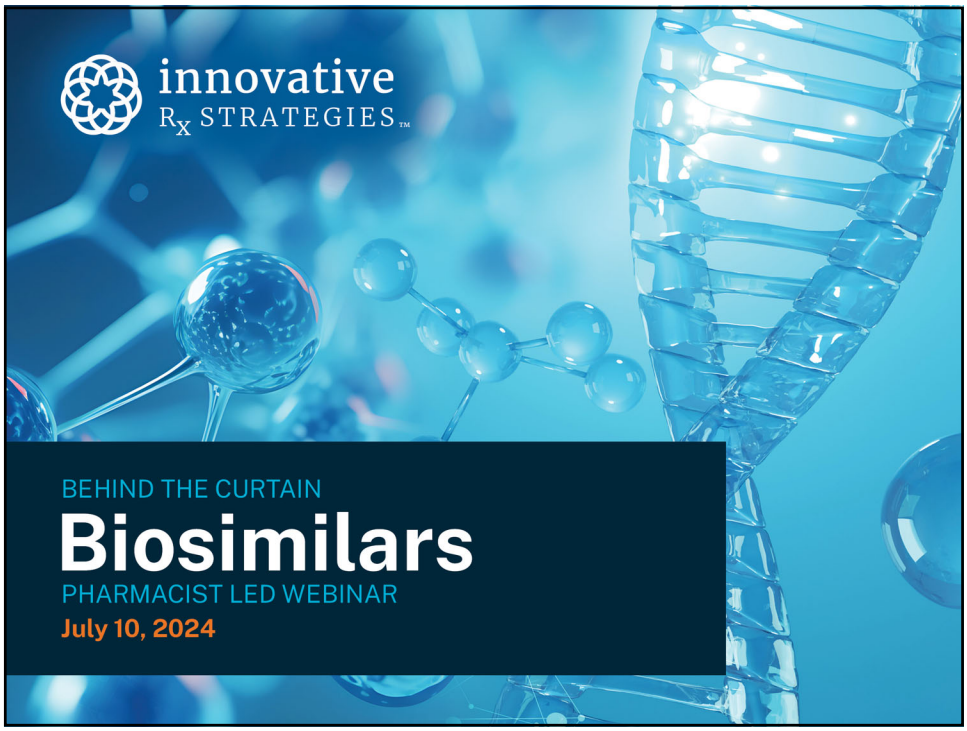
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BEHIND THE CURTAIN
Biosimilars
PHARMACIST LED WEBINAR
July 10, 2024

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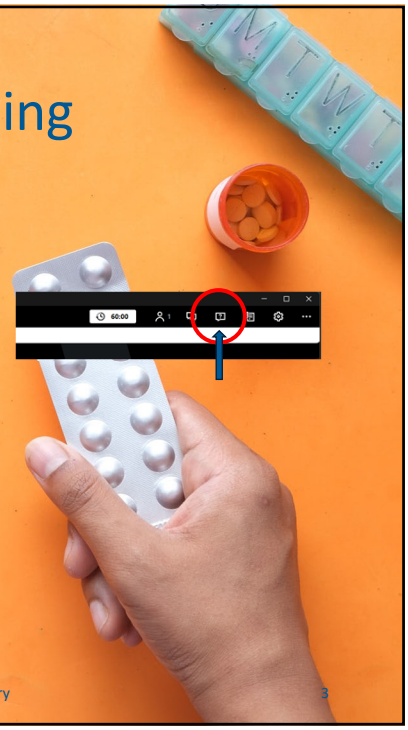

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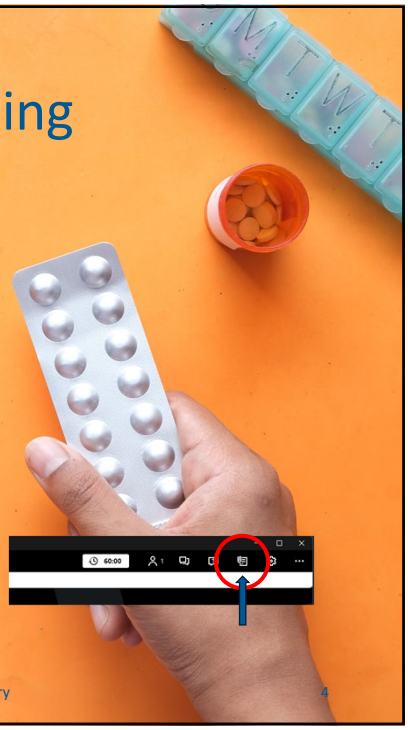

4

Team Introductions

Amy Ball
PharmD
President

Mark Matusik
PharmD
Vice President of Clinical Account Management

Megan Dorrell
PharmD, BCACP
Vice President of Clinical Strategy

5

Today's Agenda

- Background on biosimilars and how they create the POTENTIAL for savings
- Examine some of the challenges with realizing those savings
- Review the state of biosimilars in 2024 including future pipeline developments
- Provide our recommendations for optimizing your approach to biosimilars

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Biosimilar Background

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What is a Biologic

The term “biological product” means a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein (except any chemically synthesized polypeptide), or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment or cure of a disease or condition of human beings.

