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Biosimilar Market Report

11th edition, Q4 2025

FOREWORD

We are delighted to present the 11th edition of our Biosimilar Market Report, where we focus on a significant policy topic shaping the future of healthcare: **Maximum Fair Price (MFP).**

Through an interview with William Fleming, a former senior Medicare executive, we provide an in-depth look at the 2026 implementation of MFP and explore how this policy could reshape formulary design, influence the dynamics of price negotiations, and affect the future trajectory of the biosimilar market.

With this report, we bring 2025 to a close—a year once again marked by extraordinary change and progress within the biosimilar landscape. From evolving policy discussions to dynamic market movements, the past year has highlighted both the opportunities and the challenges facing our industry. Looking ahead, it is clear that 2026 will bring further shifts, with MFP and other key developments expected to transform the environment in which we operate.

As always, we remain committed to delivering timely insights on the critical developments shaping the biosimilar market. We are deeply grateful for your continued support and look forward to continuing this journey with you in 2026.

Thomas Newcomer
Vice President
Head of US Commercial Operations, Samsung Bioepis US

SAMSUNG BIOEPIS

Our mission

Samsung Bioepis is a biopharmaceutical company dedicated to accelerating access to biologic medicines by bringing high-quality, clinically proven biosimilars to patients who need them

Our mission is reflected in our name, **bio-epis;** literally meaning life (**"bio"**) and science (**"episteme"**) in Greek

Unlocking the future of healthcare by breakthrough innovation and science

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I. US Biosimilars Approval & Launch Status

FDA Approval and Launch Status of US Biosimilars

* As of September 2025, the FDA has approved a total of 80 biosimilars across 19 unique biological molecules. Of the 80 approvals, 58 biosimilars (73%) have launched in the US market.

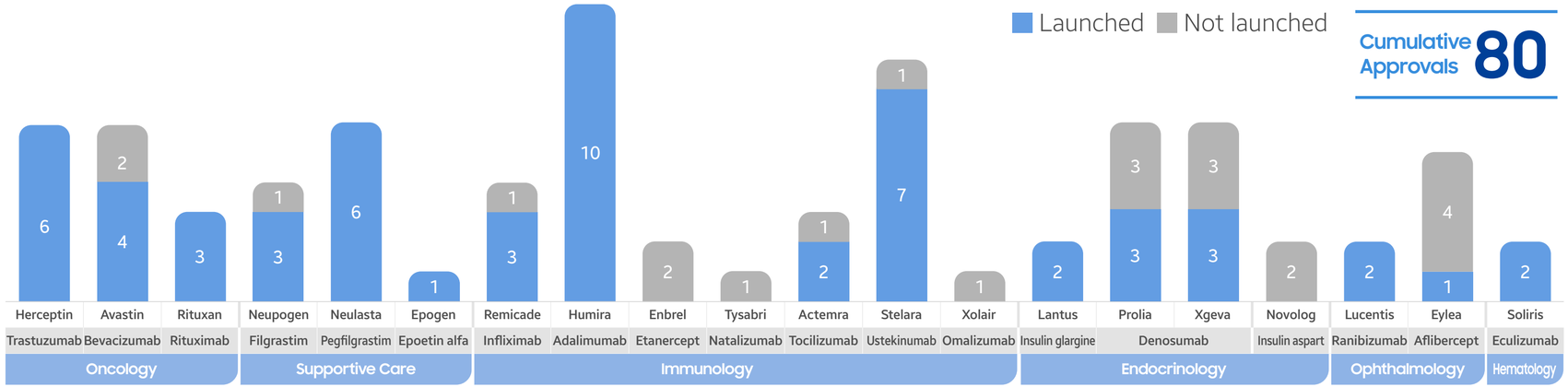
Figure 1-1. 10 FDA-approved Biosimilars in Q3`25

Reference Product	Biosimilar name	Biosimilar Manufacturer
Novolog	Kirsty	Biocon
Prolia	Bildyos	Shanghai Henlius Biotech
	Enoby	Richter
Xgeva	Bilprevda	Shanghai Henlius Biotech
	Xtrenbo	Richter

Figure 1-2. 7 Biosimilars Launched in the US Market in Q3`25

Reference Product	Biosimilar name	Biosimilar Manufacturer & Commercial Partner	Launch Date
Prolia	Conexxence	Fresenius Kabi	Jul 2025
	Stoboclo	Celltrion	Jul 2025
Xgeva	Bomyntra	Fresenius Kabi	Jul 2025
	Osenvelt	Celltrion	Jul 2025
Stelara	Imuldosa	Dong-A ST/Meiji Seika Pharma & Accord BioPharma	Aug 2025

Figure 1. Biosimilars Approval and Launch Status in the US[1]* (As of Sep 2025)



FDA: Food and Drug Administration
*Trade marks are not described to all brands

Figure 3-1. Biosimilars Approval and Launch Status in the US[1*] (As of Sep 2025, with Suffix)

