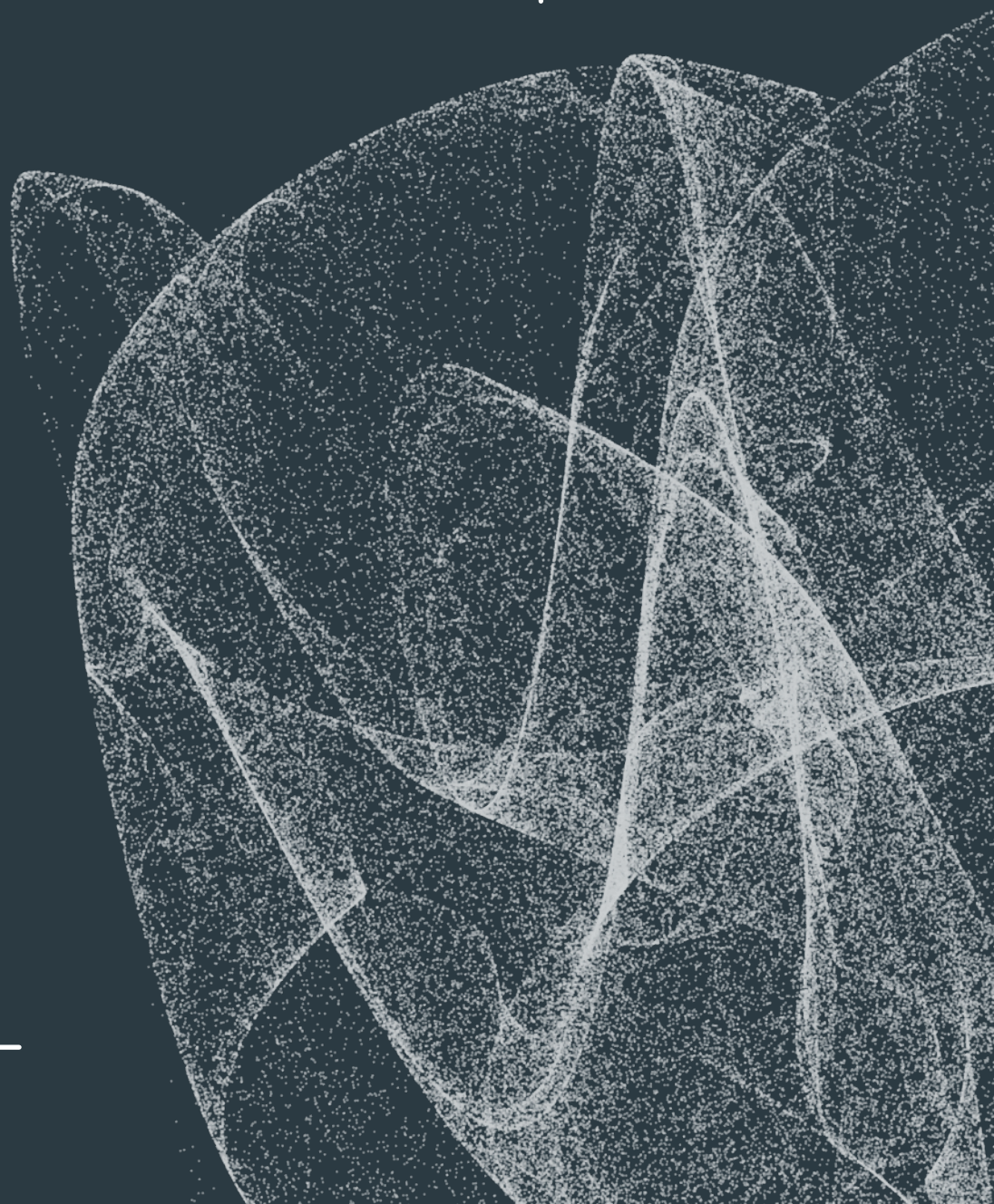
IQVIA INSTITUTE FOR HUMAN DATA SCIENCE

Biosimilar Reimbursement Policies and Their Impact on Sustainability in the U.S.

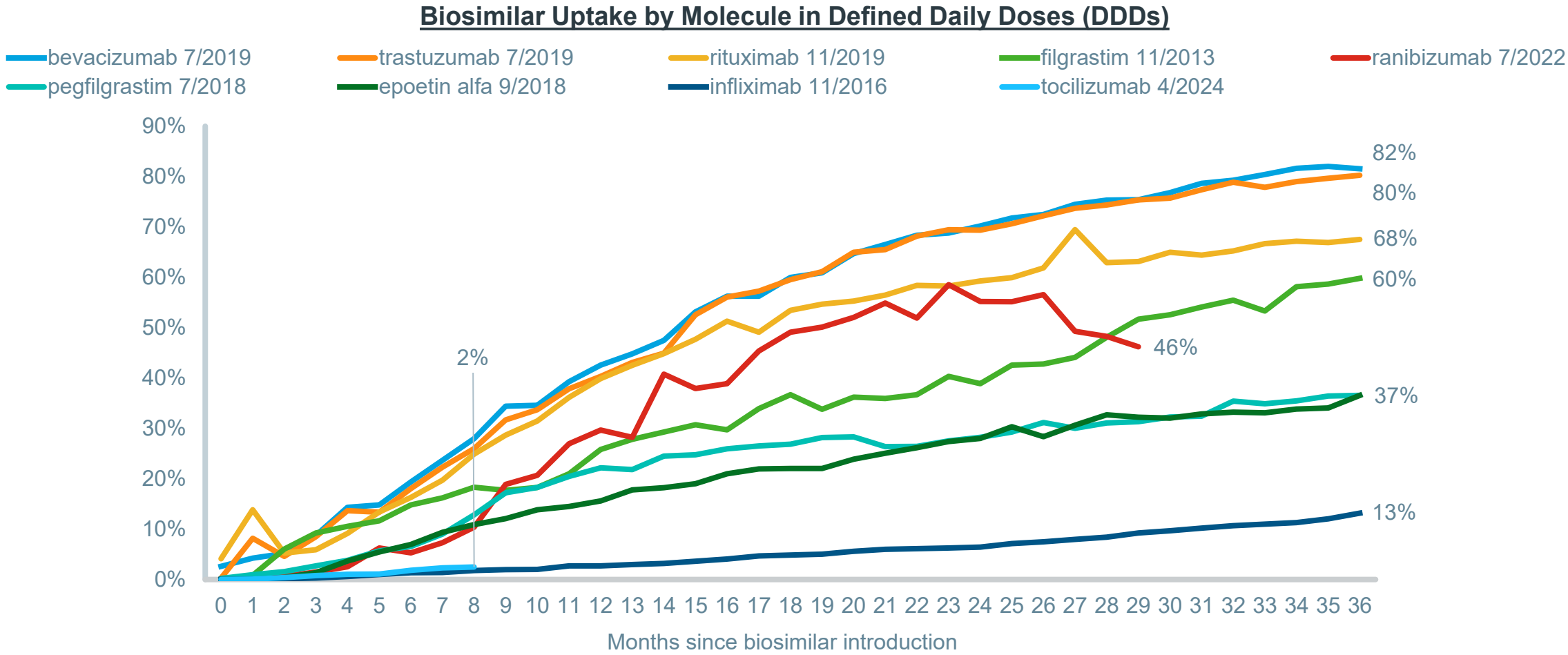
October 2025



Prepared for the GRx+Biosims Conference 2025

Medically reimbursed biosimilars have achieved varied volume uptake within the first three years on market

However, current stakeholder dynamics are making the medical biosimilar market unsustainable in the long term



Source: IQVIA National Sales Perspective, Dec 2024; IQVIA Institute, Mar 2025.