Source: Federal Register :: Definition of the Term "Biological Product"

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How are Biological Products Different?

Small Molecule Drugs	Biological Products
Generally low molecule weight	Generally high molecule weight
Usually organic or chemical synthesis	Made with/from live cells/organisms *inherent & contamination risk*
Fewer critical process steps	Many critical process steps
Well-characterized	Less easily characterized
Known structure	Structure may or may not be completely defined or known
Homogeneous drug substance	Heterogenous mixtures *may include variants*
Usually non-immunogenic	Often immunogenic

Source: U.S. Food and Drug Administration

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Biologics

- Biologics account for 46% of all pharmaceutical spending but only 2% of prescriptions
- Biologics are not new
  - ✓ Insulin
  - ✓ Human growth hormone
  - ✓ Red-blood cell stimulating agents
- Biologic medications cannot be considered "Generic Equivalents"
- Biologics must follow the biologic pathway to FDA Approval

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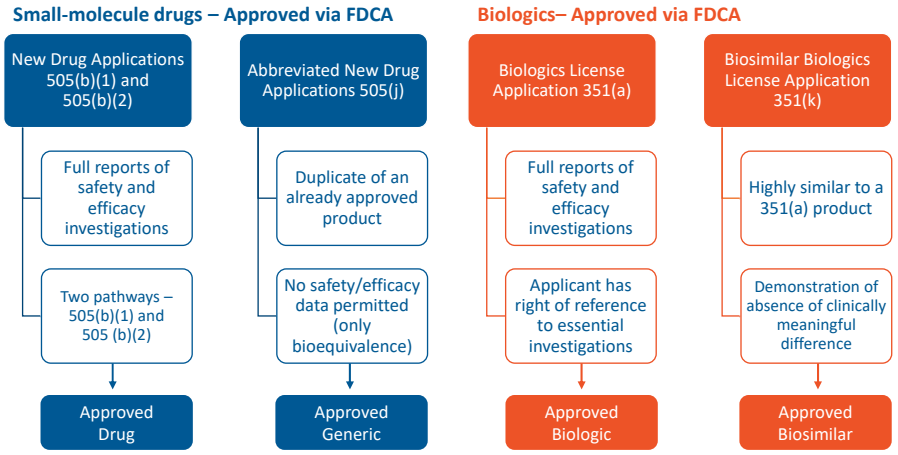
The FDA Approval Process



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What is a Biosimilar

A Biological Product that (a) is **highly similar** to a US-licensed reference Biological Product, notwithstanding minor differences in clinically inactive components, where there are **no clinically meaningful differences between the Biological Product and the reference product in terms of the safety, purity, and potency of the product**; and/or (b) is approved pursuant to 42 U.S.C. § 262(k).

Source: www.fda.gov

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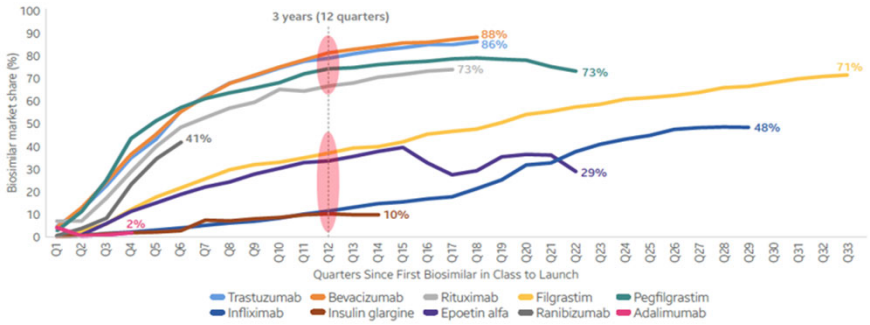
Biosimilar Volume Uptake Varies by Molecule

- **On average, biosimilars have gained 53% market share within three years (12 quarters) post initial launc molecule has demonstrated unique biosimilar uptake and can be categorized into fast or slow uptake speed.**

1) **Fast Uptake Speed**: Oncology*, ophthalmology, and pegfilgrastim biosimilars.
   Three years post launch, average biosimilar market share reached 75%.†
2) **Slow Uptake Speed:** Immunology‡, filgrastim, epoetin alfa, and insulin glargine biosimilars.
   On average, only a 23% biosimilar market share was achieved by Year 3.†

Figure 7. Biosimilar Market Share Post-Launch[5]