TA	Oncology			Immunology						
Molecule	Trastuzumab	Bevacizumab	Rituximab	Infliximab	Adalimumab	Etanercept	Natalizumab	Tocilizumab	Ustekinumab	Omalizumab
Reference Product	Herceptin (trastuzumab) Roche 1998	Avastin (bevacizumab) Roche 2004	Rituxan (rituximab) Genentech&Biogen 1997	Remicade (infliximab) Janssen 1998	Humira (adalimumab) AbbvVie 2002	Enbrel (etanercept) Amgen 2003	Tysabri (natalizumab) Biogen 2004	Actemra (tocilizumab) Genetech 2010	Stelara (ustekinumab) Janssen 2009	Xolair (omalizumab) Genentech&Novartis 2003
Biosimilar	Ogivri (trastuzumab-dkst) Biocon 2017	Mvasi (bevacizumab-awwb) Amgen 2017	Truxima (rituximab-abbs) Celltrion&Teva 2018	Inflectra (infliximab-dyyb) Celltrion&Pfizer 2016	Amjevita (adalimumab-atto) Amgen 2016	Erelzi (etanercept-szzs) Sandoz 2016	Tyruko (natalizumab-sztn) Sandoz 2023	Tofidence (tocilizumab-bavi) Biogen&Bio-Thera 2023	Wezlana (ustekinumab-auub) Amgen 2023	Omlyclo (omalizumab-igec) Celltrion 2025
	Herzuma (trastuzumab-pkrb) Celltrion&Teva 2018	Zirabev (bevacizumab-bvzr) Pfizer 2019	Ruxience (rituximab-pvvr) Pfizer 2019	Renflexis (infliximab-abda) Samsung Bioepis&Organon 2017	Cyltezo (adalimumab-adbm) Boehringer Ingelheim 2017	Eticovo (etanercept-ykro) Samsung Bioepis 2019		Tyenne (tocilizumab-aazg) Fresenius Kabi 2024	Selarsdi (ustekinumab-aekn) Alvotech&Teva 2024	
	Ontruzant (trastuzumab-dttb) Samsung Bioepis&Organon 2019	Alymsys (bevacizumab-maly) Amneal 2022	Riabni (rituximab-arrx) Amgen 2020	Avsola (infliximab-axxq) Amgen 2019	Hyrimoz (adalimumab-adaz) Sandoz 2018			Avtozma (tocilizumab-anoh) Celltrion 2025	Pyzchiva (ustekinumab-ttwe) Samsung Bioepis&Sandoz 2024	
	Trazimera (trastuzumab-qyyp) Pfizer 2019	Vegzelma (bevacizumab-adcd) Celltrion 2022		Ixifi (infliximab-qbtx) Pfizer 2017	Hadlima (adalimumab-bwwd) Samsung Bioepis&Organon 2019				Otulfi (ustekinumab-aauz) Formycon&Fresenius Kabi 2024	
	Kanjinti (trastuzumab-anns) Amgen 2019	Avzivi (bevacizumab-tnjn) Sandoz&Bio-Thera 2023			Abrilada (adalimumab-afzb) Pfizer 2019				Imuldosa (ustekinumab-srlf) Dong-A ST&Meji Seika &Accord Biopharma 2024	
	Hercessi (trastuzumab-strf) Accord BioPharma&Henlius 2024	Jobevne (bevacizumab-nwgd) Biocon 2025			Hulio (adalimumab-fkjp) Biocon 2020				Yesintek (ustekinumab-kfce) Biocon 2024	
					Yusimry (adalimumab-aqvh) Coherus&Meitheal 2021				Steqeyma (Ustekinumab-stba) Celltrion 2024	
					Idacio (adalimumab-aacf) Fresenius Kabi 2022				Starjemza (ustekinumab-hmny) Bio-Thera & Hikma 2025	
					Yuflyma (adalimumab-aaty) Celltrion 2023					
					Simlandi (adalimumab-ryvk) Alvotech&Teva 2024					

Launched Not launched

Continued on next page →

*Trade marks are not described to all brands

Figure 3-2. Biosimilars Approval and Launch Status in the US[1]* (As of Sep 2025, with Suffix)

TA	Endocrinology			Ophthalmology		Hematology	Supportive Care		
Molecule	Denosumab	Insulin glargine	Insulin aspart	Ranibizumab	Aflibercept	Eculizumab	Filgrastim	Pegfilgrastim	Epoetin alfa
Reference Product	Prolia/Xgeva (denosumab) Amgen 2010	Lantus (insulin glargine) Sanofi 2000	Novolog (insulin aspart) Novo Nordisk 2000	Lucentis (ranibizumab) Novartis 2006	Eylea (aflibercept) Regeneron 2011	Soliris (eculizumab) Alexion 2007	Neupogen (filgrastim) Amgen 1991	Neulasta (pegfilgrastim) Amgen 2002	Epogen (epoetin alfa) Amgen 1898
Biosimilar	Jubbonti/Wyost (denosumab-bbdz) Sandoz 2024	Semglee (insulin glargine-yfgn) Biocon 2021	Merilog (insulin aspart-szjj) Sanofi-Aventis 2025	Byooviz (ranibizumab-nuna) Samsung Bioepis 2021	Opuviz (aflibercept-yszy) Samsung Bioepis&Biogen 2024	Bkemv (eculizumab-aeeb) Amgen 2024	Zarxio (filgrastim-sndz) Sandoz 2015	Fulphila (pegfilgrastim-jmdb) Biocon 2018	Retacrit (epoetin alfa-epbx) Hospira&Pfizer 2018
	Ospomyv/Xbryk (denosumab-dssb) Samsung Bioepis 2025	Rezvoglar (insulin glargine-aglr) Eli Lilly 2021	Kirsty (insulin aspart-xjhz) Biocon 2025	Cimerli (ranibizumab-eqrn) Sandoz 2022	Yesafili (aflibercept-jbvf) Biocon 2024	Epysqli (eculizumab-aagh) Samsung Bioepis 2024	Nivestym (filgrastim-aafi) Hospira&Pfizer 2018	Udenyca (pegfilgrastim-cbqv) Coherus 2018	
	Stoboclo/Osenvelt (denosumab-bmwo) Celltrion 2025				Ahzantive (aflibercept-mrbb) Formycon&Klinge 2024		Releuko (filgrstim-ayow) Amneal&Kashiv 2022	Ziextenzo (pegfilgrastim-bmez) Sandoz 2019	
	Conexxence/Bomyntra (denosumab-bnht) Fresenius Kabi 2025				Enzeevu (aflibercept-abzv) Sandoz 2024		Nypozi (filgrastim-txid) Tanvex 2024	Nyvepria (pegfilgrastim-apgf) Hospira&Pfizer 2020	
	Bildyos/Bilprevda (denosumab-nxxp) Shanghai Henlius Biotech & Organon 2025				Pavblu (aflibercept-ayyh) Amgen 2024			Stimufend (pegfilgrastim-fpgk) Fresenius Kabi 2022	
	Enoby/Xtrenbo (denosumab-qbde) Richter&Hikma 2025 Celltrion							Fylnetra (pegfilgrastim-pbbk) Amneal&Kashiv 2022	