There are 4 key dynamics impacting different stakeholders and posing risk to long-term sustainability of the medical benefit biosimilar system

1. Coverage & Access
2. Average Sales Price (ASP) Dynamics
3. Provider Net Cost Recovery
4. Patient Cost Impact

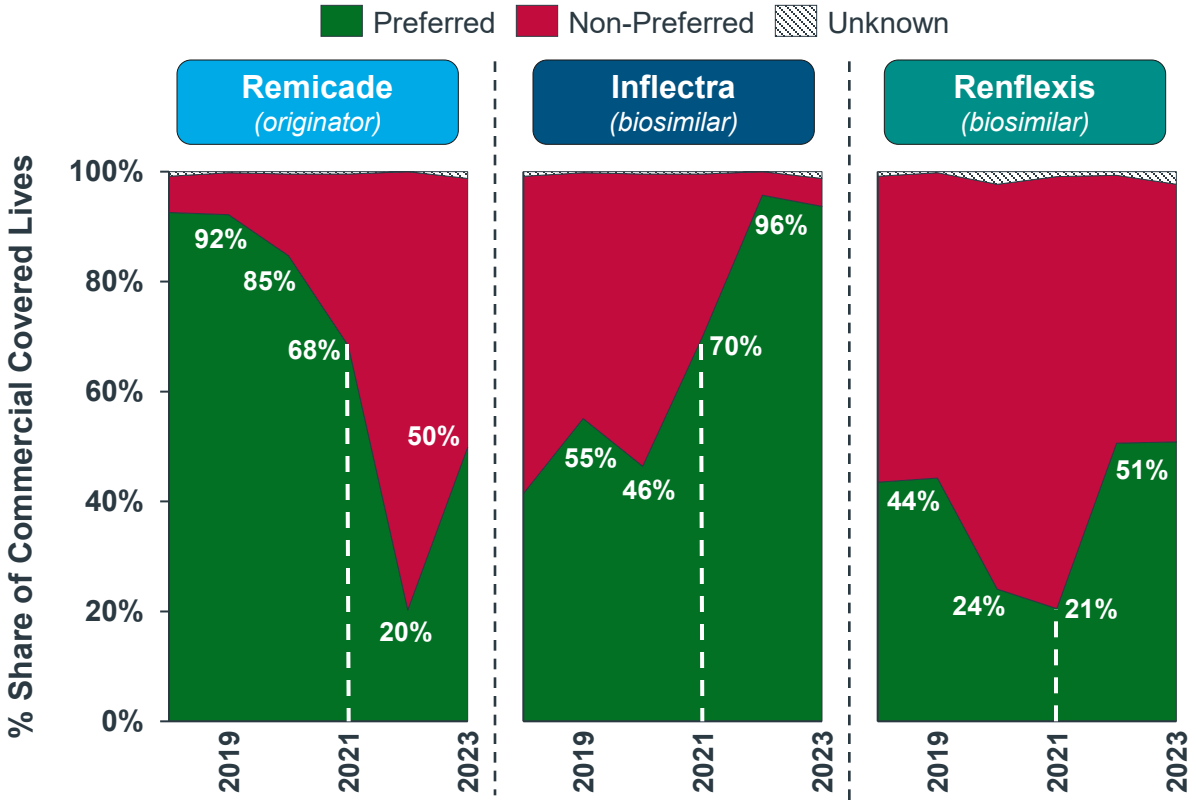
Source: IQVIA Institute and IQVIA US Market Access & Strategy Consulting

In the infliximab market, originator Remicade's coverage allowed it to have the highest proportion of preferred status among commercial lives until 2021

As a result, substantial biosimilar uptake was delayed ~5 years post-launch while Remicade held >70% of market share

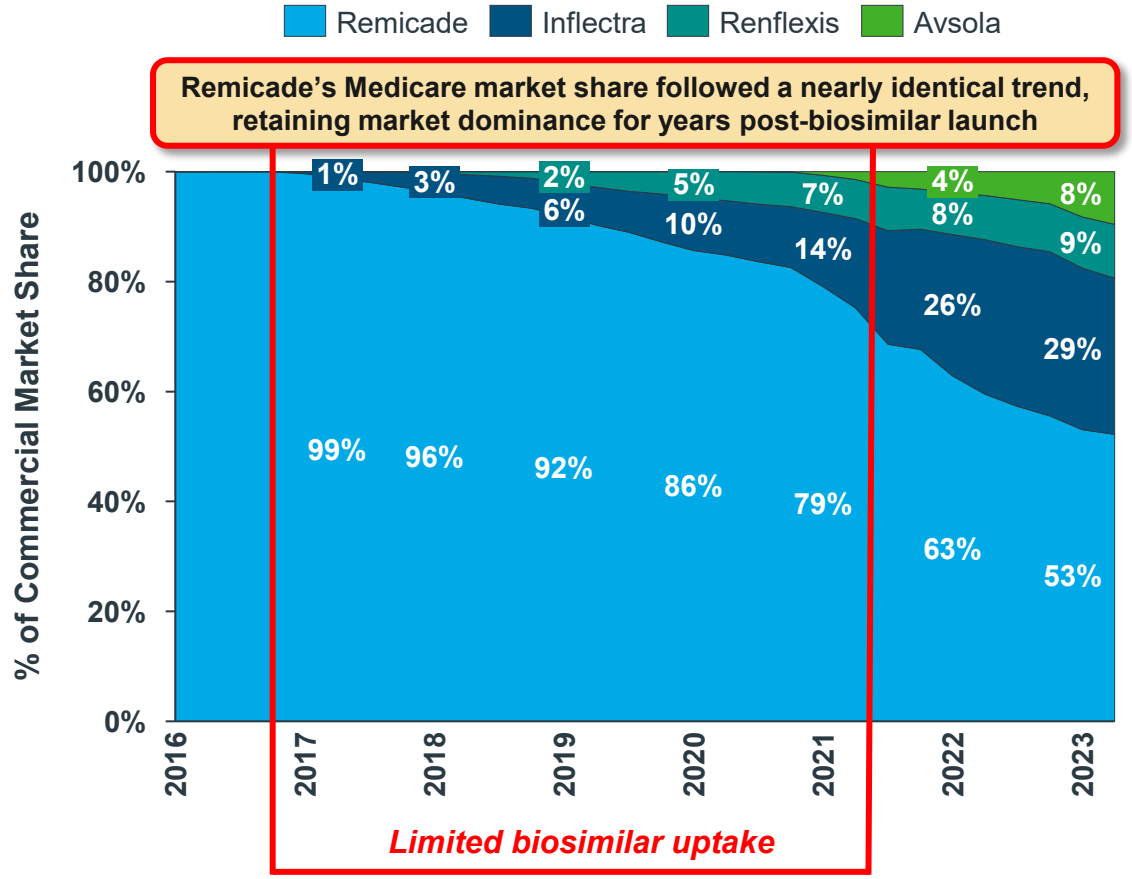
Infliximab Commercial Comparative Formulary Status

(MMIT PAR Feed Data, Covered Lives, 2018-2023)



Infliximab Volume Share in Defined Daily Doses (DDDs)*

(IQVIA MIDAS Data, Q1 2016 – Q2 2023)



Source: MMIT PAR Feed Data, IQVIA MIDAS Data, IQVIA Institute and IQVIA US Market Access & Strategy Consulting

*Inflectra Launch Date: Q4 2016; Renflexis Launch Date: Q3 2017; Avsola Launch Date: Q3 2020.

