OCT 27-29, 2025

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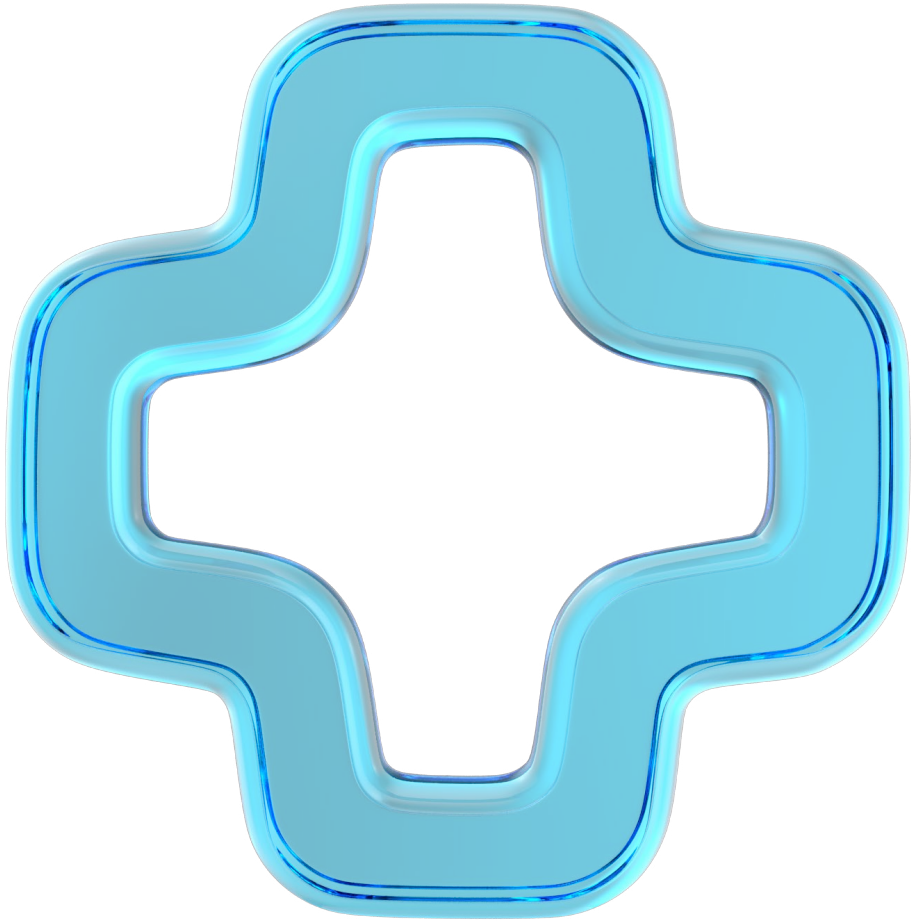
Biosimilars at a Crossroads: Utilization Management and the Path to Sustainable Access

October 27, 2025

Panelists



Danielle Bryan, PharmD, CSP
Program Director, Trade Relations, Vanderbilt Specialty Pharmacy Services

Victoria Facchini, PharmD
Director, Medical Pharmacy Strategy, Prime Therapeutics

Sean McGowan
Senior Vice President, Biosimilars & Branded Oncology, Amneal Pharmaceuticals