*Trastuzumab, bevacizumab, and rituximab
†Averages include products that are 3 years or older ‡Infliximab and adalimumab

Source: Samsung Bioepis. Biosimilar Market Report Q2 2024

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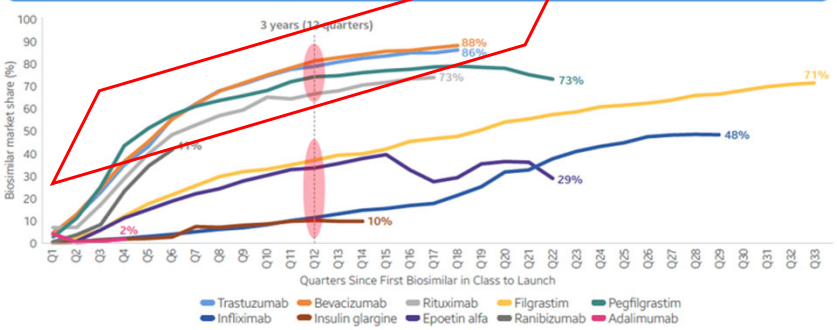

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Source: Samsung Bioepis. Biosimilar Market Report Q2 2024

14

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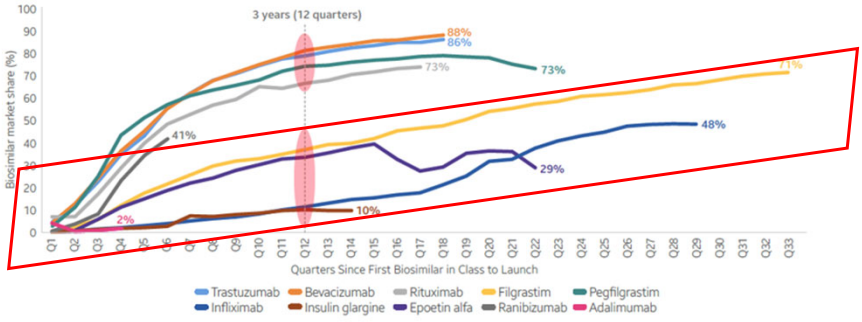

* Trastuzumab, bevacizumab, and rituximab
† Averages include products that are 3 years or older ‡ Infliximab and adalimumab

Source: Samsung Bioepis. Biosimilar Market Report Q2 2024

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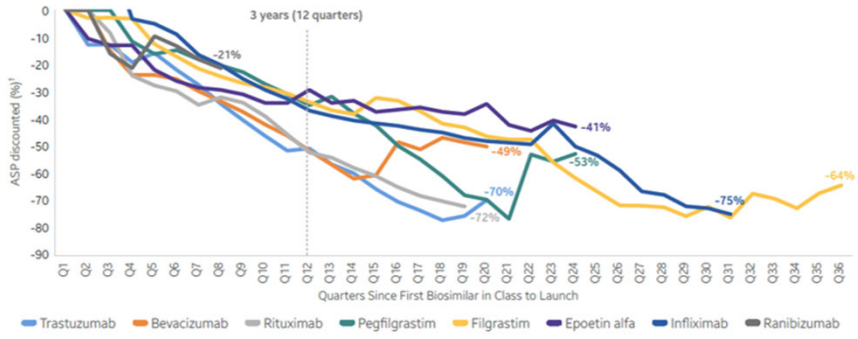
Biosimilar are Reducing Drug Costs Across Multiple TAs by Lowering Prices

- Biosimilar launches have led to significant price decreases over time. On average, ASP declined by 41% three years (12 quarters) post first biosimilar launch with more mature markets demonstrating increasing price concessions.
- Recent observed increases in ASP for some markets (e.g. bevacizumab, pegfilgrastim) are an artifact of newly-launched, low-market share biosimilars with ASPs that reflect WAC pricing.

Figure 8. ASP Trend by Molecule[3]



TA: Therapeutic area; ASP: Average sales price
* Trastuzumab, bevacizumab, and rituximab are included † ASP discounted % vs. reference product ASP when first biosimilar in class launch

Source: Samsung Bioepis. Biosimilar Market Report Q2 2024

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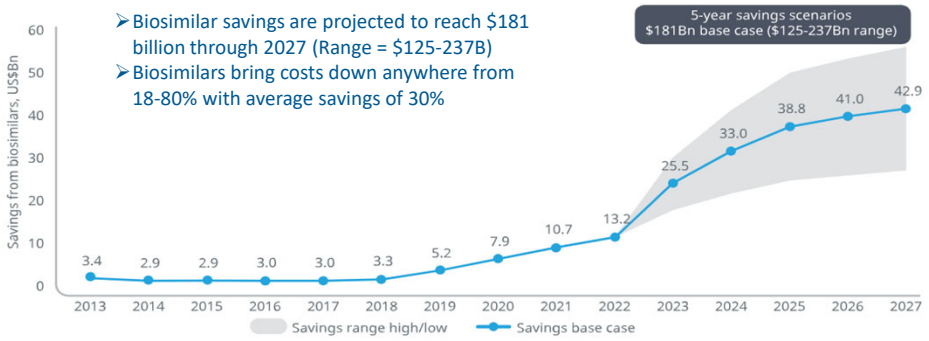
Savings potential with biosimilars

