Biosimilars in the autoimmune category

Opportunities and considerations

CVS Health

Spurring competition and savings

The global anti-inflammatory biologics market is projected to reach nearly $150 billion by 2027, according to estimates.[1] This is an exciting time in health care as the marketplace anticipates a wave of biosimilars in the autoimmune category. 2023 brings the launch of several biosimilars to Humira, one of the world's best-selling drugs for nearly 20 years, followed by biosimilars to Stelara.[2]

A robust biosimilar pipeline creates an opportunity to meaningfully reduce drug costs in the autoimmune category; we expect plan sponsors will benefit from significant savings.

CVS Caremark has extensive experience creating additional value for clients and members with innovative formulary strategies. We were the first pharmacy benefits manager to implement formulary exclusions in 2012, and the first to add biosimilars and follow-on biologics to our formularies when Basaglar was preferred over Lantus for the treatment of diabetes in 2017. Our strategy created a 21.7 percent reduction in cost per long-acting insulin prescription and lower overall costs of $0.34 per member per month.[3]

We have seen that these products can provide additional safe and high-quality options for patients living with chronic conditions, and create competition that drives significant savings. The pipeline is robust, and our strategies will continue to evolve to support a vibrant biosimilars market.

The wave begins[4]

The autoimmune category will see a wave of biosimilars coming to market over the next two years, including several Humira (adalimumab) biosimilars launching in July 2023. These will be followed by additional entrants, including anticipated biosimilars to Stelara, in 2023 and 2024. Each new product launch will shift market dynamics and increase competition.

As indicated in the chart at right, some biosimilars are interchangeable with the reference biologic product. To receive this designation, the biosimilar must meet additional conditions during the U.S. Food and Drug Administration (FDA) approval process. Depending on state law, a pharmacist can automatically substitute an interchangeable biosimilar at the pharmacy without a prescriber or member request.

As of December 2022, the FDA has approved 40 biosimilars but only three as interchangeable — Semglee, a biosimilar insulin product; Cimerli, for treating retinal disease; and Cyltezo, one of the Humira biosimilars launching in 2023.

While important, interchangeability is not a primary factor in driving adoption. For example, over 93 percent of Lantus scripts were transitioned to Basaglar in 2017 without interchangeable status.[3]

Humira biosimilars
(FDA-approved products as of December 2022)

01/31/23	Amjevita
07/01/23	Cyltezo
	Hadlima
	Abrilada
	Idacio
	Yusimry
07/31/23	Hulio
09/30/23	Hyrimoz

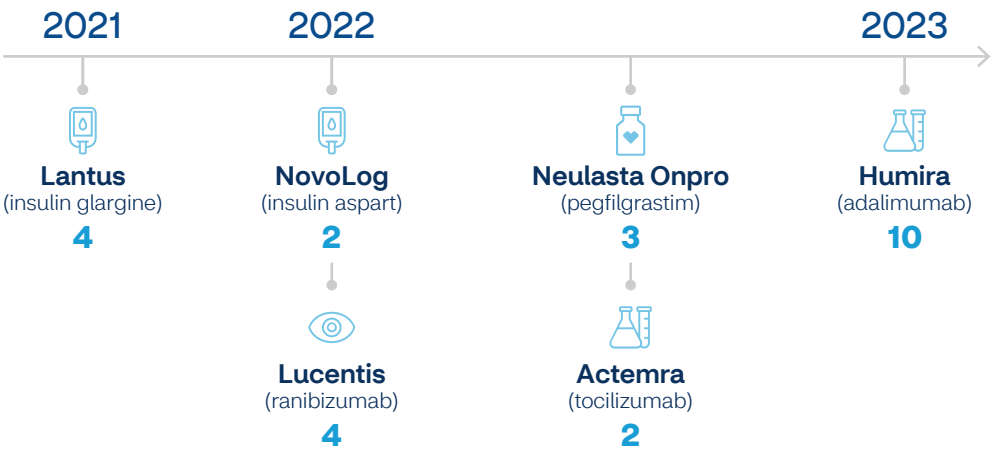
Stelara biosimilars
(Pending FDA approval)

09/01/23	Ustekinumab (Amgen)
11/06/23	Ustekinumab (Teva/Alvotech)

Interchangeability status:

- Approved
- In development
- N/A
- Pending approval

The biosimilars pipeline[5]



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Number of biosimilars in phase III trials, pending FDA approval, or FDA-approved

Condition:

- Diabetes
- Opthalmology
- Immunology
- Supportive Care

The biosimilars era is here

The biosimilars pipeline is robust, with approximately 100 products currently in preclinical and clinical development.[6] In addition to autoimmune diseases, these biosimilars will treat ophthalmic, immunologic, and musculoskeletal conditions. All told, the global biosimilars market is anticipated to reach $30 billion by 2025.[7]

As we await the launches of these various products, we continue to refine and update our formulary strategy based on past experience and complex considerations.