Long-term Market Sustainability for Infused Biosimilars in the U.S. Report by the IQVIA Institute for Human Data Science.

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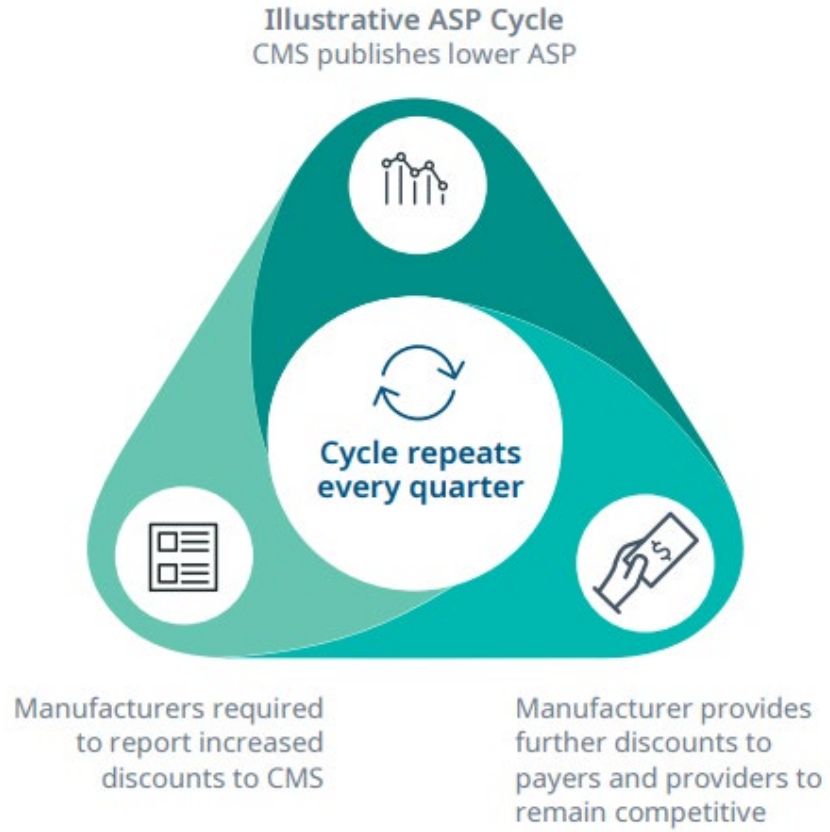
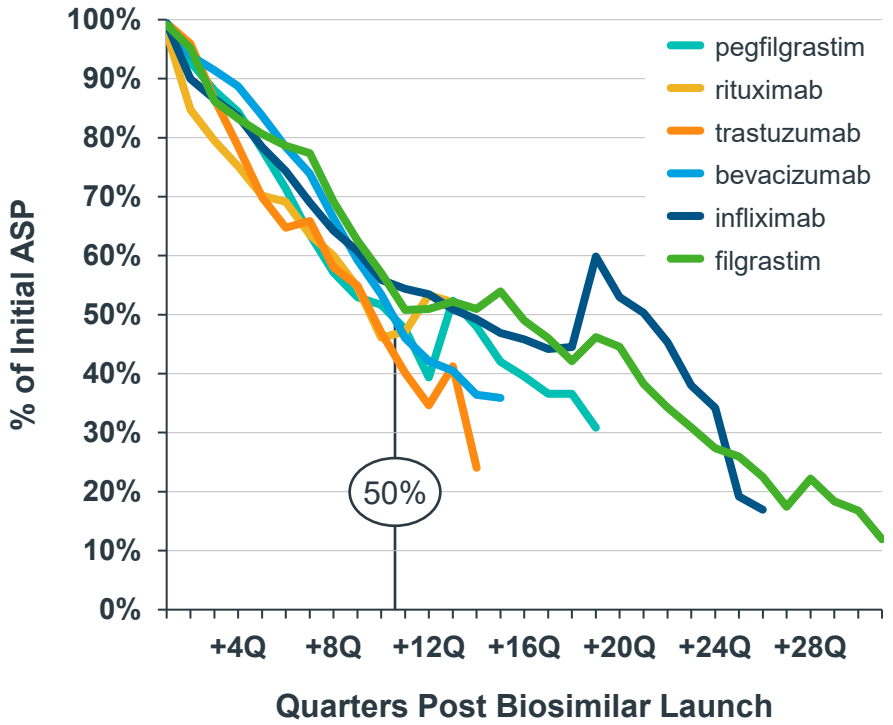
Biosimilar ASPs quickly enter a continual cycle of reductions as their manufacturers compete for access when discounting to payers and providers

- *Product ASPs are calculated by CMS every quarter as the averaged price after all manufacturer discounts given to providers and other stakeholders*
- *Across payer channels, ASP is used as a benchmark for provider reimbursement (e.g., in Medicare B, provider reimbursement is generally ASP+6% for brands or ASP+8% of originator's ASP for biosimilars)*



Average Biosimilars ASP Declines Post-Launch by Market

(CMS ASP Data, Q4 2015 – Q3 2023)

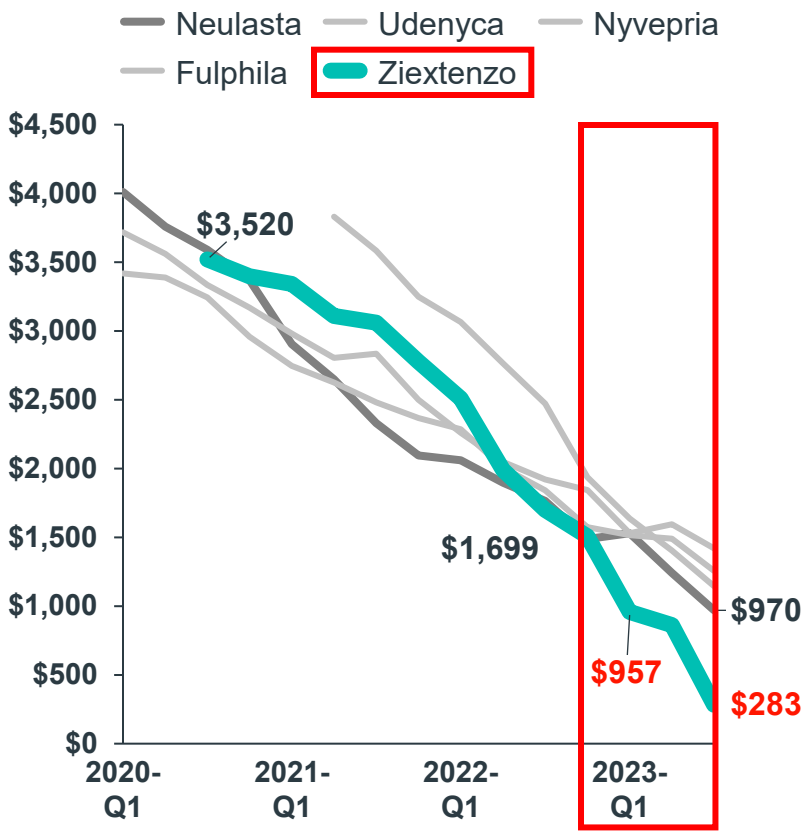


Source: CMS ASP Data, IQVIA Institute and IQVIA US Market Access & Strategy Consulting