- Biosimilar savings are projected to reach $181 billion through 2027 (Range = $125-237B)
- Biosimilars bring costs down anywhere from 18-80% with average savings of 30%



Source: IQVIA MIDAS, Jun 2022; IQVIA Institute, Nov 2022.
Notes: Historical savings were calculated by comparing actual molecule spending to projected spending if total molecule volume had been at originator pre-expiry prices. Projected future savings based on estimated continuing impact of biosimilar events in progress, as well as future expected expiries. The range of savings values shown in the biosimilar savings scenarios include assumptions for high, low, and average (base case) biosimilar volume uptake and price discounts relative to originators. Timing of expected biosimilar entry based on patent information and litigation/settlements as of Oct 2022.
Report: Biosimilars in the United States 2023–2027: Competition, Savings, and Sustainability. IQVIA Institute for Human Data Science, January 2023.

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Biosimilar Challenges

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RESEARCH ARTICLE

Safety outcomes when switching between biosimilars and reference biologics: A systematic review and meta-analysis

Thomas M. Herndon[1]*, Cristina Ausin[1], Nina N. Brahme[1], Sarah J. Schrieber[1], Michelle Luo[1], Frances C. Andrada[1], Carol Kim[1], Wanjie Sun[2], Lingjie Zhou[2], Stella Grosser[2], Sarah Yim[1], M. Stacey Ricci[1]

1 Office of Therapeutic Biologics and Biosimilars, Office of New Drugs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Silver Spring, Maryland, United States of America, **2** Division of Biometrics VIII, Office of Biostatistics, Office of New Drugs, Center for Drug Evaluation and Research, U.S. Food and Drug Administration, Silver Spring, Maryland, United States of America

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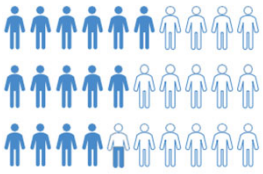
An online survey among US patients with immune-mediated conditions: Attitudes about biosimilars

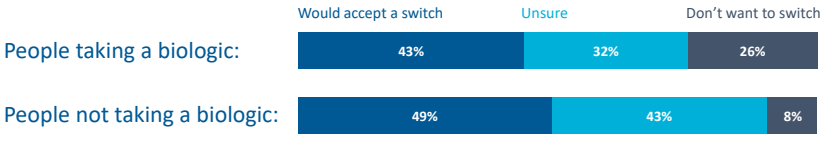
What concerns about biosimilars did people have?



6 in 10 people (59%) worried about side effects

5 in 10 people (50%) worried about long-term safety

Around 4 in 10 people (46%) worried about not knowing a lot about biosimilar medicines



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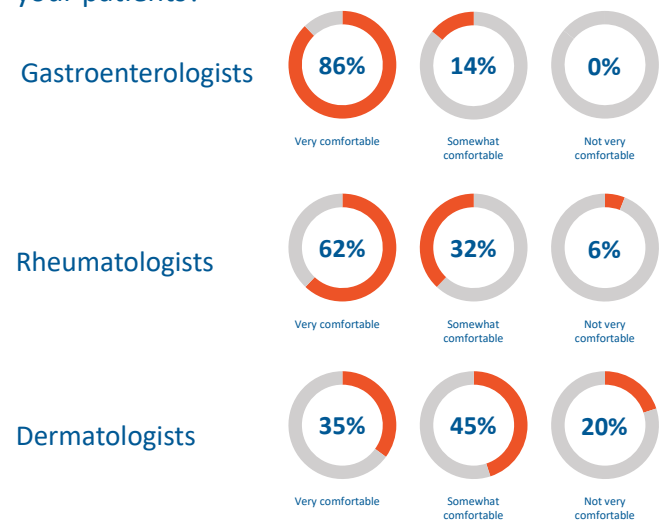
How comfortable do you feel prescribing biosimilars to your patients?



