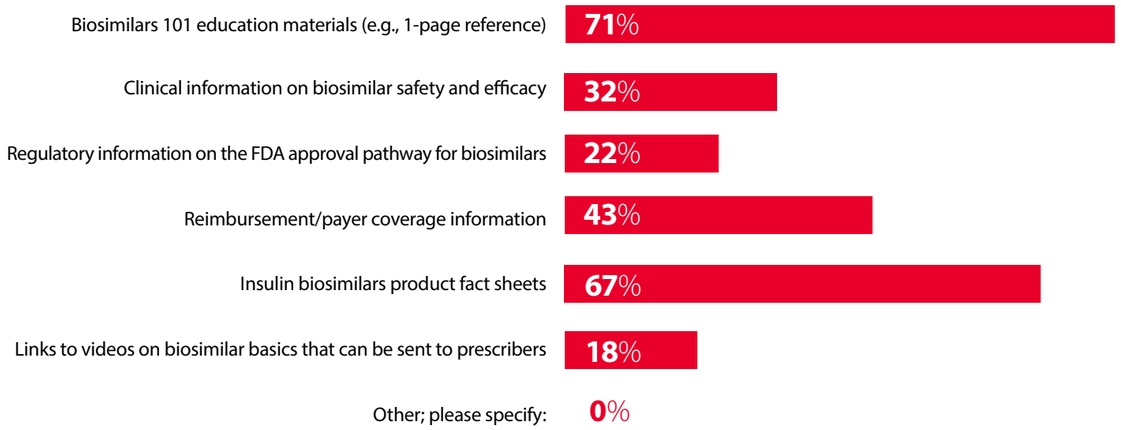


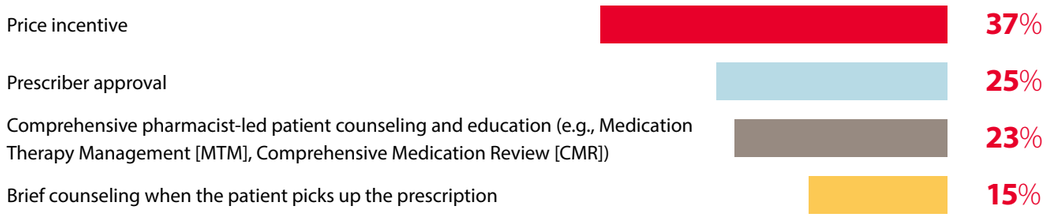
Figure 27. **What types of resources do you feel would be helpful to support your conversations with patients?** (Please select all that apply). (Surveys conducted in 2021) N = 115



62% of pharmacists said they would be more likely to substitute a biosimilar if they were financially incentivized through a Medication Therapy Management (MTM) platform.

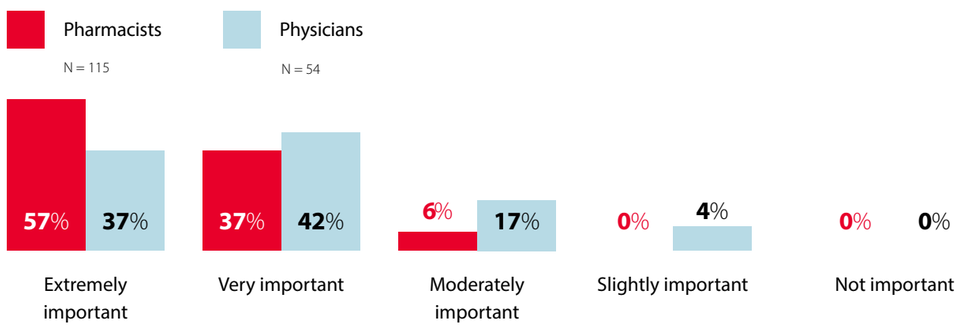
Participating pharmacists said price incentives are the key factor in promoting the switch to biosimilars.

Figure 28. **Which of the following do you think would help your patients to be more comfortable about switching from a reference product to a biosimilar?** (Surveys conducted in 2021) N = 115



The majority of physicians and pharmacists view cost savings for patients as "extremely" or "very" important.

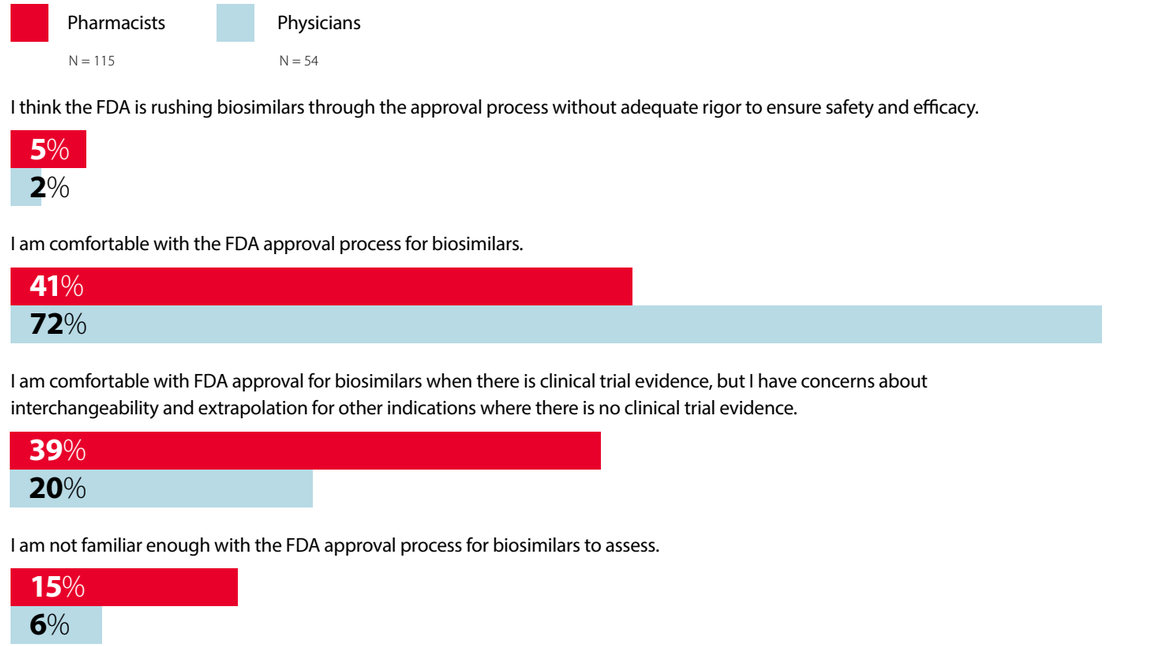
Figure 29. **When considering biosimilars as a potential substitute for a reference product, the importance of cost savings for my patient is:** (Surveys conducted in 2021)



70% of responding physicians said a discount of 20% or more would be needed to motivate them to prescribe a biosimilar over a reference product.

Participating pharmacists are less comfortable than physicians with the FDA approval process.