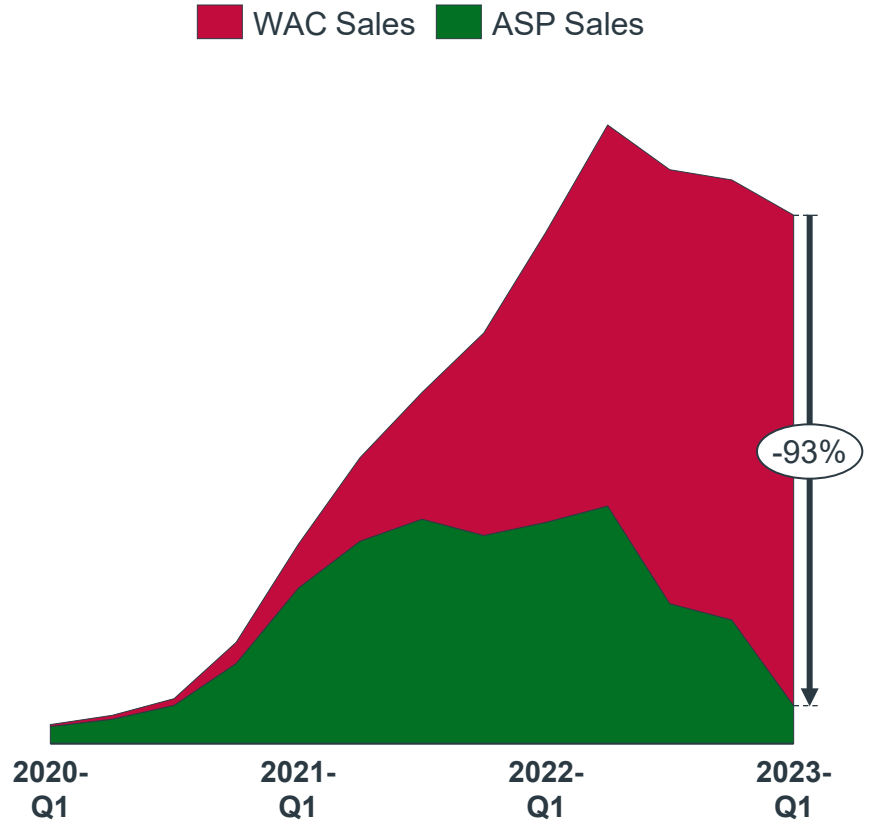
Biosimilar ASPs may become financially unsustainable for manufacturers, which could cause market exits and reduce future investments in biosimilars

The savings accrued by rapid ASP deflation today may be harming the savings promised by biosimilars in the future

Pegfilgrastim ASP Over Time by Product
(CMS ASP Data, 6mg, 2020 – Q3 2023)



Ziextenzo WAC Sales vs. ASP Sales* Over Time
(NSP Sales Data, CMS ASP Data, 2020 – Q1 2023)



Over a longer horizon, the larger risk to the sustainability of the biosimilar system could threaten:

1) **Market Withdrawal:** Manufacturers discontinue their current biosimilars or choose not to enter biosimilar markets altogether

2) **Reduced Competition:** If only one or two manufacturers remain in a market, then they can maintain or increase prices in a monopolistic manner

3) **Lost Savings:** There is a net reduction in crucial savings for the healthcare system that were promised with the launch of biosimilars

Source: CMS ASP Data, NSP Sales Data, IQVIA Institute and IQVIA US Market Access & Strategy Consulting

*WAC Sales are calculated by multiplying WAC Price by Sales Units, while ASP Sales are calculated by multiplying ASP by Sales Units
Note: ASP Sales do not include other costs of manufacturing, patient support program costs, transaction and distribution costs, etc.
Long-term Market Sustainability for Infused Biosimilars in the U.S. Report by the IQVIA Institute for Human Data Science.

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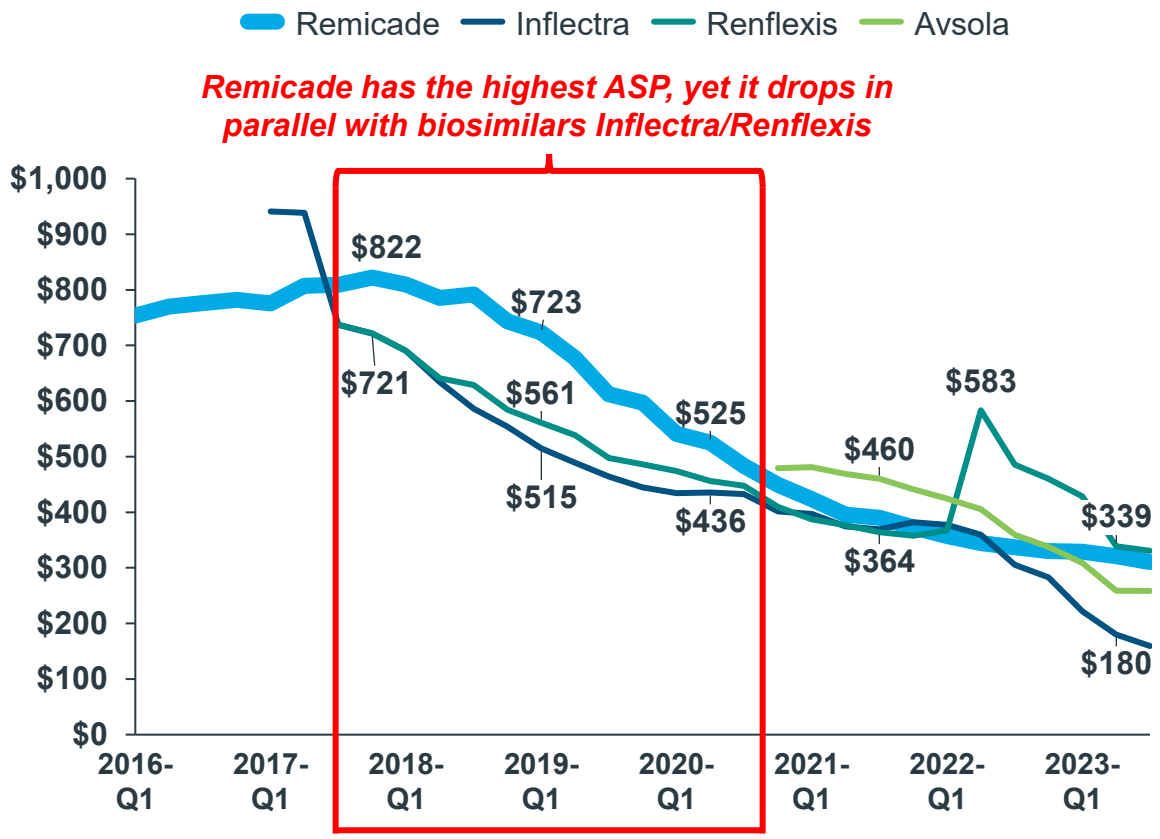
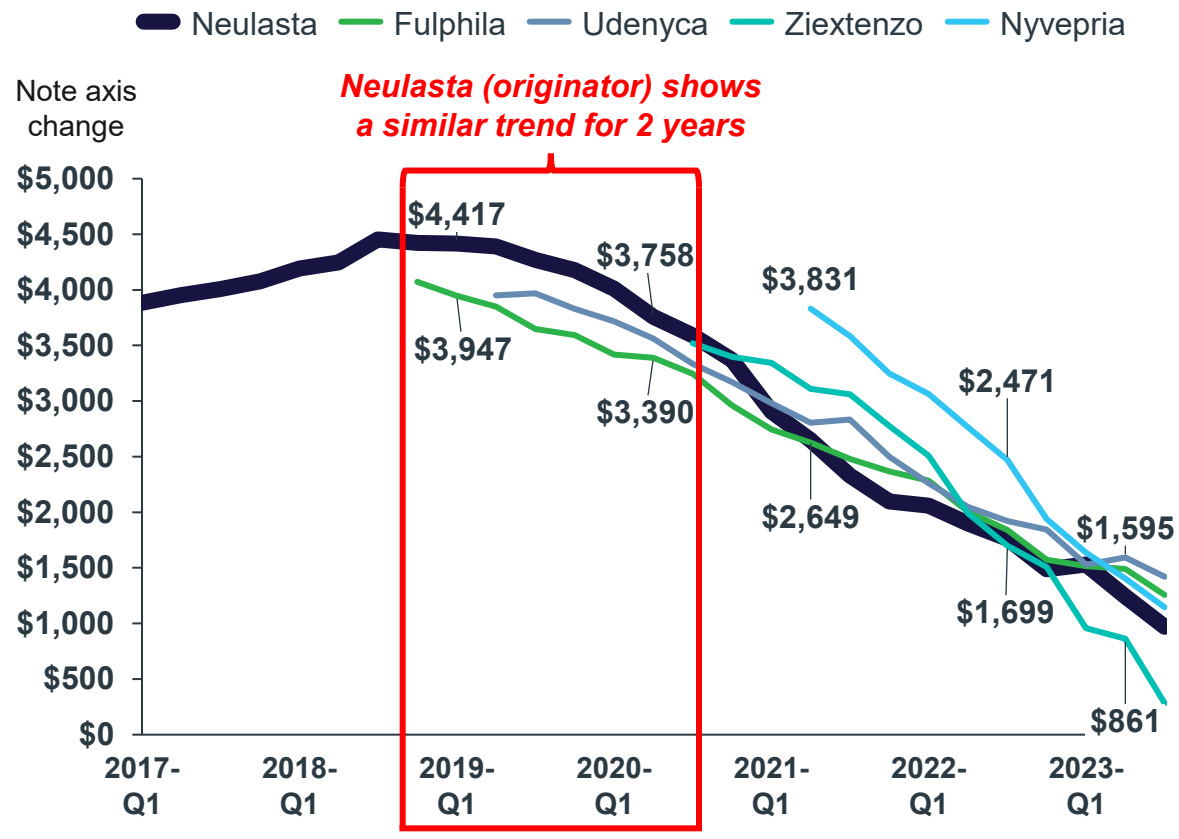
As biosimilars enter the market, ASP decreases among the originator and biosimilars can lead to higher provider net cost recovery for the originator