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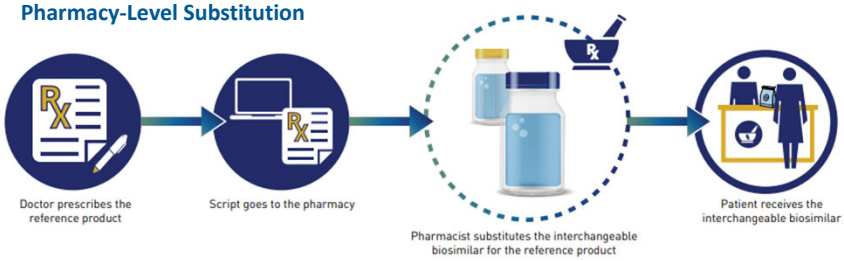
Interchangeable Biosimilars

An interchangeable biosimilar may be substituted at the pharmacy for the reference product without the intervention of the prescribing health care provider – much like how generic drugs are routinely substituted for brand-name drugs.

Pharmacy-Level Substitution



Source: U.S. FDA Administration. Interchangeable Biological Products

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Interchangeability Quick Facts

- First interchangeable biosimilar to market in 2021
- Not all biosimilars carry this indication
- Historically has involved switch studies showing efficacy
- First biosimilars with interchangeability are often granted market exclusivity
- Biosimilars are not interchangeable to each other
- Even after designation, operationalizing is state law dependent

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Interchangeable Biosimilars

Reference Product	Product	Launch Date	Benefit Type
Lantus	Semglee (insulin glargine-yfgn)	November 2021	Pharmacy
	Rezvoglar (insulin glargine-aglr)	March 2023	Pharmacy
Humira	Cyltezo (adalimumab-adbm)	July 2023	Pharmacy
	Abrilada (adalimumab-afzb)	October 2023	Pharmacy
	Simlandi (adalimumab-ryvk)	May 2024	Pharmacy
	Hyrimoz (adalimumab-adaz) Hyrimoz (HC) (adalimumab-adaz)	April 2024	Pharmacy
Lucentis	Cimerli (ranibizumab-eqrn)	October 2022	Medical
	Byooviz (ranibizumab-nuna)	October 2023	Medical
Eylea	Yesafili (aflibercept-jbvf)	Not launched	Medical
	Opuviz (aflibercept-jbvf)	Not launched	Medical
Stelara	Wezlana (ustekinumab-uub)	Not launched	Pharmacy
Prolia	Jubbonti/Wyost (denosumab-bbdz)	Not launched	Medical/Pharmacy
Soliris	Bkemv (eculizumab-eeb)	Not launched	Medical

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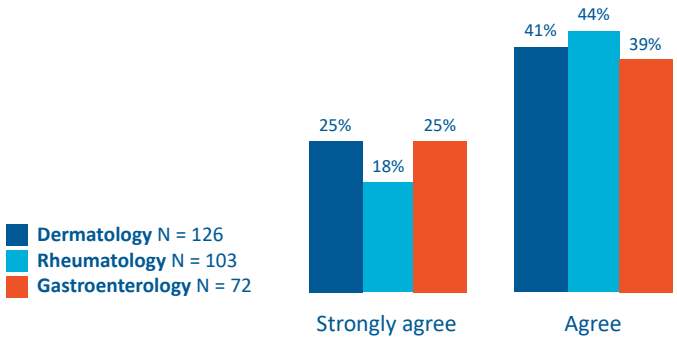
To what extent do you agree with the following statement?
I will only feel comfortable prescribing an adalimumab biosimilar if it has the interchangeability designation.



Source: Cardinal Health. 2023 Biosimilar Report

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Breaking News

- On June 20, 2024, the FDA released draft guidance updating interchangeability expectations
  - Switch studies will no longer be required
  - The FDA will consider comparative analytical and clinical data instead
  - Once final, will apply to biosimilars already under review
- Additional legislative efforts remain to make all biosimilars interchangeable
  - House: Biologic Competition Act
  - Senate: Biosimilar Red Tape Elimination Act

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Additional Challenges

- Supply Issues
- Patient Assistance Options
- Rebates
- Pricing Models
- PBM Formularies

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2024 Biosimilar Updates

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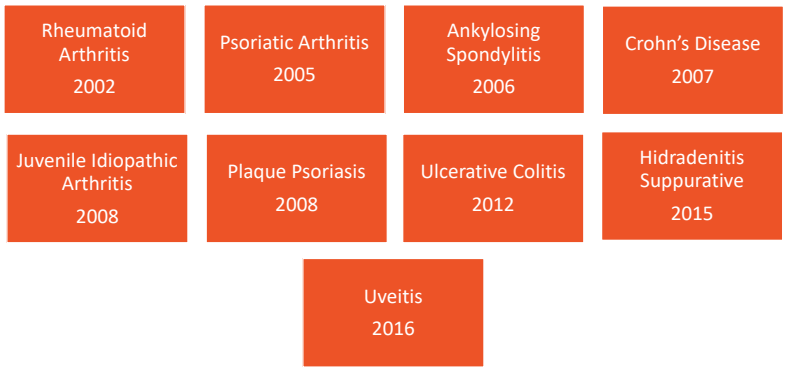
Humira (adalimumab)