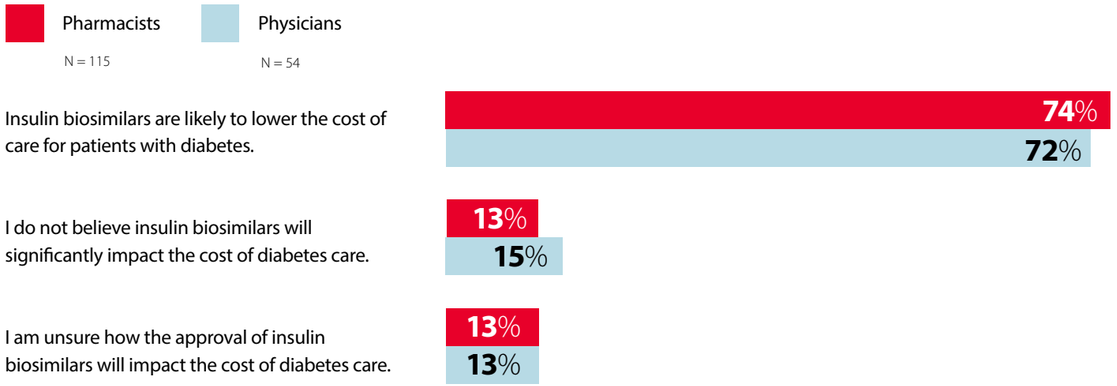
Figure 30. **Based on your understanding, which of the following statements best describes your perception of the FDA approval process for biosimlars?** (Surveys conducted in 2021)



Half of participating pharmacists (**51%**) said they are "very comfortable" substituting a biosimilar for a reference product if the biosimilar would **deliver a lower out-of-pocket cost for the patient.**

Participating physicians and pharmacists agree that insulin biosimilars will lower the cost of diabetes care.

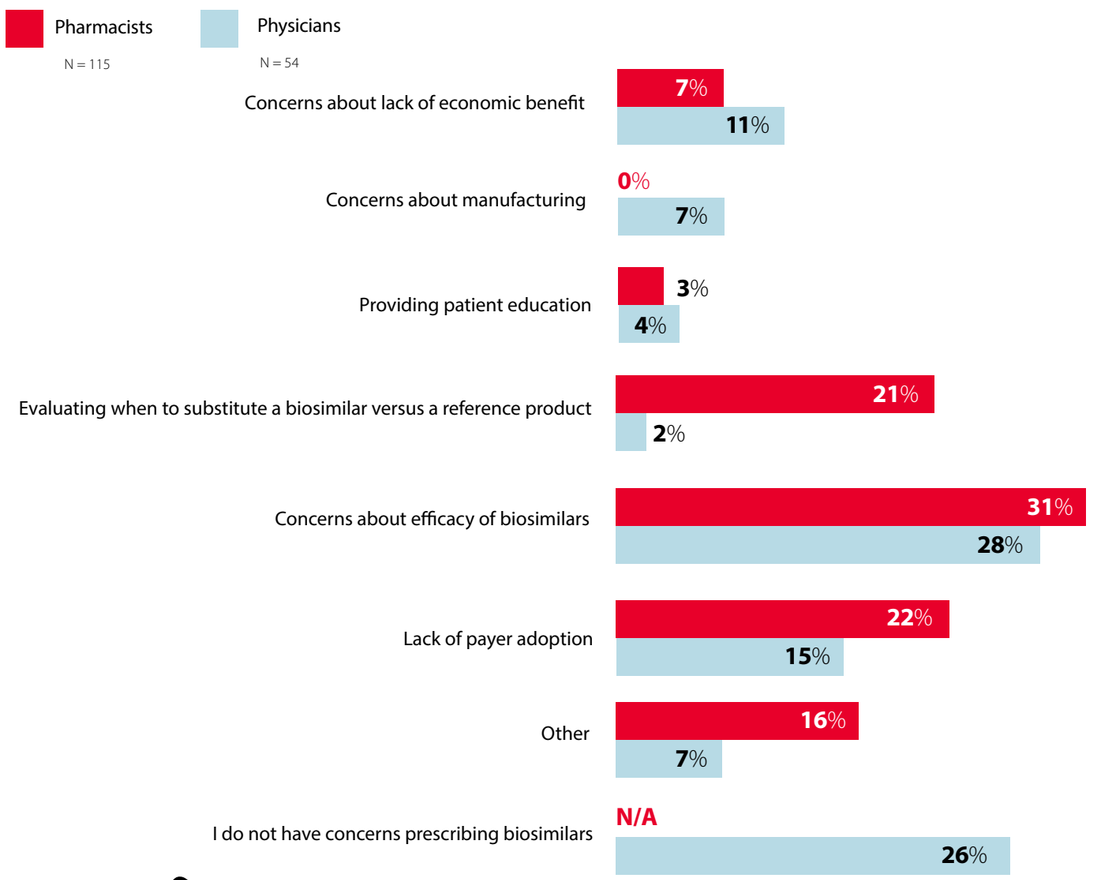
Figure 31. **Which of the following best describes your view on how new insulin biosimilars may impact the cost of diabetes care?** (Surveys conducted in 2021)



Efficacy of biosimilars is the top concern for both physicians and pharmacists.

Figure 32. **What is your top concern about substituting a biosimilar product for the reference product?**

(Surveys conducted in 2021)



78% of participating pharmacists said **favorable economics for the pharmacy are "extremely" or "very" important** when considering biosimilars as a potential treatment option.

Less than 20% of participating pharmacists were "very familiar" with interchangeability designation.

Figure 33. **How would you describe your familiarity with the interchangeability designation for biosimilars?** (Surveys conducted in 2021) N =115

Very familiar

19%

Somewhat familiar

64%

Not very familiar

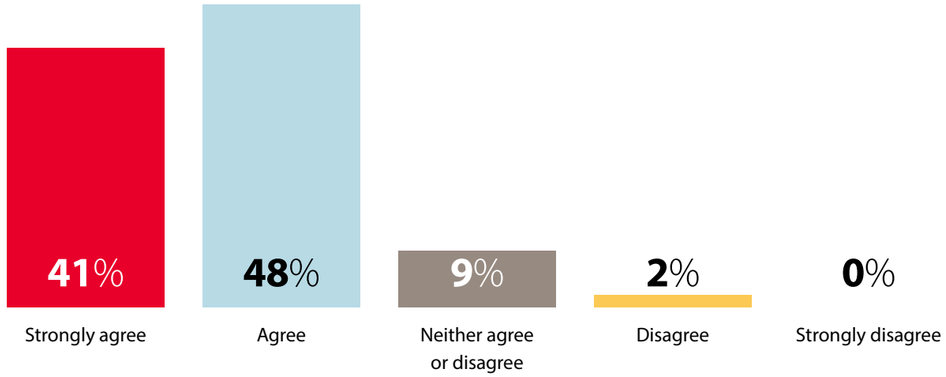
17%

61% of participating physicians said they are comfortable with **pharmacists substituting interchangeable biosimilars in place of reference products without prescriber approval.**

More than half of participating **physicians feel very comfortable prescribing biosimilars** to diabetes patients.