Moderator: Michael Sargent
Senior Director, Policy, AAM

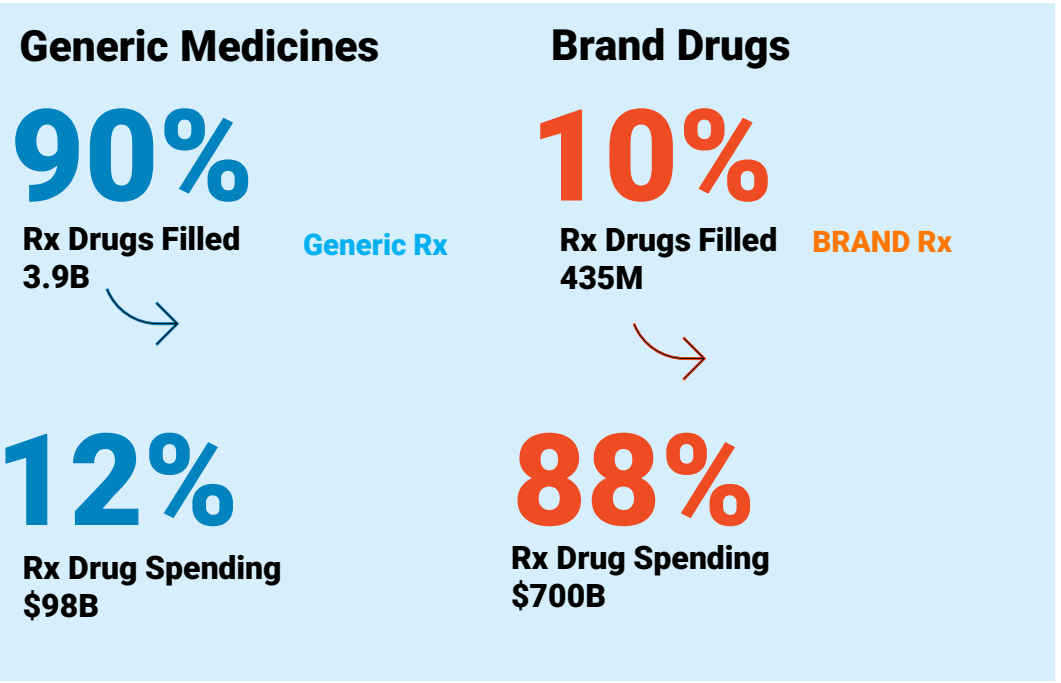
Biosimilar Savings & Market Overview

Key Takeaways

Brand Drugs Drive Costs. Generics Drive Savings.

Total Savings from Generics and Biosimilars

- Total generic and biosimilar savings in 2024: **$467 billion**
- Total generic and biosimilar savings for the past ten years: **$3.4 trillion**
- Generic share of total U.S. prescriptions filled: **90 percent**
- Generic share of total U.S. prescription drug spending: **12 percent**
- Generic share of total U.S. healthcare spending: **1.2 percent**
- Total generic savings in Medicare in 2024: **$142 billion ($2,643 per beneficiary)**
- Total generic savings in Medicaid in 2024: **$62.1 billion ($782 per enrollee)**



Biosimilar Savings

- Savings in 2024: **$20.2 billion**
- Total savings since first biosimilar entry in 2015: **$56.2 billion**
- Total days of patient therapy since 2015: **3.3 billion**
- Incremental days of patient therapy that would not have occurred without biosimilar competition: **460 million**

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Source: IQVIA National Prescription Audit, December 2024.

Biosimilars Market Overview

84
APPROVED

67
MARKETED

21
REFERENCE PRODUCTS

90% of the 118 biologics losing exclusivity in the next decade—valued at $234 billion overall—currently have no biosimilars in development.

Biosimilar savings since 2015
$56.2 BILLION

Biosimilars have been used in almost **3.3 BILLION DAYS** of patient therapy and have resulted in more than **460 MILLION INCREMENTAL DAYS** of therapy

As of July 11, 2025
Source: US FDA and AAM Commercial Assessment. Includes 9 unbranded products.
Savings and patient day data developed by the Biosimilars Council with IQVIA.