- Subcutaneous Tumor Necrosis Factor (TNF) Blocker launched in 2002
- Top selling drug worldwide with $20 Billion in sales in 2022



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Humira (adalimumab)

Year	Annual WAC Price	Estimated Rebate	Yearly Net Cost
2002	$13,572	~15%	$11,536
2022	$83,328	30-35%	$54,330- $54,163
2023	$89,994	60-65%	$31,498- $35,998
2024	$89,994	60-65%	$31,498- $35,998

Source: IPD Analytics. Drug Management and Rebate Monitor

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Humira Biosimilar Launch 2023

January 2023

- Amjevita launched as original concentration with High WAC and Mid WAC option

Biosimilar blocking strategies

- Growth of indications
- 250 patent applications, 90% of which were after approval, delaying original patent expiration by almost 6 years
- Aggressive rebate strategy to keep Humira preferred
  - Rebate strategy tied to other manufacturer products; Skyrizi and Rinvoq
- Conversion of Humira to Skyrizi or Rinvoq for appropriate indications
- Additional formulations
  - High concentration – 0.4ml versus 0.8ml
  - Citrate free formulation

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Humira Biosimilar Launch 2023

January 2023

- Amjevita launched as original concentration with High WAC and Mid WAC option

July 2023

- Seven new products, 10 new options overall
- First high concentration products
- First true Low WAC products
- First original concentration interchangeable products

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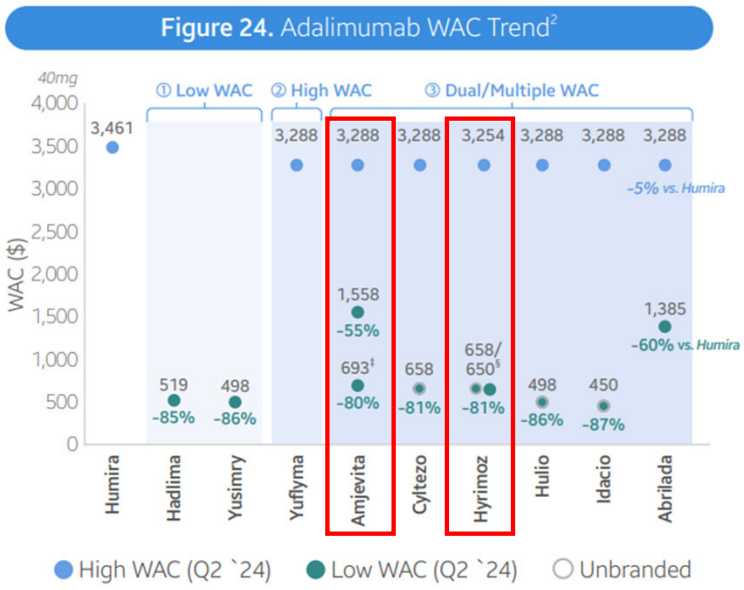

Source: Samsung Bioepis. Biosimilar Market Report Q2 2024

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Humira Biosimilar Launch 2023

January 2023	• Amjevita launched as original concentration with High WAC and Mid WAC option
July 2023	• Seven new products, 10 new options overall • First high concentration products • First true Low WAC products • First original concentration interchangeable products
July 2023	• Mark Cuban Cost Plus Pharmacy announces access to Yusimry

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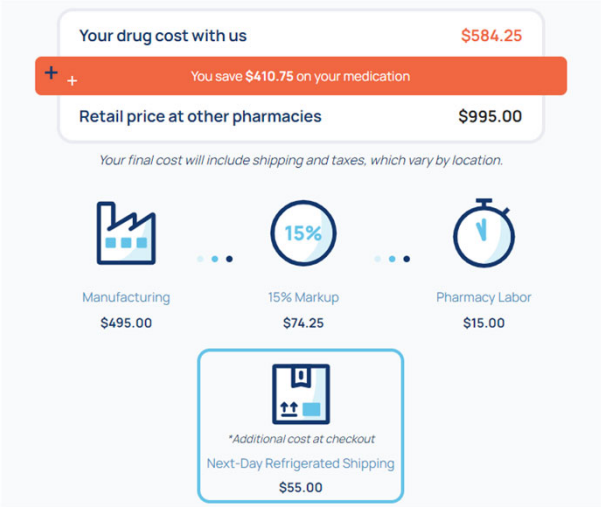
Mark Cuban Cost Plus Pharmacy