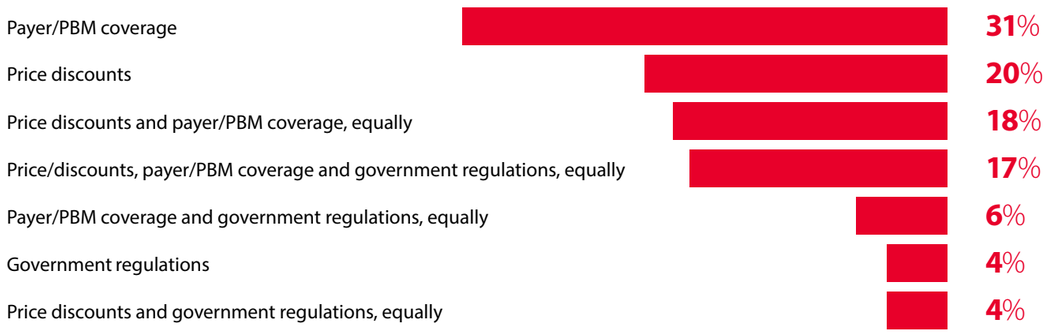
Nearly nine in 10 participating physicians strongly agree or agree that price discounts are key in driving the shift to biosimilars.

Figure 34. **To what extent do you agree with the following statement? The availability of insulin biosimilars will shift utilization away from reference products if price discounts are significant enough.** (Surveys conducted in 2021) N = 54



Participating physicians see payer coverage and price incentives as key factors impacting the shift to biosimilars.

Figure 35. **Which factor do you think will be the most impactful to shifting utilization to insulin biosimilars?** (Surveys conducted in 2021) N = 54



Participating physicians said they were either "very familiar" (35%) or "somewhat familiar" (56%) with the interchangeability designation for biosimilars.

Payer Trends

"Just two years ago, most biosimilar products had very limited payer coverage and were often placed on lower formulary tiers than their reference product counterparts."

Jeff Baldetti, MBA
Director of Biosimilars
Cardinal Health

Robust biosimilar access will continue to depend on the strategies of managed care stakeholders

While payer policies were initially slow to embrace biosimilars in the U.S., the tide may be starting to turn as payer coverage rates, as well as overall adoption rates and cost savings, have improved dramatically since 2019. Although significant progress has been made, the journey is far from over.

Just two years ago, most biosimilar products had very limited payer coverage and were often placed on lower formulary tiers than their reference product counterparts.[21] These formulary and utilization management strategies, such as prior authorizations and step therapy (See Figure 41-1 for definitions), while key tools to help managed care stakeholders predict utilization and lower drug costs, can slow the adoption of biosimilars and restrict patient access to these products. Without equivalent coverage in payer medical policies or PBM formularies at minimum, biosimilars stand at a significant access disadvantage compared to their reference products.

Aggregate Coverage Scores for Biosimilars and Reference Products Over Time

Many commercial payers utilize formulary and utilization management tools to control costs and better predict product use in their member populations. However, the variation in utilization management strategies by product and payer can sometimes create additional steps before patients can access specific treatments. Providers are often tasked with navigating several payer policies when evaluating biosimilars, as their patient populations are often represented by a variety of payers. Insights into these payer strategies provide added nuance to better understand how well covered, and therefore how accessible, certain products like biosimilars are for patients. Using data accumulated from payer formularies and medical policies at the aggregate U.S. level, this analysis reviewed how coverage of biosimilars and their reference products have changed over the two-year period between December 2019 and November 2021 (collectively, Figures 36-41). For this exercise we looked specifically at a spectrum ranging from full product coverage with no step therapy requirements (6 = best coverage available) to no product coverage or unknown coverage (1 = worst coverage available). We can call these "coverage scores." Higher coverage scores equate to overall better coverage for a product, whereas lower coverage scores equate worse coverage for a product.

The payer coverage levels for biosimilars have increased significantly since 2019 while levels for reference products have generally declined.

Figure 36. **Therapeutic oncology — Avastin (bevacizumab) and related biosimilars**

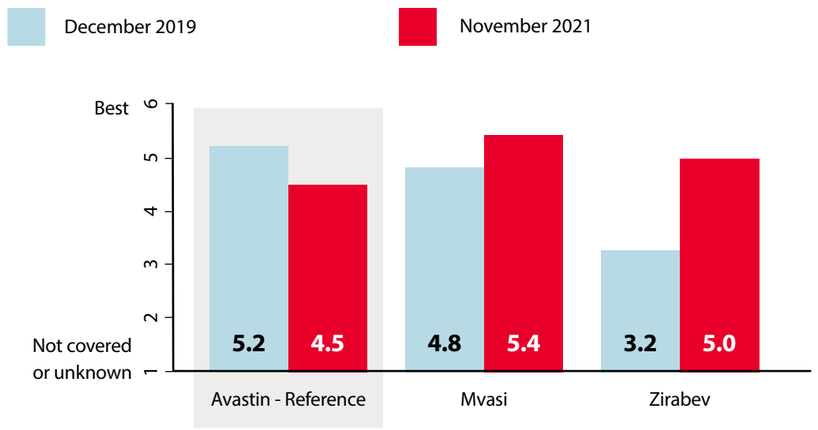
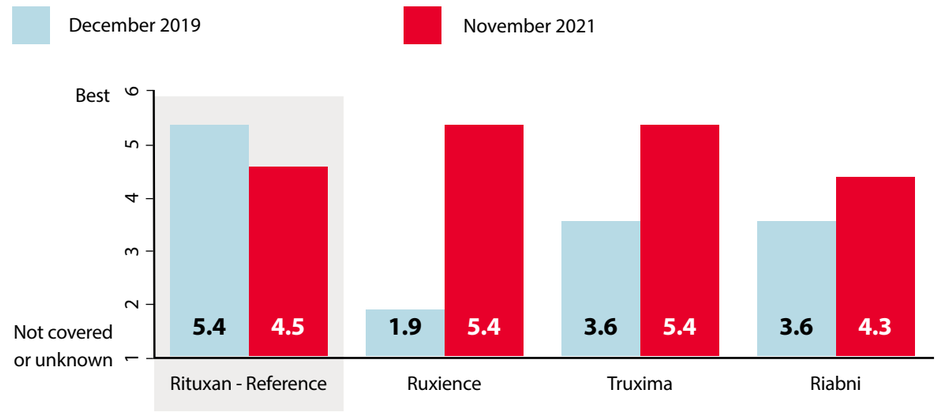


Figure 37. **Therapeutic oncology — Rituxan (rituximab) and related biosimilars**



Source: Managed Markets Insight & Technology, LLC (MMIT) Analytics Accessed November 2021.

"Payer coverage for biosimilar treatments has improved greatly over the last two years, likely contributing to the rise in adoption rates."