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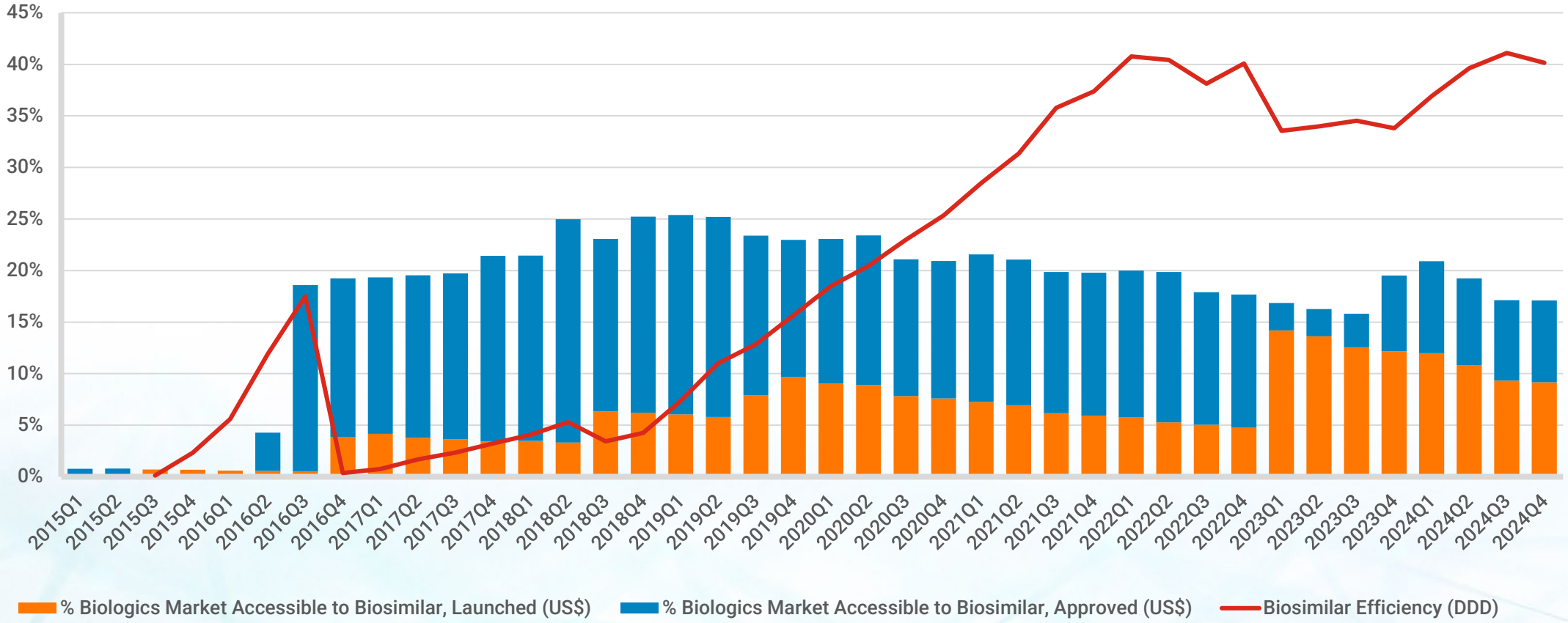
Although Improving, Biosimilar Market Share Remains Low

Biosimilar Market Share Is on Average 40%, Up From 20% Last Year



Source: IQVIA National Sales Perspective, December 2024; IQVIA Institute, June 2025.

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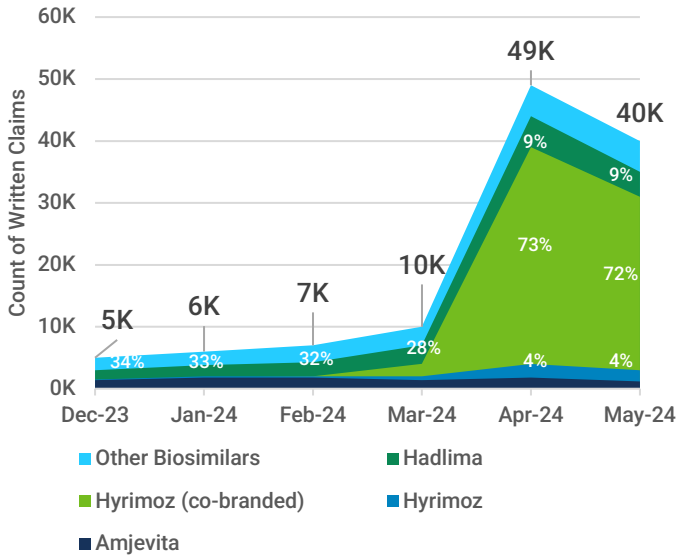
While the Launch of Co-branded Treatments Grew Biosimilar Use in 2024–Q2, PBMs Continue to Play a Large Role in Patient Access to Biosimilars

Most Biosimilar Growth Can Be Attributed to Co-Branded Hyrimoz, and Volume Still Trails AbbVie's Imm. Portfolio

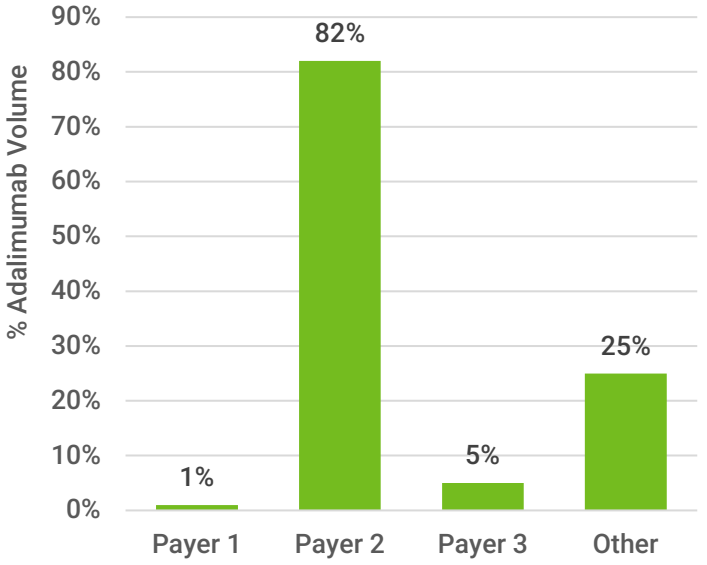
Co-Branded Hyrimoz is Driving Increased Biosimilar Utilization