Launched Not launched

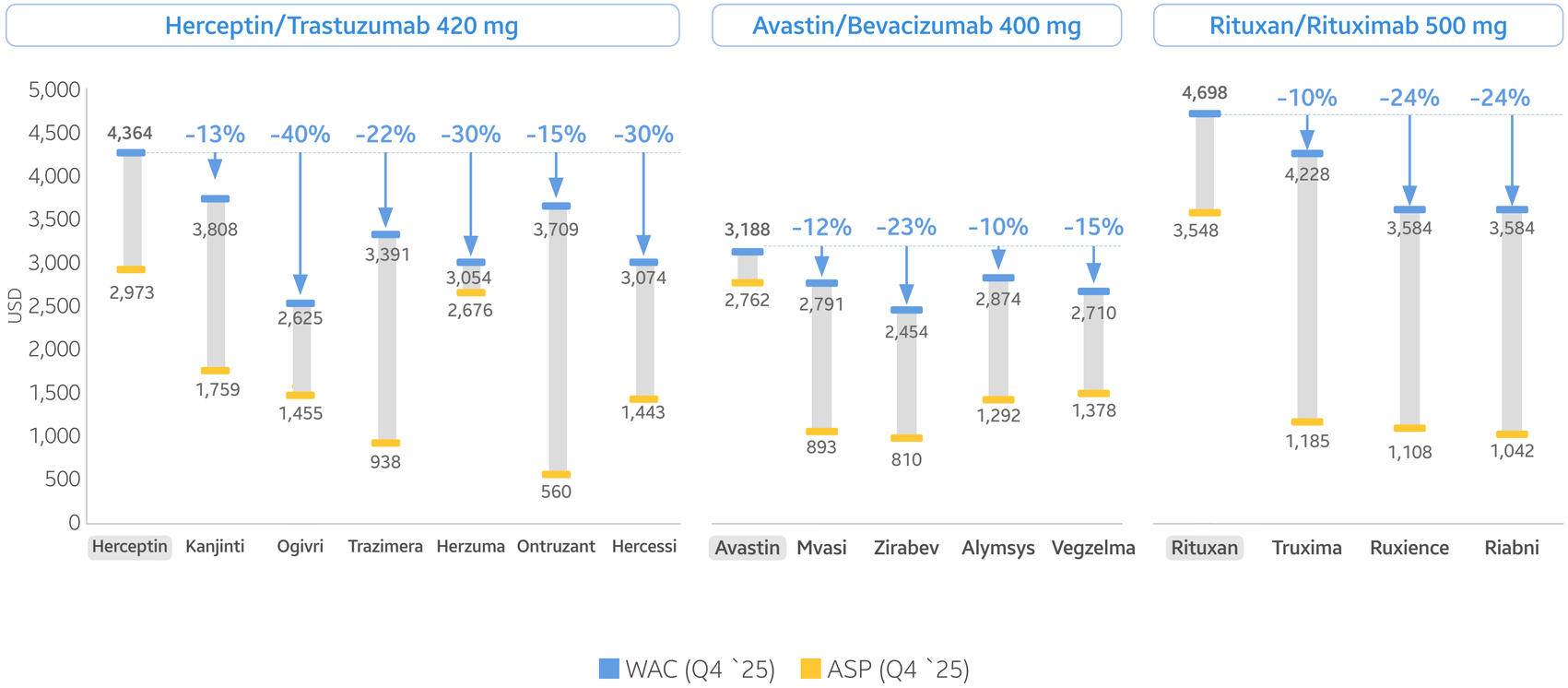
*Trade marks are not described to all brands

II. Biosimilar Price
(Medical Benefit & Pharmacy Benefit)

Oncology WAC and ASP – Q4 2025

- Across oncology biosimilars, WAC prices discounted between 10-40% compared to reference products.
- Biosimilar Q4 2025 ASP discounts as compared to the reference product's ASP average -50%, -60%, and -69% for the trastuzumab, bevacizumab, and rituximab markets, respectively.

Figure 4. Q4 2025 WAC and ASP[2,3]