As a result, early adopters of biosimilars often had to navigate complex administrative and inventory challenges associated with carrying multiple therapeutically equivalent treatment options to provide biosimilars to their patients.

Utilization management strategies like prior authorizations and step edits are still widely used today, but these policies are beginning to move in favor of biosimilars. As shown in Figures 36 - 41, almost every biosimilar had a lower average coverage score than its reference product in 2019, meaning providers and patients had to take additional steps to access biosimilars.

Today, biosimilars are beginning to gain greater utilization, with much of this change driven by more favorable coverage policies from managed care entities. By November 2021 (as shown by the red bars in Figures 36 - 41), almost every biosimilar had experienced a dramatic increase in its coverage score. In many cases the coverage scores of the biosimilars now exceed the score of their reference products, while at the same time, most reference products have seen moderate coverage score decreases. In aggregate, it is safe to say that payer coverage for biosimilar treatments has improved greatly over the last two years, likely contributing to the rise in adoption rates.

While it is clear that biosimilar adoption is greatly influenced by payer coverage decisions, what is striking is how closely these coverage scores and adoption rates can move in lockstep. As illustrated in Figure 42, by plotting biosimilar adoption rates in the market against the aggregate percentage of lives where the biosimilars are considered in a covered or better position in the U.S., there is an astonishing 97% correlation. While correlation does not always represent a causal effect, the close alignment between these two metrics reminds us that the success of biosimilars is a multi-stakeholder responsibility.

Figure 38. **Therapeutic oncology — Herceptin (trastuzumab) and related biosimilars**

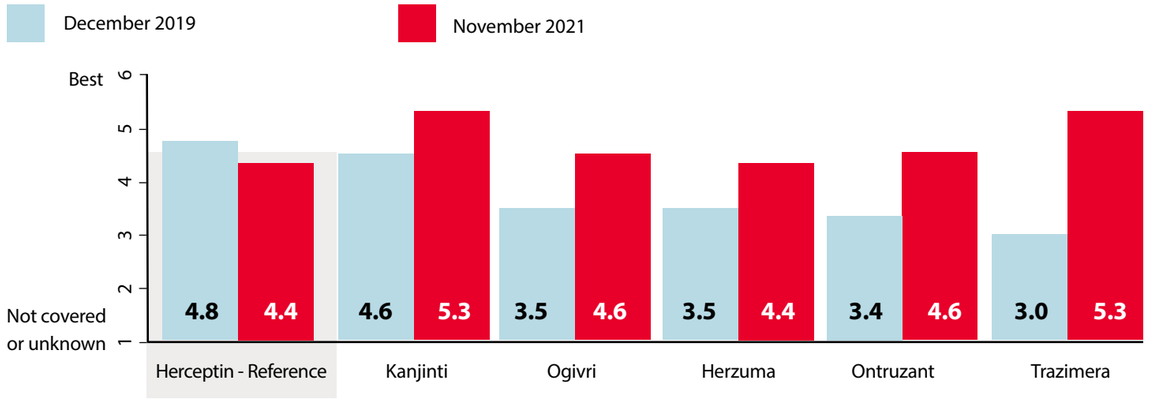
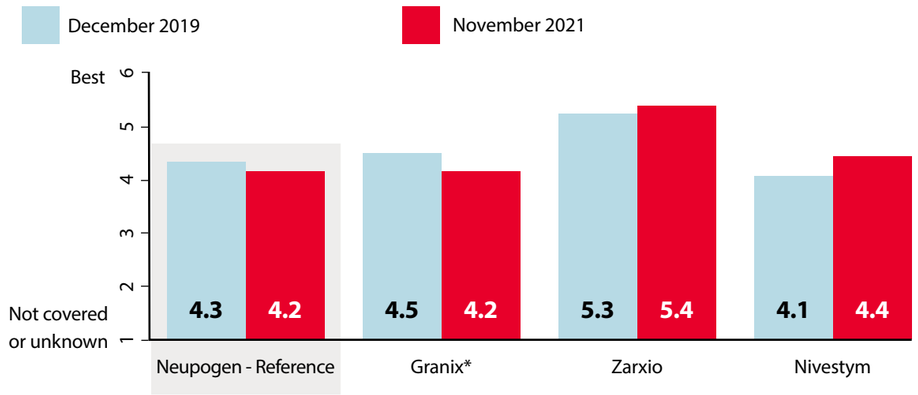


Figure 39. **Supportive care oncology — Neupogen (filgrastim) and related biosimilars**



Source: Managed Markets Insight & Technology, LLC (MMIT) Analytics Accessed November 2021.

*Granix is not a true biosimilar since it was not approved through the Biosimilar 351(k) pathway.

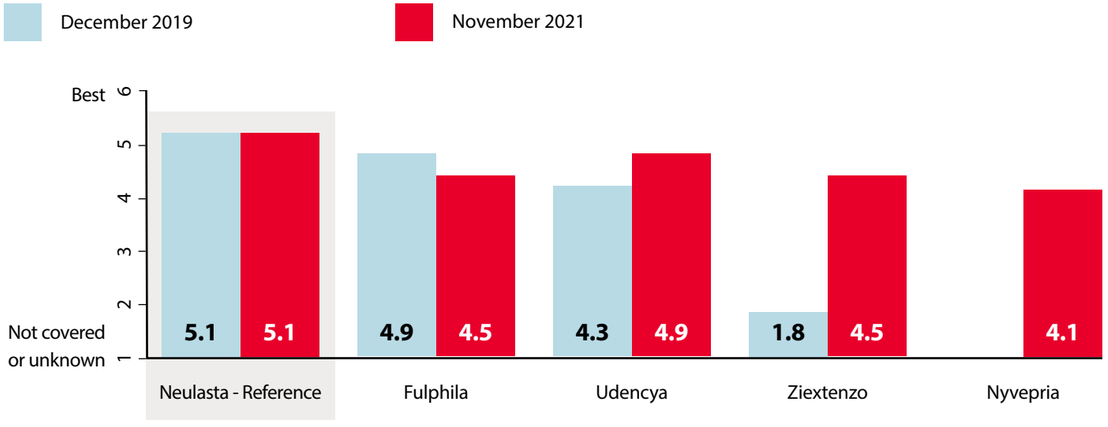
As the biosimilars market continues to evolve, it is no longer a question of "if" the biosimilar will have coverage, but "which" biosimilar product from the slate of FDA approved options will have the best coverage with each payer. Providers and administrators will still be tasked with navigating the complexities of payer policies that vary by payer, region and therapeutic area, but biosimilars will now be more competitively positioned alongside reference products.

It is also important to note that, while all of the approved biosimilars for the last six years have been products administered in a hospital or physician clinic under the medical benefit, the next "wave" of biosimilars will be available in the retail/specialty pharmacy channel and primarily covered under the pharmacy benefit.

With the approval and official relaunch of the first interchangeable biosimilar in November 2021— a long-acting insulin, Semglee — Viatris made the decision to commercialize two versions of their landmark interchangeable product, including a branded, high list price product (~5% discount to Lantus), and an unbranded, low list price product (~65% discount to Lantus).