Adalimumab Biosims **Written Scripts by Brand** *(LAAD Rx; Filled Claims; All Channels; Feb 2023 – May 2024)*



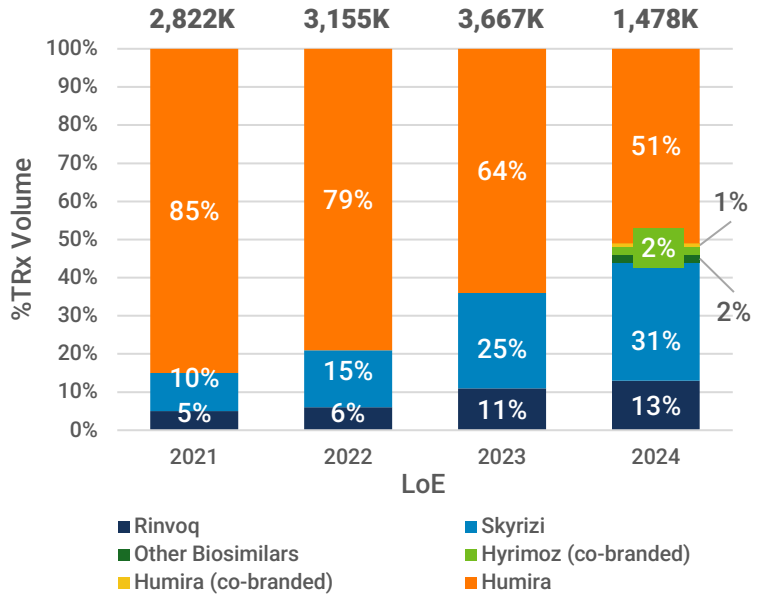
Large PBMs Continue To Favor Humira or Co-branded Options

% of Ada. **TRx from Biosimilars by Payer – May 2024** *(LAAD Rx; Filled Claims; All Channels; May 2024)*



Product Hopping Outpaces Biosimilars

Adalimumab, Skyrizi, and Rinvoq **TRx by Brand** *(LAAD Rx+Mx; Filled Claims; All Channels; Jan 2021 – May 2024)*



Source: IQVIA LAAD 3.0, US Market Access Strategy Consulting analysis.

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Health System Specialty Pharmacy Perspective

Danielle Bryan, PharmD, CSP

Considerations for Stakeholders

Important during Development and Rollouts

Clinical Considerations

- Payer coverage
- Patient Support Services
  - Copay card
  - Patient Assistance Programs
  - Product replacement
- Contacts
  - Local sales rep
  - Field reimbursement manager (FRM) or similar
- Product Characteristics
  - Strength availability
  - Indications
  - Interchangeability
  - Shelf life/storage requirements
- Sample offerings

Considerations for Implementation

Operational Considerations
• Government and Commercial payor coverage/strategy • Pricing • Availability/stock • Storage

Wins/Opportunities

Wins	Opportunities

• Formulary changes
  • Automatic PA transitions
  • PA transitions prior to mandated switches
  • Inclusion of multiple preferred options (minimize inventory concerns)
• Patient Support Programs
  • Include copay card and PAP published limits
  • Match or exceed Reference product
  • Considerations for maximizer/accumulator insurance plans
	• Patient Support Programs
	  • Copay card transaction caps
	• Lack of multiple strengths to match Reference product
	• Unavailability soon after switching
	• Avoidance of multiple switching
	• Patient apprehension
	  • Clinical outcomes
	• Private Labels

Biosimilars Utilization Management

Victoria Facchini, PharmD

Prime THERAPEUTICS™

Biosimilars Utilization Management

Biosimilar Landscape and Uptake in the Managed Care Space

Prime's History and Experience with Biosimilars

2016

Biosimilar program established:
- First client launches a **biosimilar-over-reference** policy on the medical benefit