Source: https://costplusdrugs.com/

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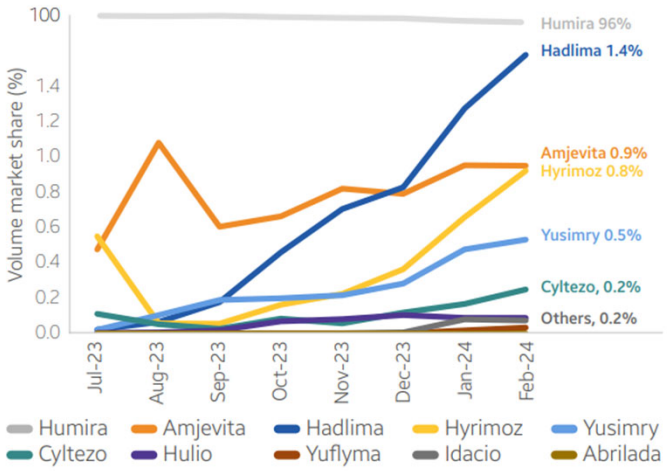
Figure 23. Adalimumab Volume Market Share[6]



WAC: Wholesale acquisition cost
‡Amjevita only launched in low WAC for high concentration §Cordavis price of Hyrimoz

Source: Samsung Bioepis. Biosimilar Market Report Q2 2024

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Humira Biosimilars 2024

April 2024	• CVS/Caremark remove Humira from formulary

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PBM Vertical Integration

- In 2023, **CVS Health** launched Cordavis, a wholly owned subsidiary
- Cordavis selects manufacturers to co-develop and commercialize biosimilars for the U.S. market
- CVS Caremark removed Humira from formulary on in April 2024
- In 2021, **Express Scripts** launched Quallent, a wholly owned subsidiary
- Quallent is a private-label pharmaceutical distributor who sources manufacturers to help pharmacies supply medications
- Accredo launched an interchange program with member pay $0 biosimilars in June 2024

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Humira Biosimilars 2024

April 2024	• CVS/Caremark remove Humira from formulary
May 2024	• First high concentration interchangeable product approved

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Humira Biosimilars 2024

April 2024	• CVS/Caremark remove Humira from formulary
May 2024	• First high concentration interchangeable product approved
June 2024	• ESI Accredo launch their interchange program

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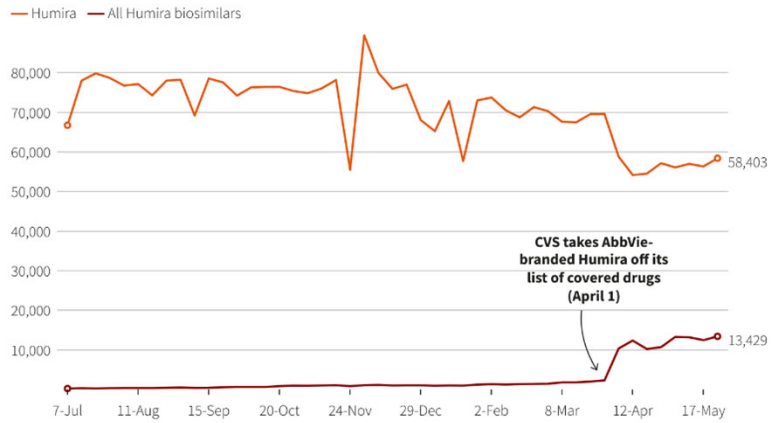
Formulary Change Impact



Source: https://www.reuters.com/business/healthcare-pharmaceuticals/abbvies-tight-grip-humira-market-raises-concerns-about-biosimilars-2024-06-07/

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Adalimumab Pricing Examples

Product	Location	Annual Net Price
Humira	PBMs	$31,498- $35,998
Unbranded Cyltezo	PBMs	$17,099
Hyrimoz	Cordavis/CVS Health	$16,900
Simlandi	PBMs	$13,949
Unbranded Simlandi	Quallent/ESI	$13,494
Unbranded Cyltezo	Quallent/ESI	$13,494
Yusimry	PBMs	$12,935
Yusimry	Mark Cuban Cost Plus	$7,400

Source: IPD Analytics. Drug Management

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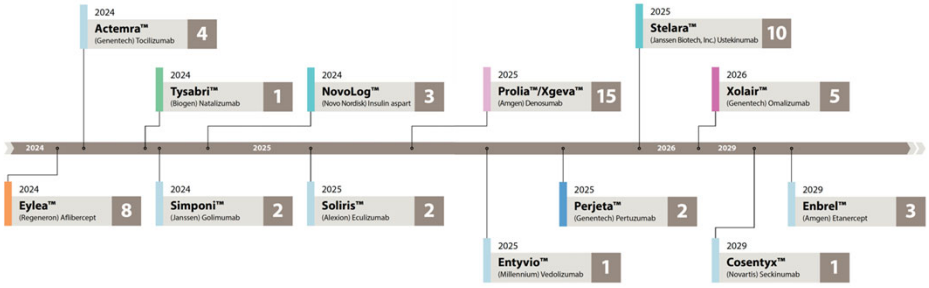
Biosimilar Pipeline