Both originators Remicade and Neulasta held higher, but similarly decreasing ASPs compared to their biosimilars for ~2-3 years after the first biosimilar entered the market

Infliximab ASP Over Time by Product
(CMS ASP Data, 100mg, Q1 2016 – Q3 2023)



Pegfilgrastim ASP Over Time by Product
(CMS ASP Data, 6mg, Q1 2017 – Q3 2023)



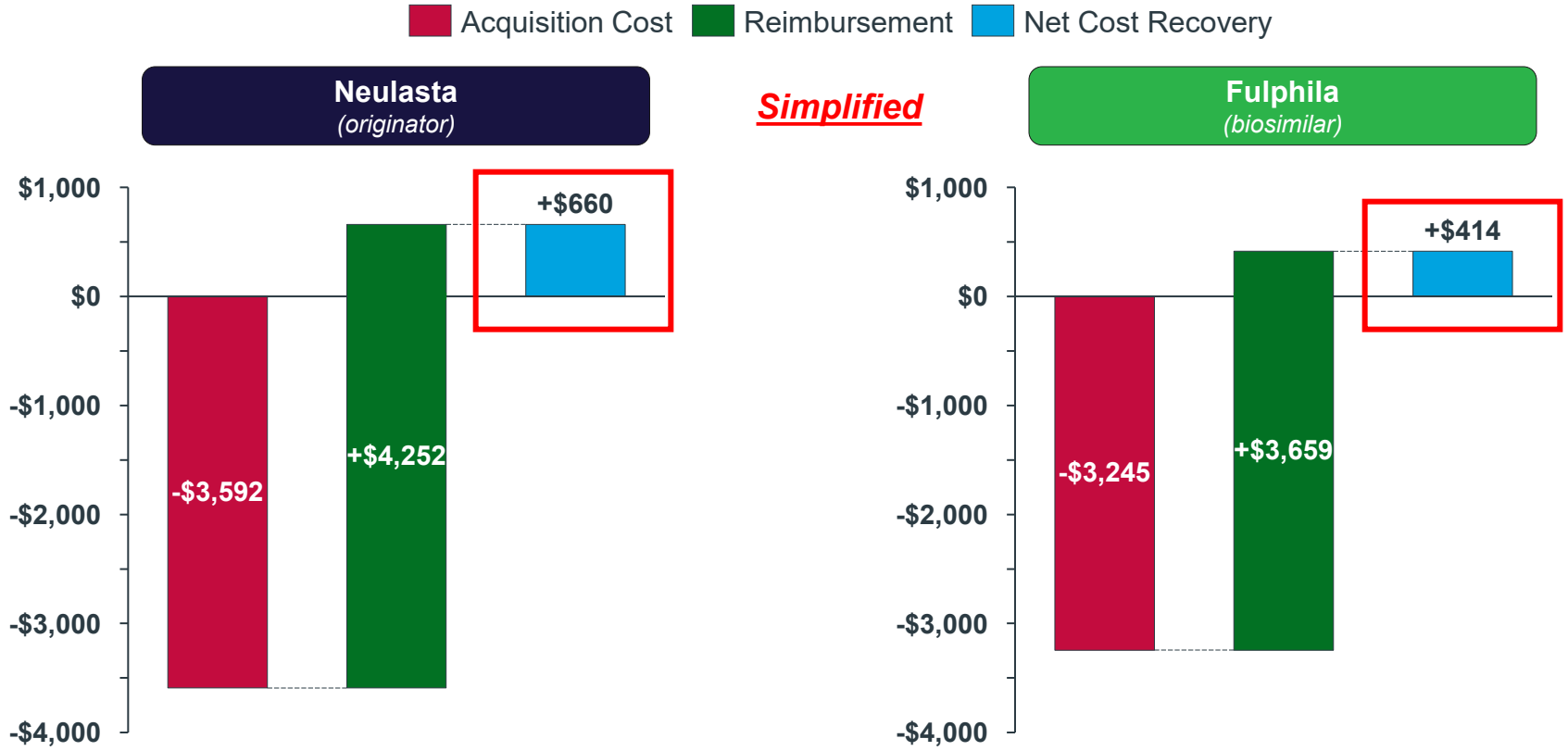
Source: CMS ASP Data, IQVIA Institute and IQVIA US Market Access & Strategy Consulting

Though providers on average paid less upfront for biosimilar Fulphila, their net recovery for originator Neulasta would still have been higher in Q1 2020

The difference in average provider net recovery from Neulasta to Fulphila (~$246) in Q1 2020 could be negligible for a single dose of 6mg; however, this gain is impactful for providers over large quantities for entire patient populations

Pegfilgrastim Provider Average Net Cost Recovery* by Product

(CMS ASP Data, Medicare B, 6mg, Q1 2020)



- Acquisition costs can vary, and in some cases, **reimbursement may be insufficient to cover the acquisition cost of the product**, which can leave providers underwater (i.e., losing money) on biosimilar infusions
- **Discounts provided to non-provider stakeholders (e.g., payer rebates) are also included in the ASP calculation**, so providers can be consistently in the red in some biosimilar markets