"While it is clear that biosimilar adoption is greatly influenced by payer coverage decisions, what is striking is how closely these coverage scores and adoption rates can move in lockstep."

Figure 40. **Supportive care oncology — Neulasta (pegfilgrastim) and related biosimilars**



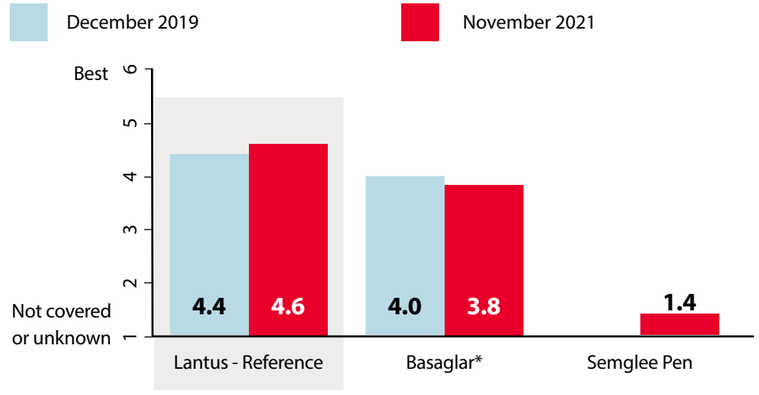
Source: Managed Markets Insight & Technology, LLC (MMIT) Analytics Accessed November 2021.

As noted in Figure 41, Semglee had a very low average coverage score, despite its attractive list price. However, recent announcements from major PBMs seem to show that Viatris' dual product approach could prove more effective in driving payer coverage the second time around. Thus far, two major PBMs (Express Scripts and Prime Therapeutics) have publicly stated plans to include the interchangeable insulin biosimilar as the preferred agent on their national preferred formularies (NPFs) starting in 2022. Express Scripts will shift the branded version of interchangeable Semglee to preferred status on their NPF,[22] and Prime Therapeutics will shift both the branded and unbranded versions of Viatris' interchangeable biosimilar to preferred status on their NPF.[23] Both PBMs will plan to move the reference product, Lantus, to non-covered status. While these early moves are encouraging, it is likely many additional payers and PBMs will continue to take a "wait and see" approach to evaluating these new interchangeable biosimilars.

As more interchangeable products come to market over the next several years, managed care stakeholders, specifically PBMs, will have to navigate how these lower-cost biosimilar products, which often cannot support the same level of discounts and rebates that branded biologics can, fit into the landscape. These strategic choices made by managed care stakeholders will in turn continue to influence the strategic choices biosimilar manufacturers take as they plan future commercial launches. However, one thing is clear — until coverage increases more broadly, we will likely see slower than expected adoption in the pharmacy benefit biosimilars. While there is no playbook of best practices that can be applied directly from the medical benefit to the pharmacy benefit, we know that the success of biosimilars in any therapeutic area or channel depends on many stakeholders, with payers playing a significant role in shaping access to products. Insulin biosimilars will serve as a key learning experience for all biosimilars to follow in the Part D space and likely will lay the foundation for competition in the pharmacy benefit for years to come.

As more payers implement favorable biosimilar policies, the ultimate promise of biosimilars becomes a more likely reality: increased competition, lower prices and greater patient access to high-quality treatment options. Managed care stakeholders hold the key to realizing much of the savings potential of biosimilars and can accelerate, or hinder, their progress. Without adequate coverage, patients will struggle to gain access to these high-quality, potentially lower-cost treatment options. Widespread access to biosimilars is arguably the most vital piece to bending the cost curve for complex biologic treatments and paving the way for the next wave of therapeutic innovations in the U.S.

Figure 41. **Diabetes care — Lantus (insulin glargine) and related biosimilars**



Source: Managed Markets Insight & Technology, LLC (MMIT) Analytics Accessed November 2021.

*Basaglar is not a true biosimilar since it was not approved through the Biosimilar 351(k) pathway.
Note: Nyvepria, Avsola, and Semglee had not launched by Dec. 2019 and therefore does not have a "blue" bar.

"Managed care stakeholders hold the key to realizing much of the savings potential of biosimilars and can accelerate, or hinder, their progress."

Figure 41-1. Terms related to payer coverage.

Prior authorization: Is a utilization management strategy used by payers to review a prescriber's intended treatment option for their patient "prior to" dispense/administration to decide whether the insurer will reimburse or cover the patient's treatment. If prior authorization is denied, prescribers must resubmit additional documentation or choose a different treatment option for their patient (e.g., an alternative drug).

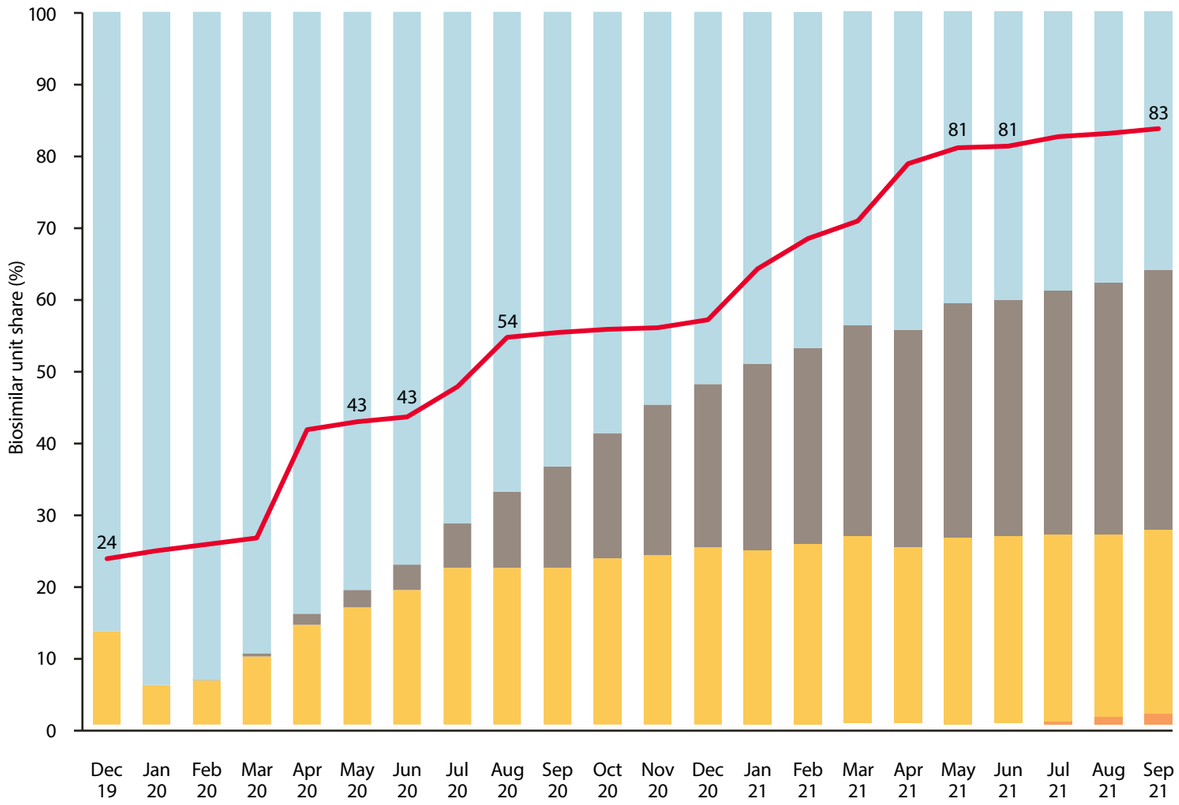
Step therapy (Step edits): Is a utilization management strategy used by payers to define the sequence of drug products a patient must "step through," or fail first on, before they can access a certain drug product. Generally, patients are required to fail treatment first on a cheaper treatment option before moving on to more expensive options.