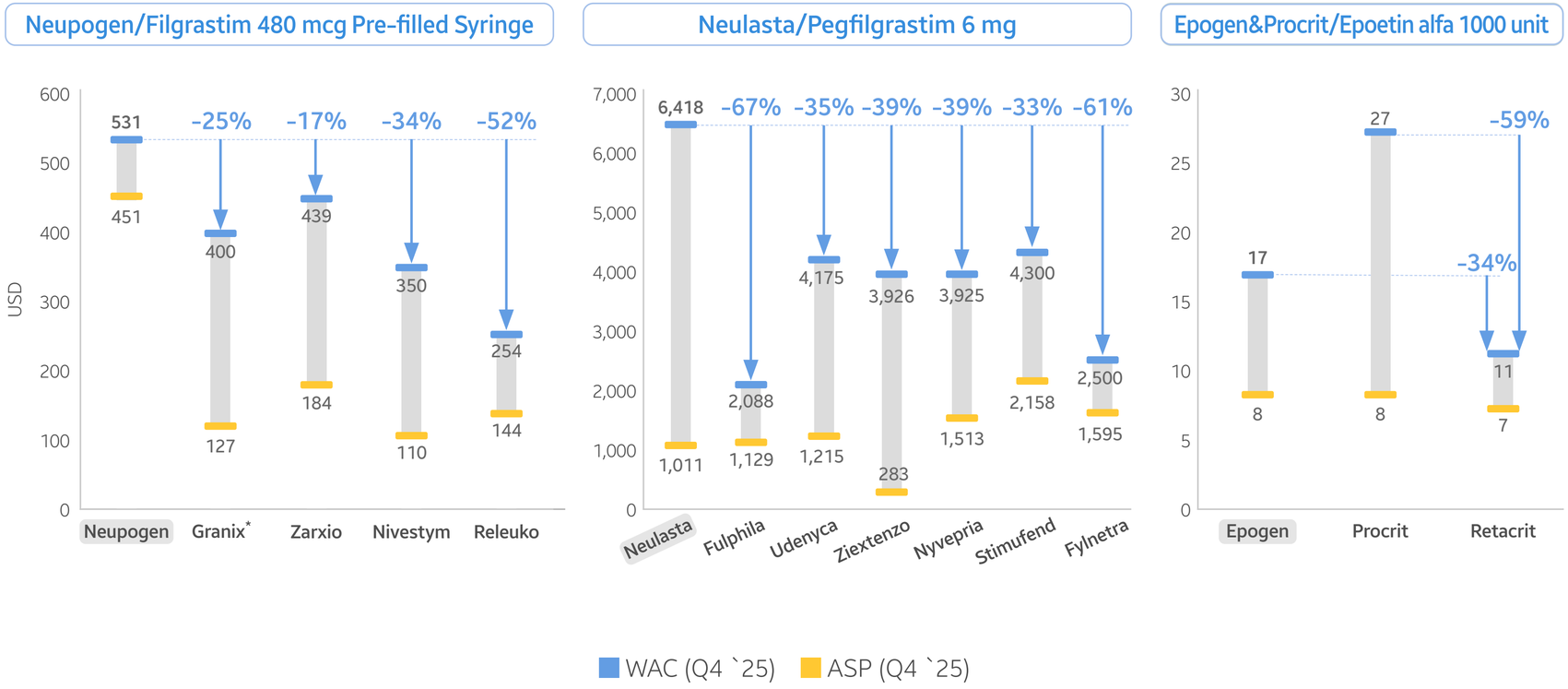


Products are listed in order of launch
ASP: Average Sales Price; **WAC**: Wholesale Acquisition Cost

Supportive Care WAC and ASP - Q4 2025

- Across supportive care biosimilars, WAC prices discounted between 17-67% compared to reference products.
- Amgen, the manufacturer for reference biologics filgrastim (Neupogen) and pegfilgrastim (Neulasta), only provides competitive ASP pricing in the pegfilgrastim market.

Figure 5. Q4 2025 WAC and ASP[2,3]