2017

Growth in biosimilar **savings** as more clients opt into biosimilar-first programs

2018

Expands biosimilar program to include infliximab (Remicade), a top spend drug
- Establishes **Oncology Biosimilar Workgroup** in preparation for future launches

2019

Biosimilar program is further expanded by adding multiple new categories and **targeted Oncology Biosimilar Program** is launched
- Oncology biosimilars hit market, and early adopter clients **implement** biosimilar-over-reference strategies in oncology

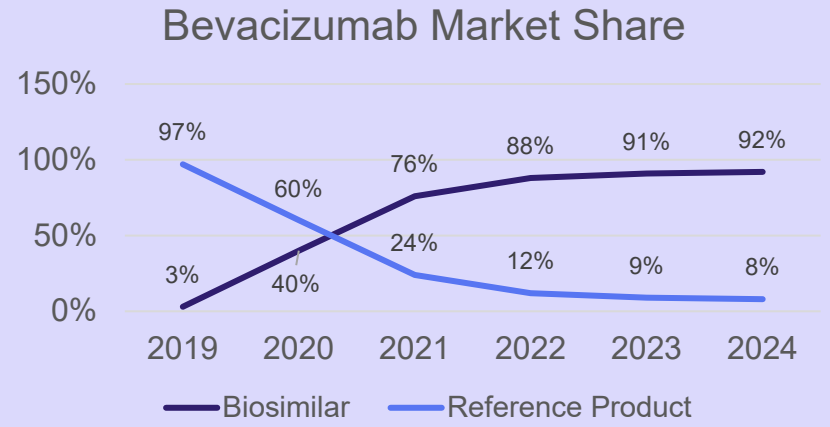
2020

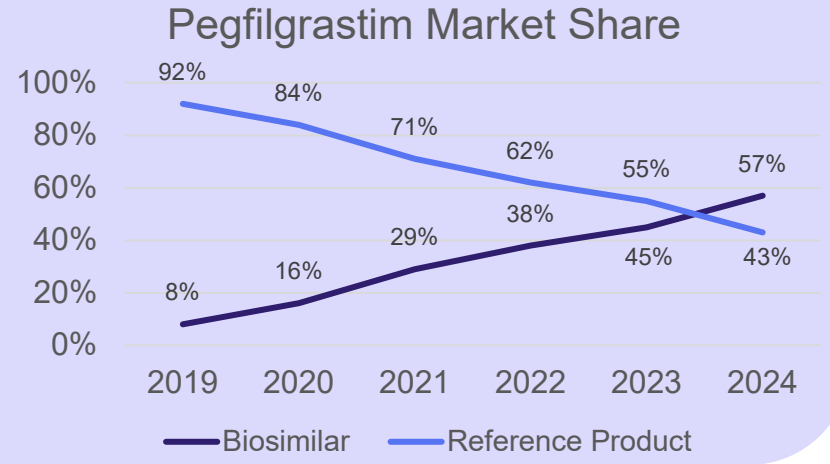
Rapid expansion of program as more clients adopt Oncology Biosimilar Program
- Oncology biosimilar utilization surges, program **achieves 90% success rate*** in early program adopters

2021 – 2025

So far…

Biosimilar uptake continues to increase, and oncology biosimilar **savings** are realized