The future of biosimilars: Drugs in development[5]

#
Number of biosimilars in phase III trials, pending FDA approval, or FDA-approved

Condition:

Opthalmology

Immunology

Bone Health

$75B
Total spend on biosimilar products through 2030[8]

$30B
Global biosimilars market size by 2025[7]

100
Biosimilars in preclinical and clinical development[6]

40
FDA-approved biosimilars in the U.S. as of December 2022[9]

26
Biosimilar products have launched in the U.S., covering 9 reference biologics[10]

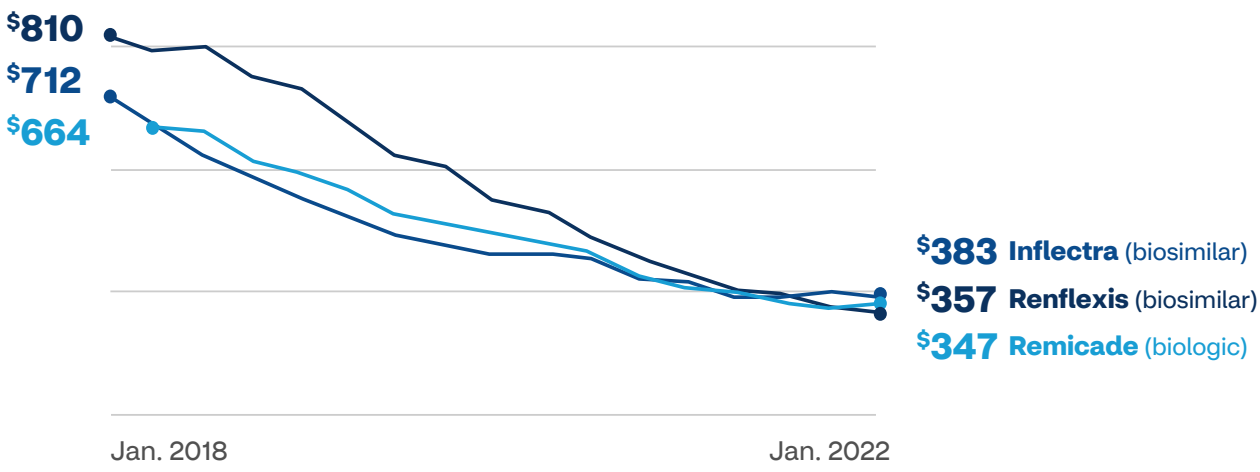
Competition drives down costs

Autoimmune conditions are the number one driver of spend for plan sponsors. Biologic treatment costs for one member can reach hundreds of thousands of dollars per year. While autoimmune conditions affect only 1 percent of commercially insured plan members, the category accounted for 42 percent of specialty spend in 2022.[11]

We have several preferred biosimilars on our commercial template formularies. Past experience has shown that the vibrant competition spurred by biosimilars entering the market drives down prices for both biosimilars and the biologic reference product over time.

You can see the effects of biosimilar price competition at work with Inflectra (infliximab-dyyb). At launch, its price was only about 10 percent lower than the reference product, blockbuster rheumatoid arthritis drug Remicade. In four years Inflectra dropped in price by half, while Remicade prices dropped 50 percent as well.[12] The potential for plan sponsor savings in the autoimmune category is significant due to the number of planned market entrants.

Infliximab average sales price (ASP) evolution from 2018–2022[12]



The introduction of infliximab biosimilars for Remicade have driven down the price for both the reference product and its biosimilars by >50%[12]

Formulary considerations

Thoughtful consideration of multiple factors facilitates the balance between brand biologics and biosimilars and is necessary to ensure members have coverage for more affordable, life-saving medications. New-to-market evaluation is the process we use to evaluate new products, including biosimilars, as they come to market for many of our commercial templates. These placement decisions are informed by exploring the complex interplay of clinical appropriateness and efficacy, product attributes, and price.

We review the critical features of each biosimilar that will impact adoption, including:

- ✔ Formulation
- ✔ Delivery mechanism
- ✔ Adequate supply
- ✔ Member experience

Clinical appropriateness and efficacy

How well does each biosimilar replicate the strengths, forms, and indications of the reference biologic?

Product attributes and availability

How do these attributes of the biosimilar compare with the reference product?

- Formulation
- Delivery mechanism
- Adequate supply
- Member experience

Price

How can we provide coverage of clinically effective drugs at the lowest possible cost? Our strategy is to drive to lowest net cost in the category, taking potential utilization into account as well as product price.

Taken together, all of these considerations are essential to making thoughtful, deliberate formulary decisions. Initially, we believe this will likely result from a combination of the reference product, biosimilar competitors, and other branded products.

Biosimilars help to drive a vibrant, competitive market. Over the next two years, we expect our clients to benefit from significant savings in the autoimmune categories where biosimilar competition exists.

Initially, we believe the lowest net cost strategy in this category will be a combination of the reference product, biosimilar competitors, and other branded products. Our biosimilar approach is aligned to our lowest net cost strategy, providing our clients with maximum savings while minimizing member disruption.

Glossary[13]

Biologic medicines

Biologics (brand biologics or reference products) are large, complex molecules that are derived from living cells or organisms. They're highly sensitive to their manufacturing and handling conditions.

Biosimilar drugs

Biosimilar drugs are highly similar to the FDA-approved reference product with no clinically meaningful differences in safety and effectiveness.

Biosimilars vs. generics

Biosimilars are not considered true generics. Unlike traditional drugs, biosimilars are made from living organisms and don't contain identical ingredients to their reference counterparts.

Follow-on biologic

Follow-on biologics are copies of an original biologic; they're neither a generic nor a biosimilar and cannot be substituted for the original. The structure of a follow-on product is not an exact copy, leading to possible differences in safety and efficacy.

Interchangeability

An interchangeable biosimilar is one that produces the same clinical outcome as the reference product in any given patient. Interchangeable biosimilars have met stringent FDA criteria and may be substituted for the biologic by the pharmacist without the intervention of the prescriber (depending on state law).

The biosimilars pipeline is dynamic and status changes frequently. The information in this document is current as of January 30, 2023.

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3. 2018 CVS Health Drug Trend Report. CVS Health Enterprise Analytics, 2019.
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