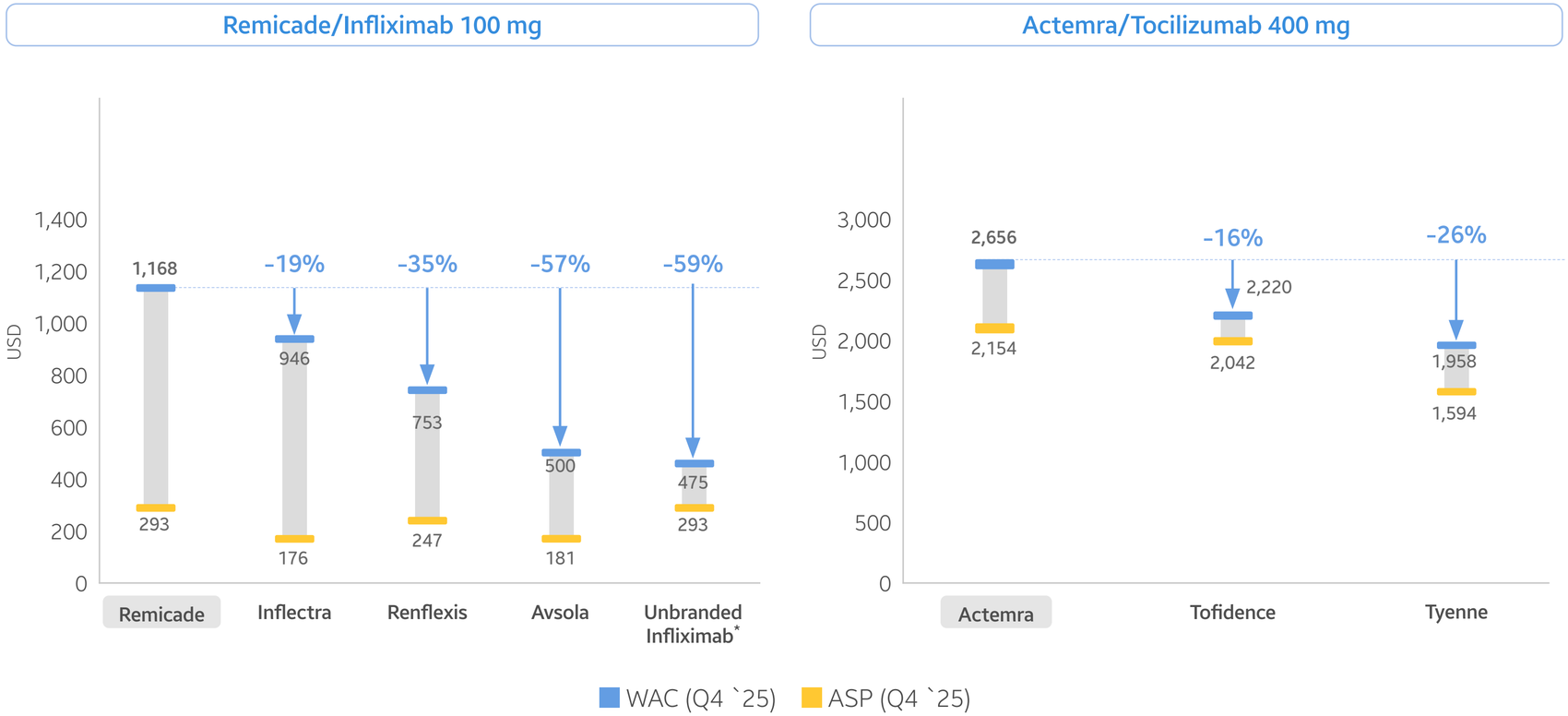


Products are listed in order of launch
ASP: Average Sales Price; **WAC**: Wholesale Acquisition Cost
*Granix is not a biosimilar; approved under the FDA's New Drug Application pathway

Immunology WAC and ASP - Q4 2025

- Infliximab biosimilars launched with progressively lower WACs, ranging from -19% to -59% in discounts.
- Tocilizumab biosimilars, with only two entrants, have more modest WAC discounts between -16% to -26%.

Figure 6. Q4 2025 WAC and ASP[2,3]

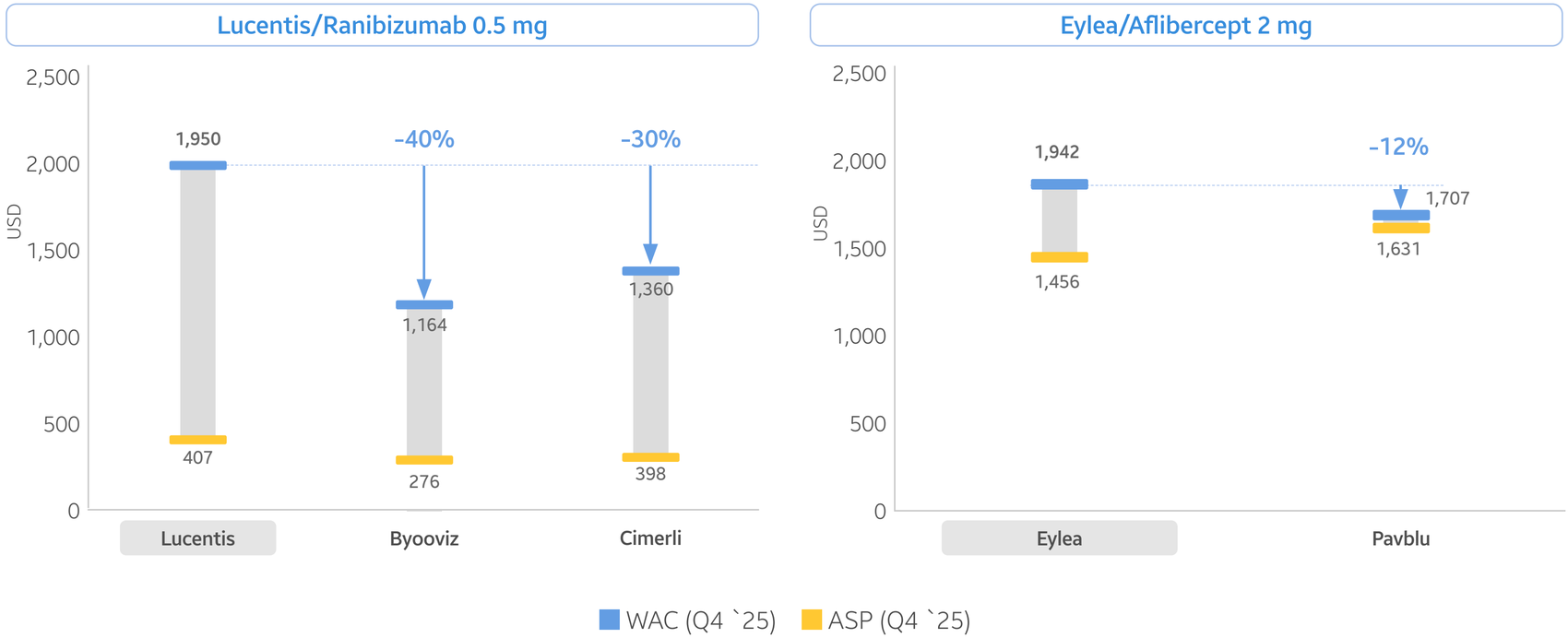


Products are listed in order of launch
ASP: Average Sales Price; **WAC**: Wholesale Acquisition Cost
*Janssen's Remicade without the brand name

Ophthalmology WAC and ASP – Q4 2025

- Ranibizumab WACs represent -30% to -40% WAC discounts as compared to the reference product.
- The ASP of ranibizumab biosimilars remained unchanged in Q4 2025 compared to the previous quarter.
- With four products awaiting clearance to launch, aflibercept only faces one biosimilar competitor offering a WAC discount of -12%.