Semglee (Insulin glargine): The FDA first approved Semglee under the generic 505(b)(2) New Drug Application pathway in June 2020, and then the product was automatically deemed a biologic under section 351(a), based on a policy enacted March 2020 that transitioned insulins, and several other products, to be regulated as biologics. In July 2021, the FDA officially approved Semglee (insulin glargine-yfgn) as an interchangeable biosimilar via the 351(k) pathway. The relaunch of Semglee (insulin glargine-yfgn) and its unbranded version, Insulin Glargine-yfgn, took place in November 2021.

A strong correlation is shown between biosimilar adoption and increases in payer coverage.

As an example, there is a 97% correlation between Rituxan biosimilars adoption and the percentage of plans covering Rituxan biosimilars at parity or in preferred positions.

Figure 42. **Rituxan Biosimilars Adoption vs. % of Covered or Better Status**



Note: Red line represents the percentage of aggregate lives in the U.S. where their payer carries Rituxan biosimilars at a covered or better status.

Sources: Managed Markets Insight & Technology, LLC (MMIT) Analytics Accessed November 2021 and IQVIA: Accessed via IQVIA National Sales Perspective (NSP) SMART Data. (October 2021).

Five Biosimilar Predictions for 2022

Heidi Hunter
President, Cardinal Health Specialty Solutions

Biosimilars are forecasted to deliver over $133 billion in aggregate savings by 2025,[24] and more importantly, total savings to patient out-of-pocket costs based on just the current biologics with biosimilars approved are estimated to reach up to $238 million.[25] With more than 40 different reference products being discussed for biosimilar development, the momentum around bringing biosimilars to market is stronger than ever.[26]

2022 is set to be a turning point in the U.S. as biosimilars expand into new therapeutic areas and sites of care and reimbursement models continue to evolve. While biosimilars were primarily focused on oncology and to a lesser extent rheumatology during the past seven years, the next five years will focus on the opportunities to bring biosimilars to a broader patient population across diabetes, ophthalmology, and most notably, immunology. The year ahead is sure to include many significant biosimilar milestones; we predict the following five trends will be particularly worth watching.

1. Insulin biosimilars will reveal how managed care stakeholders will respond to interchangeable biosimilars, and retail pharmacists will be positioned as key change agents

As the first biosimilar product to fall under the pharmacy benefit in the Part D space, insulin will serve as the ultimate case study to reveal how the managed care landscape will evaluate and position these products — and how payers and PBMs will design plans and formularies to deliver the greatest savings to patients, a much-debated topic. Without robust coverage for biosimilars, the extent of cost savings and intended benefit of the interchangeability designation may be limited for patients. Managed care stakeholders have the opportunity to be catalysts for biosimilar adoption, bringing much-needed competition to the market. The question of how quickly they will embrace this opportunity is likely to be answered this year.

Retail pharmacists also will play a critical role in delivering the promise of biosimilars on behalf of their patients and communities. With Semglee (insulin glargine-yfgn) designated as interchangeable, pharmacists can substitute it in place of its reference product without prior prescriber approval, per state laws. As a result, pharmacists are now positioned to not only play an essential role in educating patients and ensuring clinical confidence in biosimilars, but also to serve as key change agents who may steer millions of diabetes patients to high-quality, lower-cost treatment options.

2. Manufacturers of reference biologics will take further steps to protect market share in preparation for the launch of Humira biosimilars in 2023

Beginning next year, AbbVie's Humira (adalimumab) — the all-time top selling drug in the world[27] — will face competition from up to seven biosimilar competitors that have already received FDA approval, as well as several more candidates in the pipeline. The impact on the rheumatology and immunology market as a whole could be dramatic — not just for Humira but for all immunology therapies in the class, including Janssen's Stelara (ustekinumab) and Genentech's Actemra (tocilizumab), which are also anticipated to face biosimilar competition over the next few years.

Several innovator biologic companies have already taken steps to defend their market position by raising prices, creating new formulations or by generating new innovative therapies. According to a 2021 report from the House Committee on Oversight and Reform, the list price of Humira had increased 27 times, leading to a price that is 470% higher than when the drug launched in 2003.[28] Other reference product manufacturers have employed similar pricing strategies. As a result, when biosimilars come to market, the branded biologic manufacturers will be in a position to offer deep rebates to payers and PBMs, which may in turn keep its net price on par – or even lower – than biosimilar competitors.

Innovator companies have also added new formulations and delivery mechanisms, such as autoinjector devices,[29] which, in addition to providing patients with more treatment options, also extend patent protection. We expect to see continued advancements in innovator formulations and administration mechanisms in 2022 and beyond.

We will also see more focus from innovator companies on transitioning patients to completely new treatment options, seeking to advance the path toward obsolescence of biosimilars and originator biologics as a whole. It is also likely that several branded biologic companies may introduce their own "authorized biologic" versions of their products at a lower price in advance of the biosimilars launching, which could protect patient share and help fend off competition.

At the same time, the manufacturers of the adalimumab biosimilars have a lot to potentially gain in 2023 – and they know the competition for share will be fierce. We anticipate some may be launching market conditioning and educational campaigns over the next year to establish brand awareness and educate prescribers, patients and pharmacists in advance of their arrival in 2023.

"The next five years will focus on the opportunities to bring biosimilars to a broader patient population across diabetes, ophthalmology, and most notably, immunology."

3. Biosimilar uptake in ophthalmology will be slow, as the focus on innovating in retinal care continues

The number of patients diagnosed with wet age-related macular degeneration (AMD), the world's leading cause of blindness in older adults, is continuing to grow annually – with the National Eye Institute predicting the number of cases will more than double by 2050. With an average annual cost of $2,000 per treatment, the biotech industry is focused on developing more effective AMD therapies and delivering treatment options that lower the cost of care.[30] The latter of these goals may start to be addressed by the launch of Byooviz (ranibizumab-nuna), the first biosimilar in ophthalmology, which was approved in September 2021 and expected to launch in June 2022.