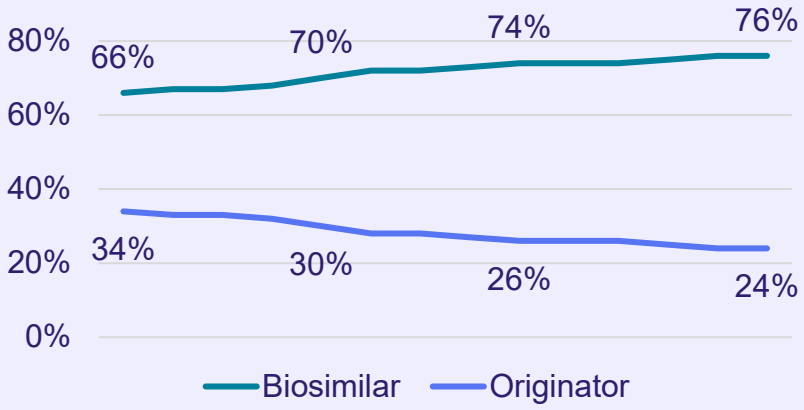




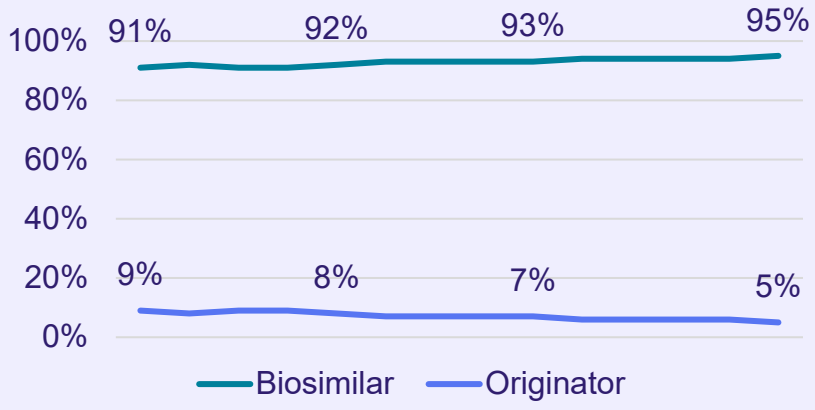
Biosimilar landscape and uptake in the managed care space