Figure 7. Q4 2025 WAC and ASP[2,3]

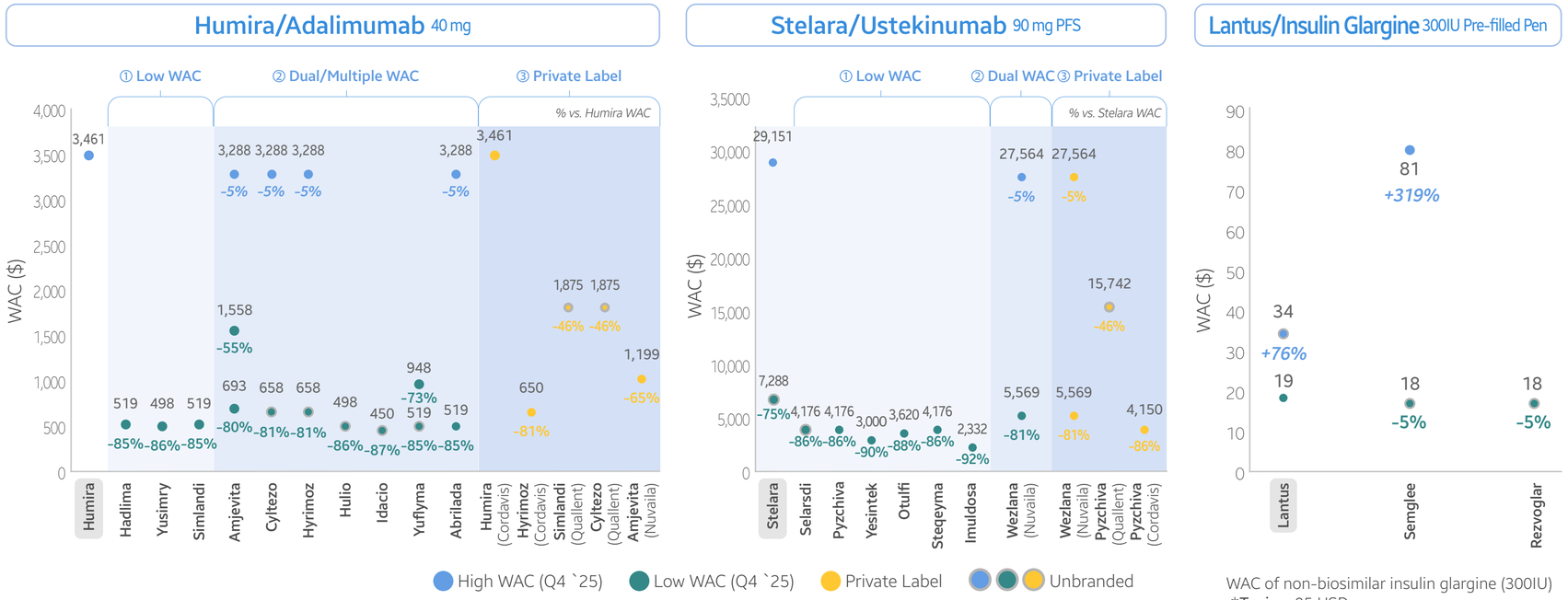


Products are listed in order of launch
ASP: Average Sales Price; **WAC**: Wholesale Acquisition Cost

Immunology & Endocrinology WAC - Q4 2025

- Adalimumab, ustekinumab, & insulin glargine categories reflect complex pricing practices such as multiple WAC options and unbranded biologics.
- In the adalimumab & ustekinumab market, private label brands offer alternative WAC prices.
- While private label brands remain common, most ustekinumab biosimilars did not adopt a dual or high WAC strategy as compared to the adalimumab market.

Figure 8. Q4 2025 WAC[2,12]



WAC of non-biosimilar insulin glargine (300IU)
*Toujeo: 95 USD
†Basaglar: 65 USD

Products are listed in order of launch
WAC: Wholesale Acquisition Cost
*Toujeo is high dose version of Lantus †Basaglar is not a biosimilar, approved under the FDA's New Drug Application pathway

III. Biosimilar Market Dynamics

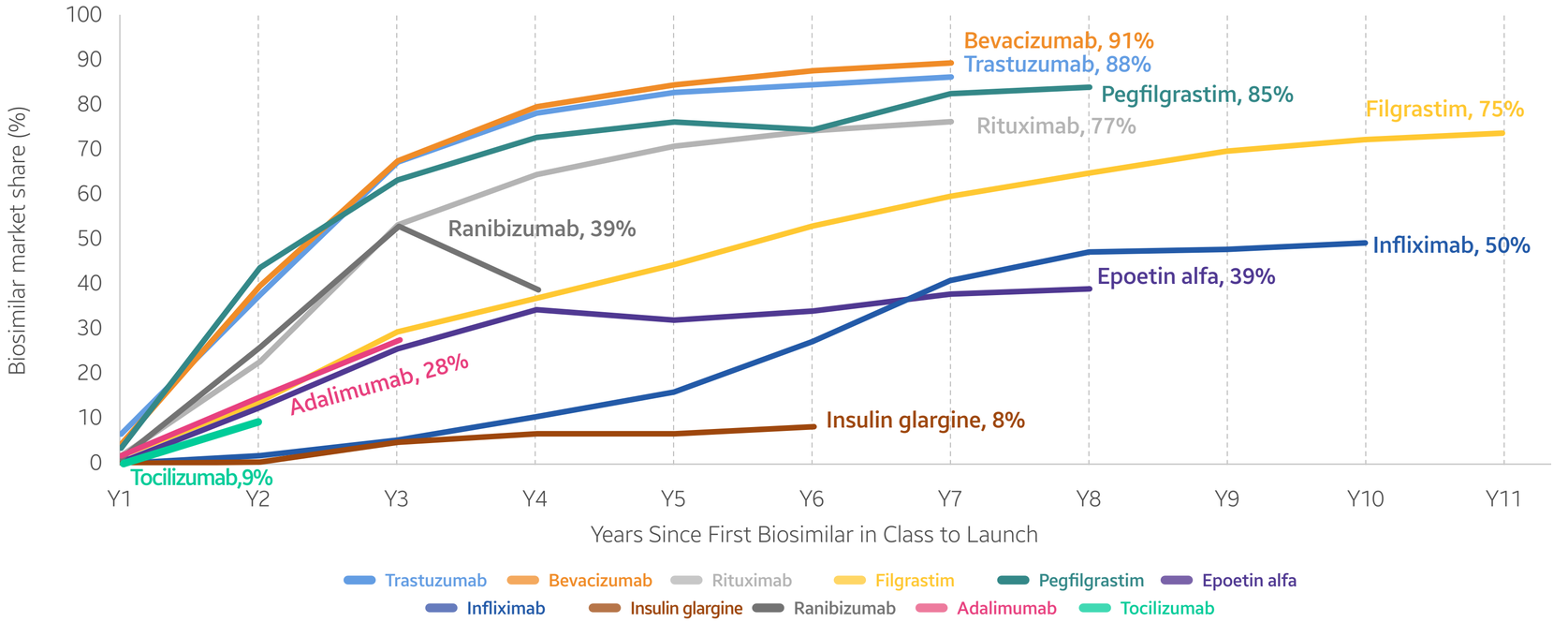
Biosimilar Volume Uptake Varies by Molecule