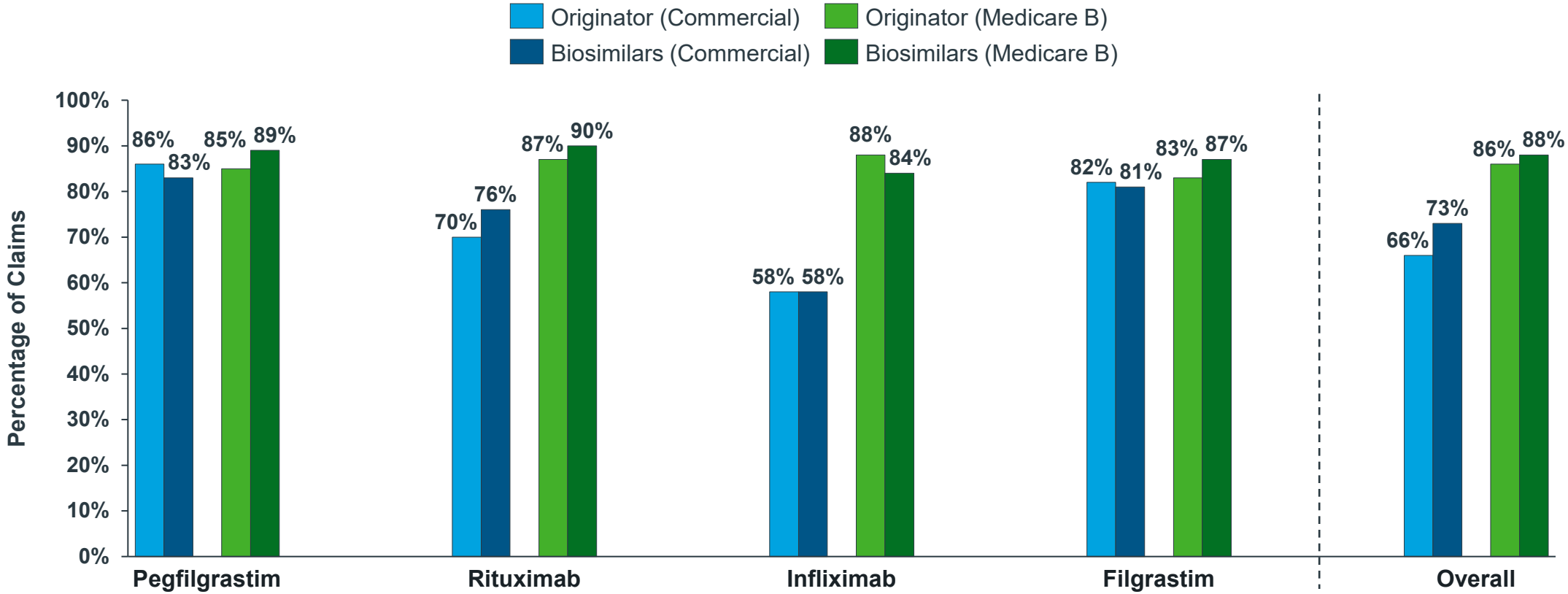
Source: CMS ASP Data, IQVIA Institute and IQVIA US Market Access & Strategy Consulting

*Net cost recovery is calculated using ASP, which is a national average sales price, for reimbursement (ASP+6% of originator) and as a proxy for acquisition cost (the ASP of a product from 2 quarters after reimbursement is used as an estimate of the average acquisition cost in the quarter of reimbursement). Note that acquisition costs using ASPs as a proxy may not account for manufacturer discounts given to non-provider stakeholders.

Most patients do not see improved OOP costs in Part B or commercial for biosimilars in comparison to originators, providing little incentive to switch

The same level of cost savings for biosimilars in relation to originators seen for other stakeholders (e.g., lower acquisition costs for providers) does not translate over to patient costs

Originator vs. Biosimilar Patients Facing <$10 OOP Costs by Payer Channel and Market
(LAAD Medical Claims Data, 2019-2022)



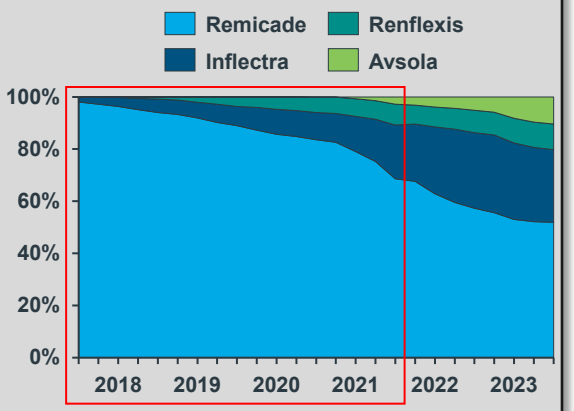
Source: LAAD Medical Claims Data, IQVIA Institute and IQVIA US Market Access & Strategy Consulting

Each of the 4 key dynamics has primary and secondary impacts on different stakeholders, contributing to an unsustainable medical biosimilar system

Coverage & Access

- **Primary Impact:** ***Biosimilar Manufacturers***, as biosimilar uptake is limited until access improves
- **Secondary Impact:** ***Providers, Healthcare System***, due to limited choice, and a portion of the savings that biosimilars may create for overall healthcare spend may not be realized

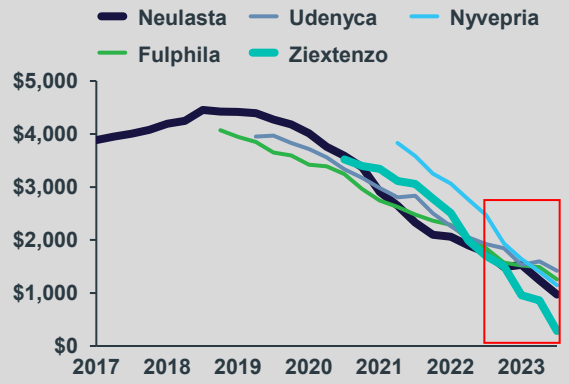
Market Share



ASP Dynamics

- **Primary Impact:** ***Biosimilar Manufacturers***, as discounts given out to remain competitive continue rising, limiting financial viability
- **Secondary Impact:** ***Healthcare System***, as biosimilar savings will decline if manufacturers discontinue and leave their markets

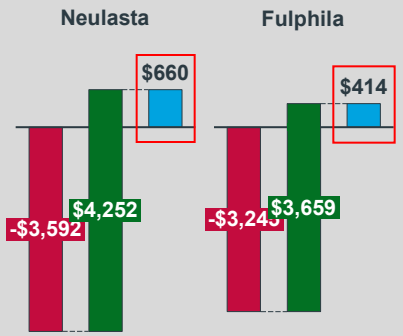
Market ASPs



Provider Net Cost Recovery

- **Primary Impact:** ***Providers***, as ASP-based reimbursement may not favorably cover their acquisition costs for biosimilars, potentially disincentivizing the use of lower cost treatments
- **Secondary Impact:** ***Biosimilar Manufacturers***, as their biosimilar uptake may be limited if providers are not reimbursed well enough for their product