Biosimilar Uptake by LOB From 1Q2022 to 2Q2025

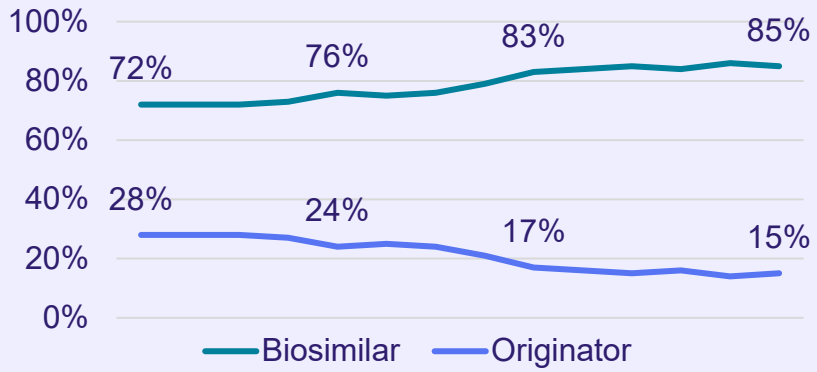
Commercial Market Share



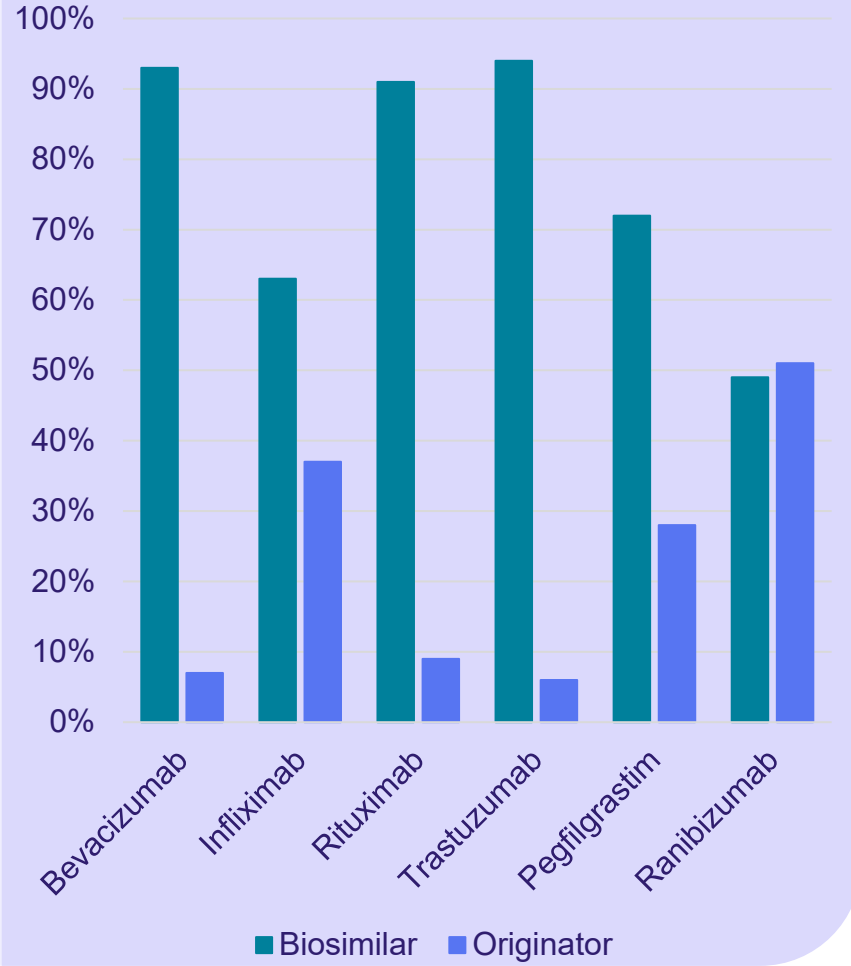
Medicare Market Share



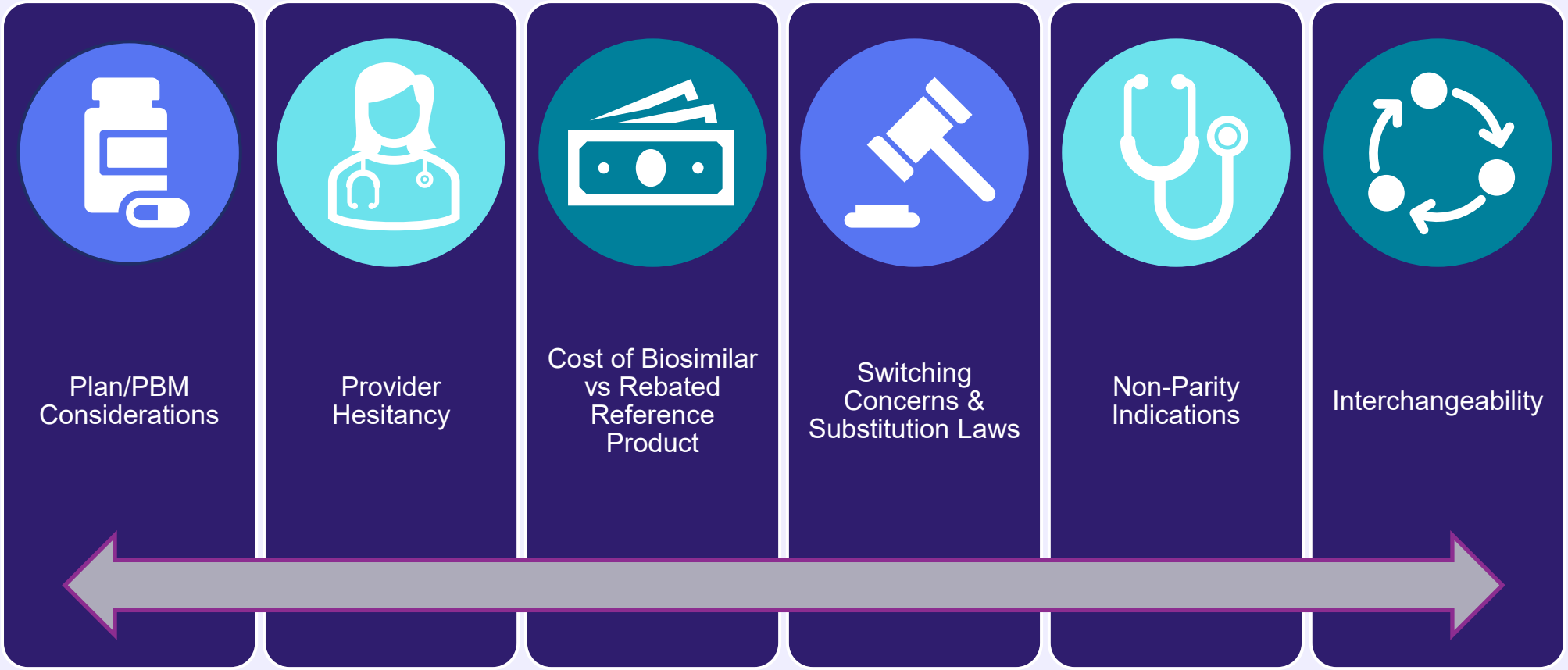
Medicaid Market Share



1H2025 Uptake by Product (all LOB)