While the entrance of biosimilars to Lucentis (ranibizumab) brings the potential for broader treatment access and lower costs for AMD patients, we anticipate biosimilar uptake in ophthalmology may be slower than other therapeutic areas for several reasons. First, the U.S. achieved one of the first ophthalmology biosimilar approvals in the world (unlike oncology and rheumatology biosimilars, which were initially approved in Europe), meaning there is limited real-world data for physicians to reference. Research conducted with ophthalmologists and retina specialists in 2021 shows a high level of skepticism about biosimilars, indicating a strong need for education and additional outcomes data to help build confidence among prescribers.[31]

Another factor that will impact adoption of biosimilars in ophthalmology is the innovator therapies that have recently launched or are expected to come to market soon to treat AMD, including Roche's new port delivery system, Susvimo with ranibizumab,[32] faricimab and several gene therapies in development.[33] As these new, and possibly more effective, treatments come to market, physicians will have more options to select from and standards of care for AMD will continue to evolve. While launch of new innovative therapies could lead to slower uptake of biosimilars, they should also lead to a wider range of treatment options and better outcomes for patients.

4. The U.S. will see more pro-biosimilar healthcare policies at both the federal and state levels

In 2021, President Biden demonstrated strong support for biosimilars. In addition to signing an Executive Order directing the FDA to make the biosimilar approval process more transparent, his administration also called for market changes that would promote biosimilars in a report outlining the administration's recommendations on lowering the cost of prescription drugs.[34]

We expect to see more pro-biosimilar focus in the future, including additional rulemaking by the FDA — as well as Federal Trade Comission (FTC) action — to support competition and enhance consumer choice by preventing efforts by reference product manufacturers to delay or block competition from biosimilar and interchangeable products. As well, per the October 2021 white paper "Innovation Strategy Center Refresh,"[35] we anticipate the Center for Medicare and Medicaid Innovation Center (CMMI) to design models that incentivize the use of biosimilars in Medicare Parts B and D to lower beneficiary and program spending on drugs. CMS may also issue guidance to ensure that biosimilars are covered under Medicare Part D and pursue additional policies, such as removal of prior authorizations and other utilization hurdles, and reductions in patient cost sharing to drive increased adoption.

In addition, as states continue their efforts to lower drug costs, we expect state legislatures in 2022 to introduce policies that will broaden access to biosimilars, such as requiring health plans and pharmacy benefit managers to cover all versions of biological agents, including biosimilars.

5. Biosimilars manufacturers and commercial partners will increasingly turn to real- world evidence (RWE) to demonstrate equivalency to providers and payers

While understanding of biosimilars among prescribers continues to grow, many healthcare providers still question whether biosimilars can deliver the same outcomes for patients as their reference products. As biosimilar manufacturers face increased pressure to demonstrate safety and efficacy, they will increasingly invest in RWE studies, which are not only less expensive to implement than randomized controlled trials, but also more representative of the patient populations in the real world. This data will be particularly relevant in ophthalmology, where there is limited RWE available.

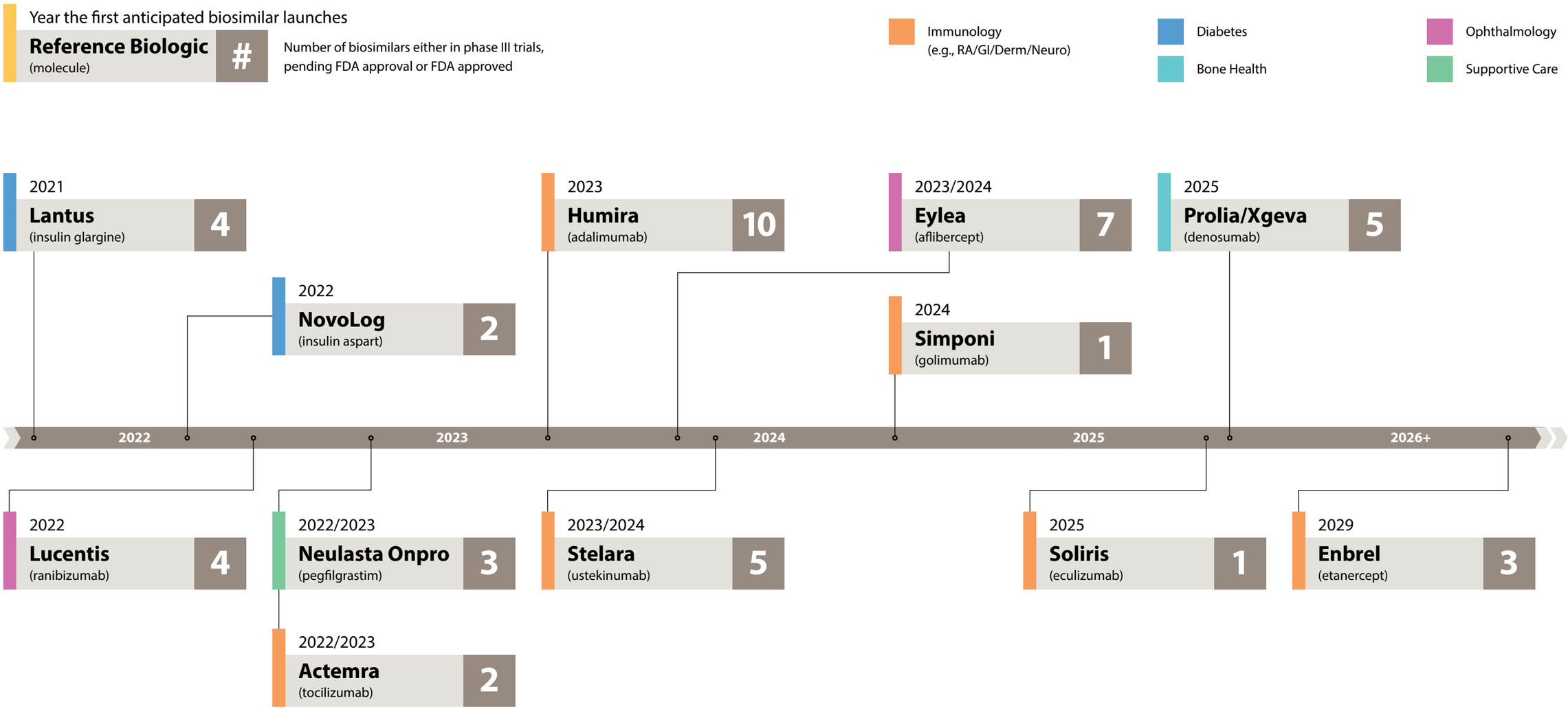
RWE studies will also provide valuable insights into whether switching patients between biosimilars of the same molecule has an impact on patient outcomes, which will become a more important question as more biosimilars come to market – specifically in categories such as immunology where there could be seven or more biosimilars referencing a single branded product. In addition, with more than 15 years and two billion patient days of biosimilars experience in the EU,[36] sharing of global resources and data represents one of the greatest opportunities to strengthen biosimilar acceptance in the U.S.