On average, biosimilars have gained 52% market share within five years post initial launch.[†] Each molecule has demonstrated unique biosimilar uptake and can be categorized into fast or slow uptake markets.

1) **Fast Uptake Speed**: Oncology[*], ophthalmology, and pegfilgrastim biosimilars.
   Five years post launch, average biosimilar market share reached 81%.[†]

2) **Slow Uptake Speed:** Immunology[‡], filgrastim, epoetin alfa, and insulin glargine biosimilars.
   On average, only a 25% biosimilar market share was achieved by Year 5.[†]

Figure 9. Biosimilar Market Share Post-Launch[4§]

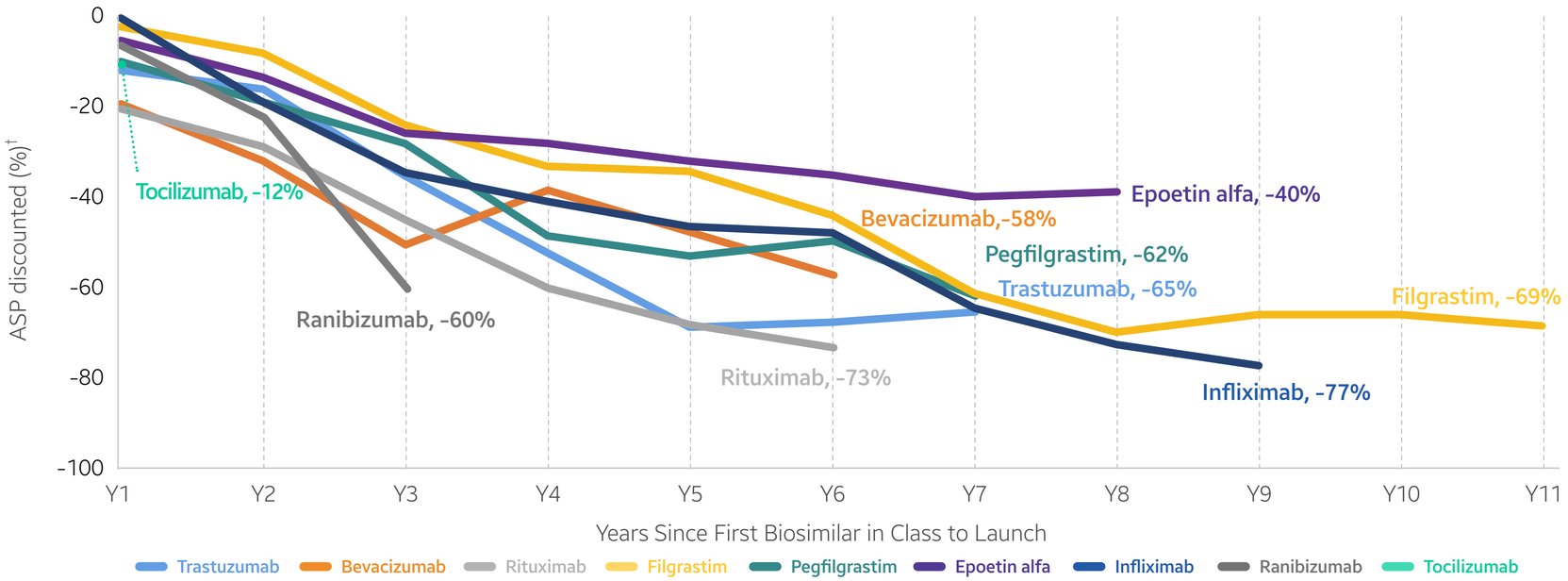


[*] Trastuzumab, bevacizumab, and rituximab [†] Averages include products that are 5 years or older [‡] Infliximab and adalimumab [§] Calculated based on calendar year

Biosimilars are Reducing Drug Costs across Multiple TAs by Lowering Prices

- Biosimilar launches have led to significant price decreases over time. In Y1, average ASP discounts have ranged from -1% (infliximab) to -22% (ranibizumab, bevacizumab).
- On average, ASP decreased by 52% within five years of the first biosimilar launch, with more mature markets achieving even greater price reductions over time (up to 77%).
- Declines in ASP within certain molecular markets do not always follow a consistent trend as they may be affected by intentional ASP repositioning and the deliberate removal of products from the market.