Barriers to Biosimilar Adoption

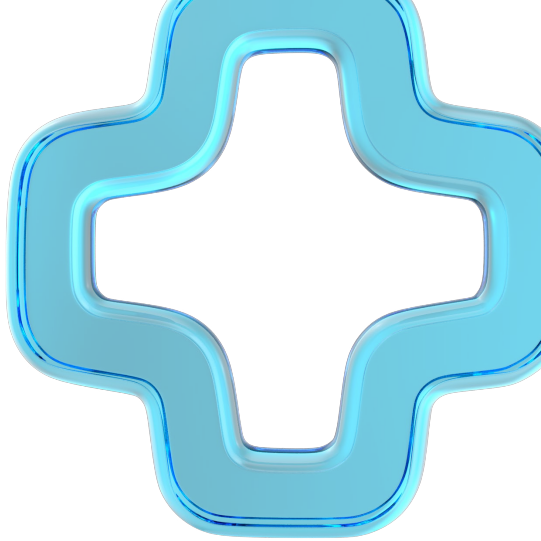


Discussion & Outlook

Outlook

- **Sustainability – Market Access and Clinical Considerations**
- **PBM and Payer Dynamics**
- **Provider Education and Clinical Confidence**
- **Interchangeability Reform and Regulatory Evolution**

Interchangeability - FDA's Current Position

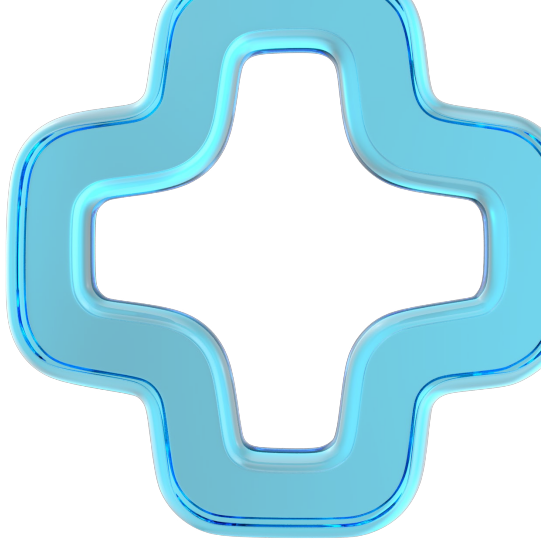


"Since publication of the interchangeability guidance [in 2019], experience has shown that for the products approved as biosimilars to date, the risk in terms of safety or diminished efficacy is insignificant following single or multiple switches between a reference product and a biosimilar product."

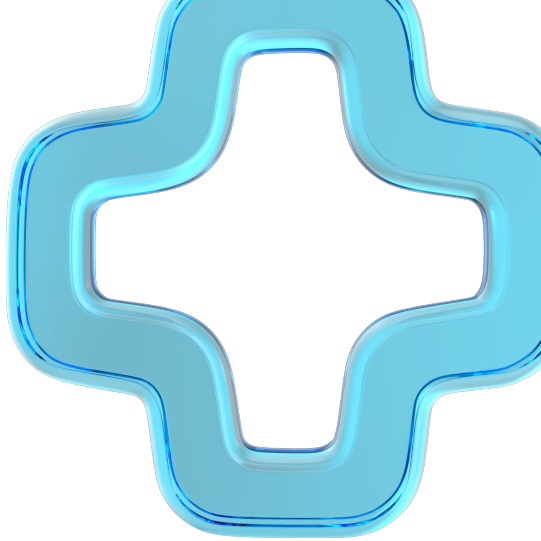
"Accordingly, FDA's scientific approach to when a switching study, or studies, may be needed to support a demonstration of interchangeability has evolved. FDA researchers found no differences in the risk of death, serious adverse events, and treatment discontinuations between participants who switched between biosimilars and reference products and participants who did not switch in a recently conducted systematic review and meta-analysis. Additionally, today's analytical tools can accurately evaluate the structure and effects biologic products, both in the lab (in vitro) and in living organisms (in vivo) with more precision and sensitivity than switching studies."

FDA, Guidance for Industry, Considerations in Demonstrating Interchangeability With a Reference Product: Update (June 2024)

S.1954/H.R. 5526, The Biosimilar Red Tape Elimination Act - Generally



- Would amend the PHS Act to state that all biosimilars, upon licensure, shall be deemed interchangeable with their respective reference product.
    - The bill still uses the term “interchangeable” because states have crafted their own laws around interchangeability. Retaining that word would provide for minimal disruption to current biosimilar distribution.
- Strikes the current PHS Act requirement that has been used to justify switching studies.
- Creates a “cooldown” period for certain biologics that were already granted exclusive interchangeable status.
- Instructs HHS and FDA to issue or retract relevant guidance.
- Passage could lead to state Pharmacy Practice Act modifications relating to substitution



Questions?