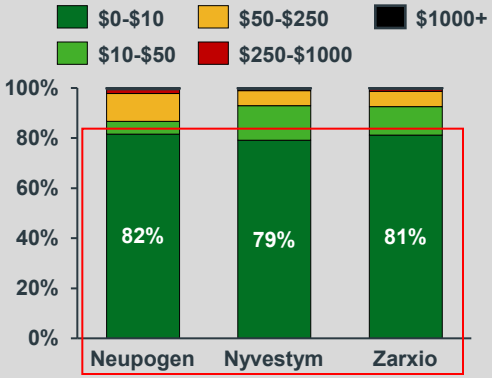
Medicare B Provider NCR



Patient Cost Impact

- **Primary Impact:** ***Patients***, as the potential savings of using the more cost-effective biosimilars are not being translated to their out-of-pocket costs
- **Secondary Impact:** ***Healthcare System***, as the recipients of treatment have no incentives to switch to the lower-cost alternatives entering the market

Commercial Patient Costs

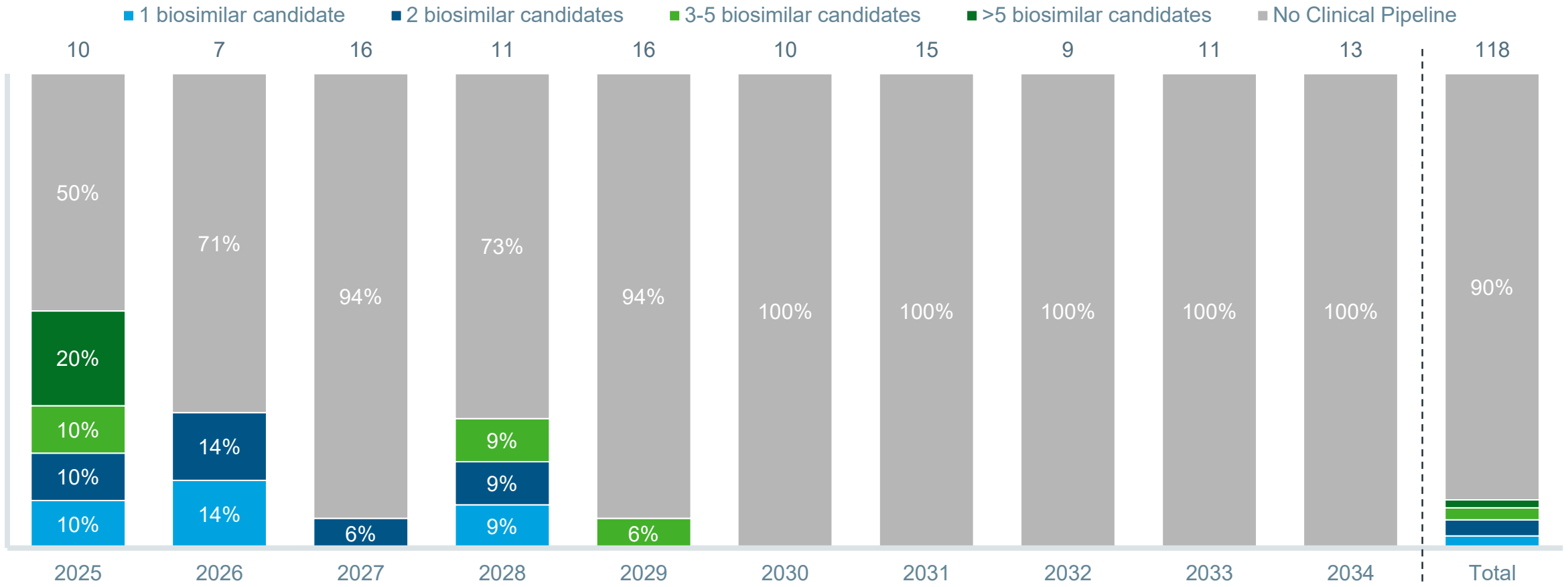


Source: IQVIA Institute and IQVIA US Market Access & Strategy Consulting

90% (106/118) of biologics facing expiry from 2025-2034 have no biosimilars currently in clinical development

An unsustainable biosimilar system could disincentivize clinical developments for biosimilars even further

Share of biologics by number of biosimilars in development, expiries 2025–2034



Source: IQVIA Ark Patent Intelligence, IQVIA Forecast Link, Jun 2024; IQVIA Global Biosimilars Database, Sep 2024; IQVIA Institute, Dec 2024.

Note: Biosimilar pipeline includes biosimilars in clinical development or approved but not launched and is based on publicly available information.
Assessing the Biosimilar Void in the U.S. Report by the IQVIA Institute for Human Data Science.

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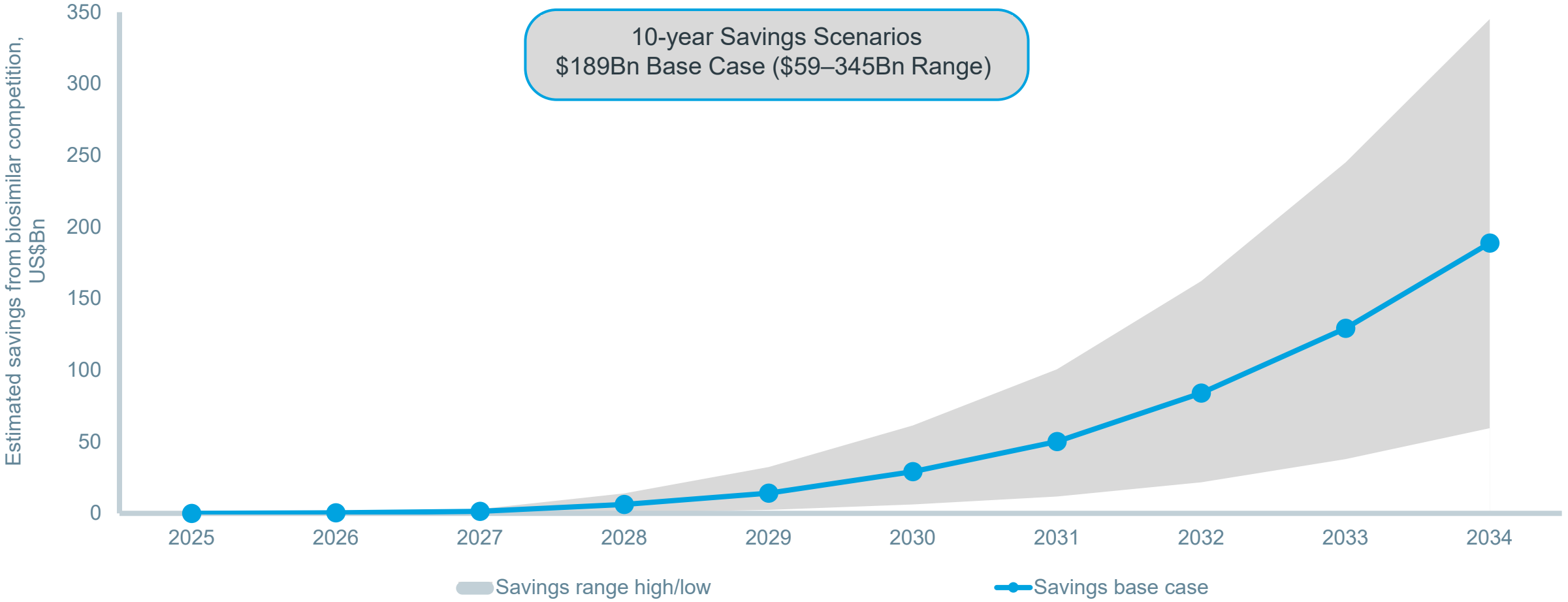
Given the limited number of biologics with biosimilars in development, an unsustainable biosimilar system could risk future healthcare system savings

Biologic estimated cumulative savings at invoice prices assuming all biologics with no biosimilar pipeline face biosimilar competition at patent expiry



Source: IQVIA Ark Patent Intelligence, IQVIA Forecast Link, Jun 2024; IQVIA Institute, Dec 2024.