Source: Cardinal Health 2024 Biosimilars Report

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Recommendations

- Prefer lowest cost at point-of-sale options
- Find PBM partners with an aggressive biosimilar strategy
  - Consider customization of formulary to drive biosimilar adoption if PBM is not aligned
- Educate members about biosimilar and generics
- Educate providers

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Questions for Your PBM

- What is your biosimilar strategy?
  - Is Humira still on your formulary?
  - Are biosimilars preferred over Humira?
  - How do you drive biosimilar use and adoption by providers?
  - How are you preparing for Stelara biosimilars?
- Are there choices that plan sponsors need to make?
  - High WAC/Low WAC
  - Humira vs. Biosimilar
- Can you supply the math involved in a lowest net cost approach?
  - What is the acquisition cost?
  - What is the rebate amount?
  - What is the manufacturer assistance amount?
- How are you educating our members on biosimilars?
- How are you education providers on biosimilars?
- What are you doing to drive biosimilar utilization?

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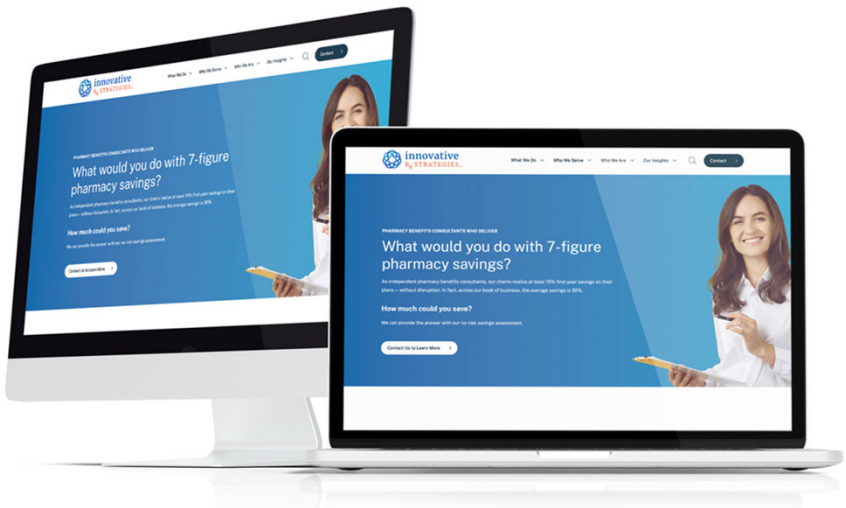
Visit our website for additional information



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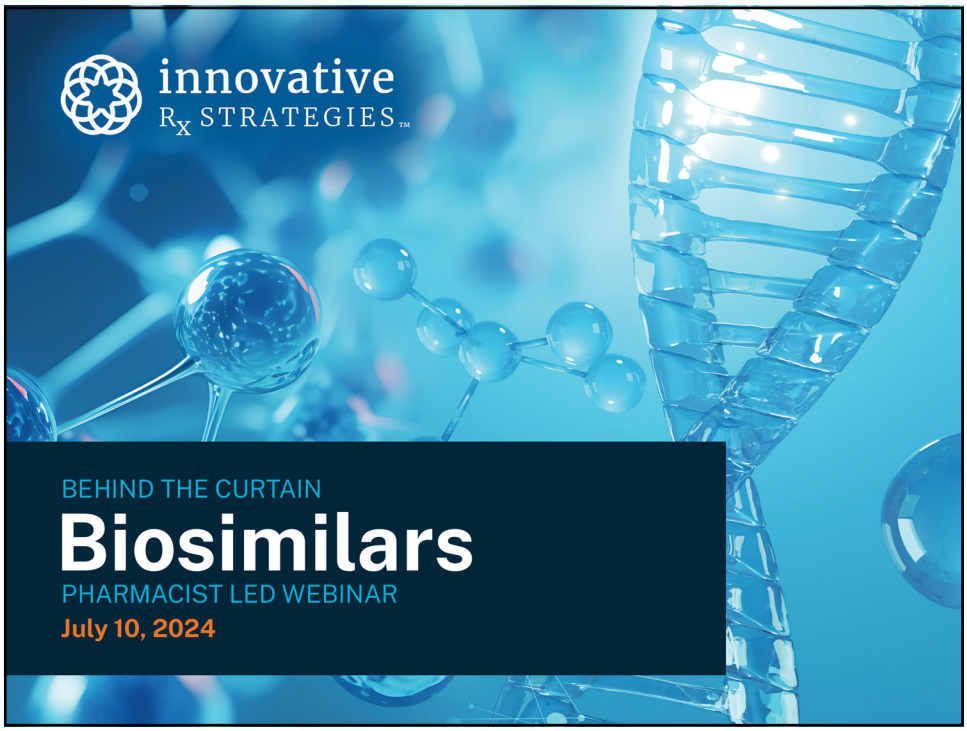
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