We also expect RWE to play a key role in advancing the development and approval of biosimilars that are early in the pipeline and providing data to help products meet the regulatory standards necessary for interchangeability designation.

Looking beyond 2022, the successful adoption of biosimilars will not only create broader healthcare access and lower costs for patients, but also free healthcare dollars systemwide to enable more investment in advanced, innovative treatments, such as cell and gene therapies, with the potential to drive overall improvements in both rare diseases and public health. Although there are still barriers to overcome, the promise of biosimilars outlined in the Biologics Price Competition and Innovation Act (BPCIA) are starting to be realized. And as momentum around biosimilars in the U.S. continues to accelerate, patients will experience expanded benefits through broader access to and affordability of life saving medications.

LOOK AHEAD

Figure 43. **New and upcoming biosimilars launches**

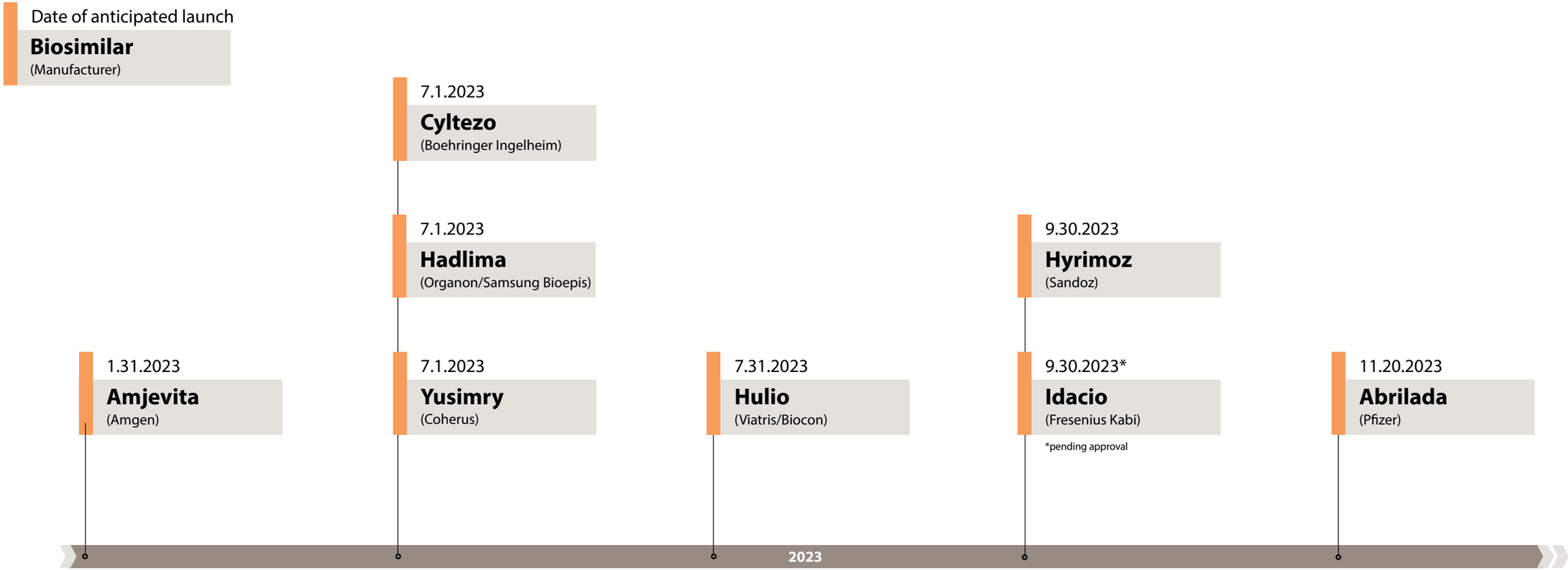


Source: IPD Analytics. Market & Financial Insights. December 2021. https://www.ipdanalytics.com.

Note: Data reflects biosimilar pipeline information as of January 2022. For updates, please visit cardinalhealth.com/biosimilars.

LOOK AHEAD

Figure 44. **Humira (adalimumab) biosimilars pipeline**



To be determined

TBD*
CT-P17
(Celltrion)
*pending approval

TBD*
AVT02
(Alvotech/Teva)
*pending approval

Source: IPD Analytics. Market & Financial Insights. December 2021. https://www.ipdanalytics.com.

For a more detailed Humira biosimilar landscape overview, please visit: cardinalhealth.com/HumiraBiosimilars.

Note: Data reflects biosimilar pipeline information as of January 2022. For updates, please visit cardinalhealth.com/biosimilars.

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Heidi Hunter, MBA, is an accomplished global healthcare leader with deep experience in innovation, development and commercialization of specialty pharmaceuticals. As President of Cardinal Health Specialty Solutions, she works with healthcare providers and pharmaceutical companies to drive business growth and improve patient outcomes. She previously served as Senior Vice President and General Manager at Boehringer Ingelheim, where she built and led their global biosimilars business. She also held senior commercial roles at UCB in Brussels; Centocor, a J&J company, and Wyeth Pharmaceuticals. She holds an MBA from The University of Chicago and a bachelor's degree in economics and German from The University of Michigan.

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Methodology

The healthcare provider research was conducted by Cardinal Health using web-based surveys in 2020 and 2021.

The oncology surveys were fielded in September, October and November 2020, and February 2021, and included more than 320 oncologists.

The rheumatology surveys were fielded in February and March 2020 and included more than 100 rheumatologists.

The ophthalmology surveys were fielded in September 2020 and January and February 2021 and included more than 100 retina specialists.

The diabetes surveys were fielded in November and December 2021 and included more than 50 physicians (endocrinologists and primary care physicians who treat diabetes) and 115 pharmacists.

About Cardinal Health and Biosimilars

With broad access to biosimilars and a deep understanding of the considerations for biosimilar utilization, Cardinal Health is positioned to be your trusted healthcare advisor and partner.

For specialty physician practices, hospitals, health systems and pharmacies, we not only distribute products — we also deliver the insights, tools and expert support providers need to evaluate biosimilars for adoption, enabling them to make clinically sound and cost-effective treatment decisions.

For biopharma companies bringing new biosimilars to market, our capabilities support the product lifecycle from pre-clinical to post-commercial launch. Our team of seasoned experts works to accelerate and simplify the process to achieve commercial success with guidance on regulatory approval pathways, real-world evidence generation, educational programs and market insights, logistics planning and implementation, and patient hub services to support patients through their treatment journey.

Cardinal Health works with all healthcare stakeholders, including providers, payers, pharmacists, biopharma companies, policy makers and patients, to provide education and build a broader understanding of the role that biosimilars can play in facilitating high-quality, lower cost care. Learn more about our solutions and resources at **www.cardinalhealth.com/biosimilars**.

Visit our website to access biosimilars resources, solutions, and insights.
cardinalhealth.com/biosimilars

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