Notes: Savings is for upcoming biologic expiries that currently have no biosimilar pipeline. Savings estimated as the difference between forecasted molecule sales following biosimilar entry compared to pre-expiry sales. Future erosion of molecule level sales from pre-expiry based on past market dynamics for molecules facing biosimilar competition.
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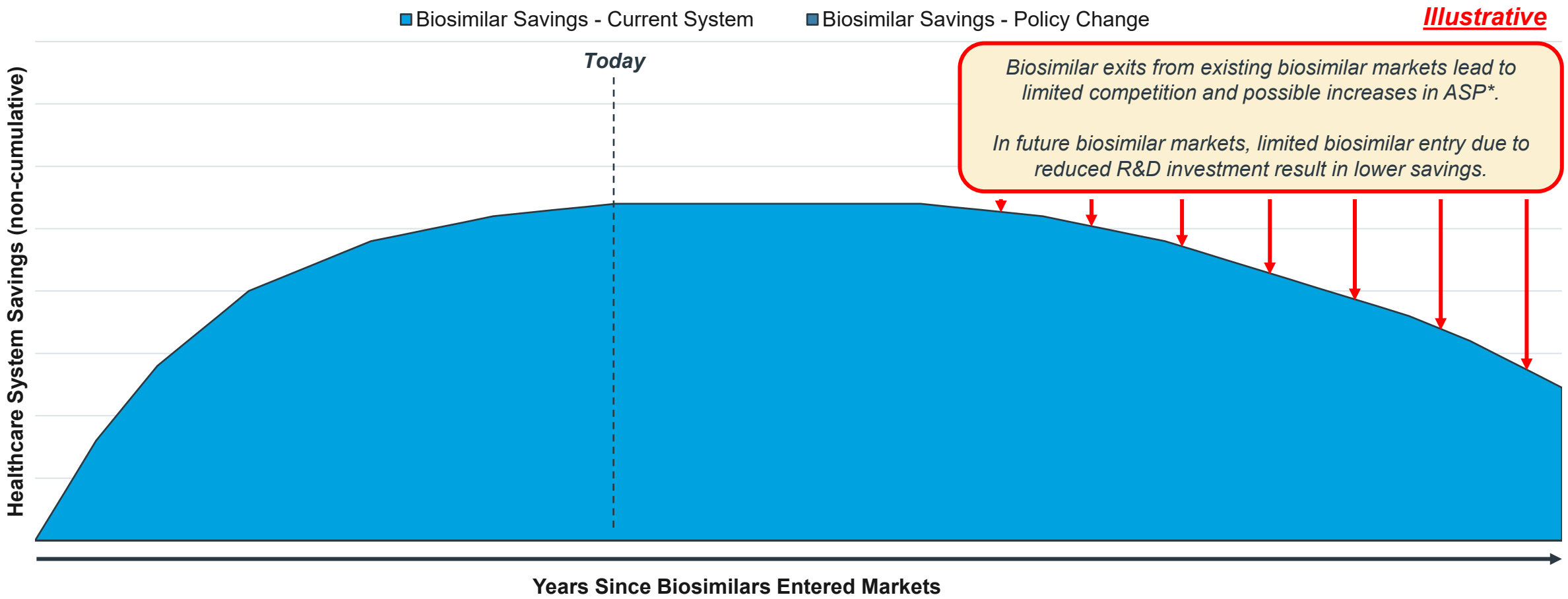
Without any policy change, medical benefit biosimilar manufacturers could be disincentivized to remain in or enter markets, reducing healthcare savings

In the long term, fewer biosimilar entrants in various biologic markets would maintain high costs

Medical Benefit Biosimilar Healthcare System Savings Over Time

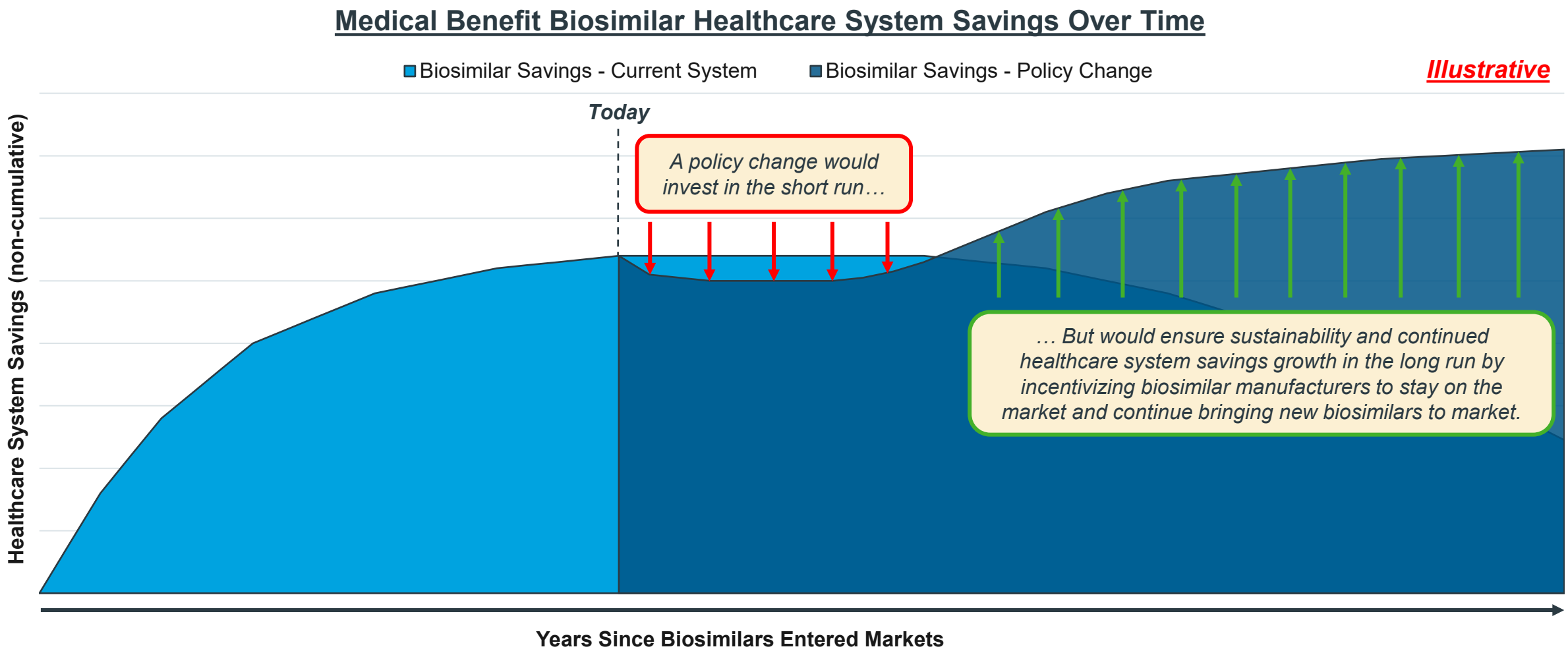


Source: US Market Access Strategy Consulting analysis

*As competition within a market is reduced due to biosimilar(s) exits, the remaining product(s) could increase prices despite inflation penalties.

Changing the current ASP system for biosimilars would trade some savings to incentivize biosimilar uptake and continued total savings

Policy changes should ensure that sufficient economic incentives exist for continued biosimilar development



Source: US Market Access Strategy Consulting analysis