Figure 10. ASP Trend by Molecule[3]



TA: Therapeutic Area; ASP: Average Sales Price
† ASP discounted % vs. reference product ASP when first biosimilar in class launch

Market Share and ASP Trends - Herceptin (Trastuzumab)

- As of Q2 2025, the biosimilar share of the trastuzumab market was 88% (unchanged vs. last quarter).
- As of Q4 2025, average ASP of all biosimilar products is $1,472, representing a -19% from last quarter mainly driven by a decrease in Hercessi's ASP.
- Market shares have remained mostly stable, with Hercessi gaining some share shortly after launch.

Figure 11. Trastuzumab Volume Market Share[4]

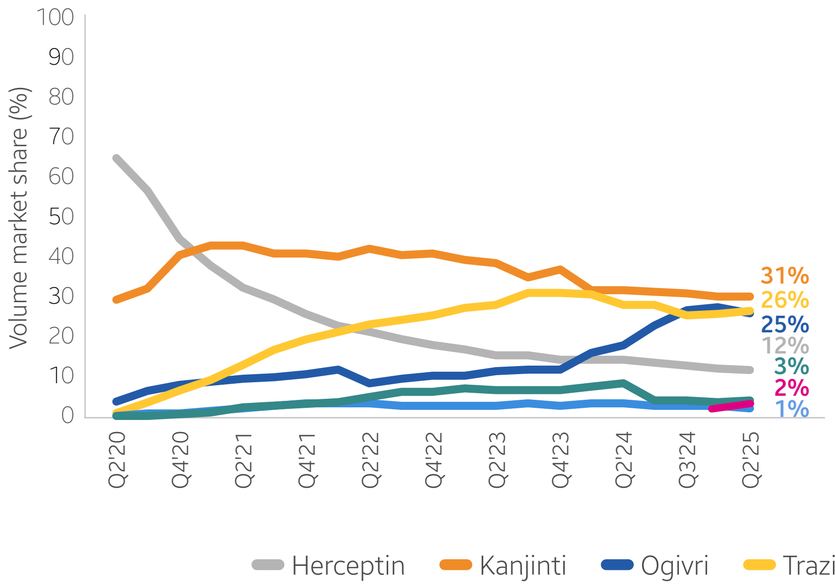
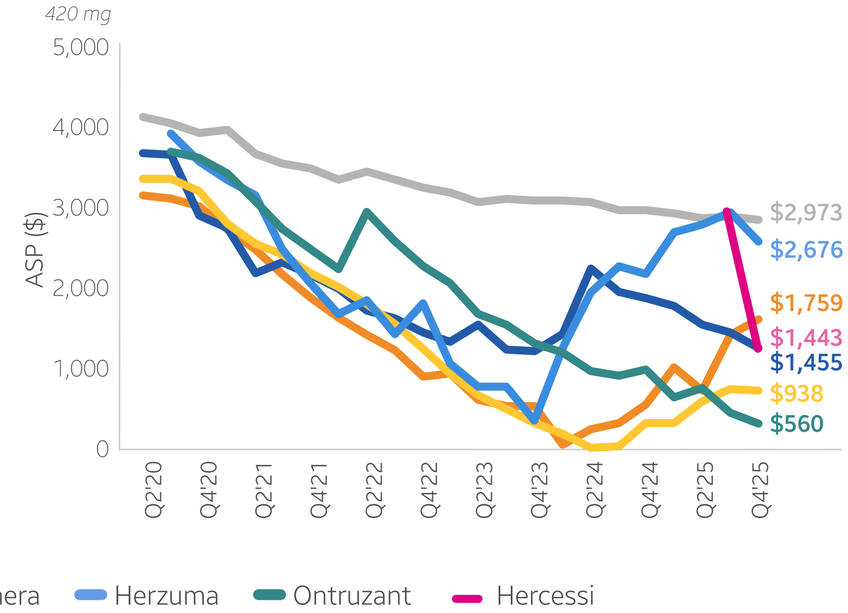


Figure 12. Trastuzumab ASP Trend[3]



Products are listed in legends in order of launch
ASP: Average Sales Price

Market Share and ASP Trends - Avastin (Bevacizumab)

- As of Q2 2025, the biosimilar share of the bevacizumab market was 92% (+2% vs. last quarter).
- As of Q4 2025, the average ASP of all biosimilar products is $1,093 (-7% vs. last quarter).
- Following the resolution of its supply shortage, Zirabev's market share has steadily increased throughout the year, with a notable 6% gain in the most recent quarter.

Figure 13. Bevacizumab Volume Market Share[4]

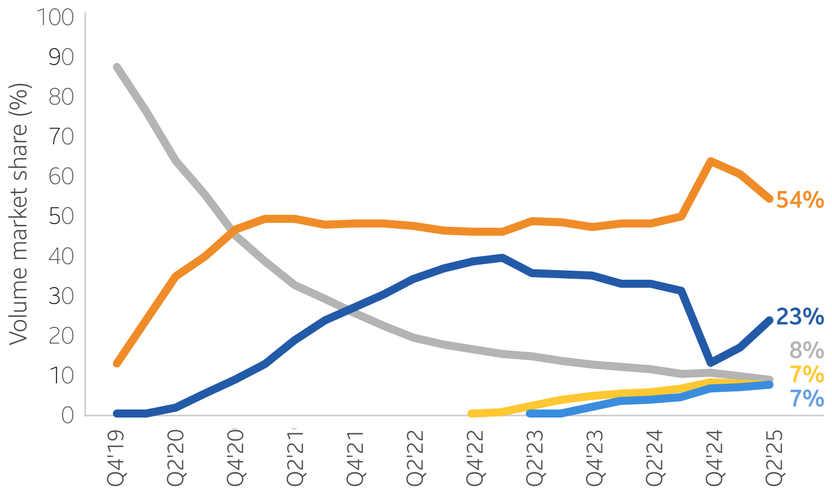
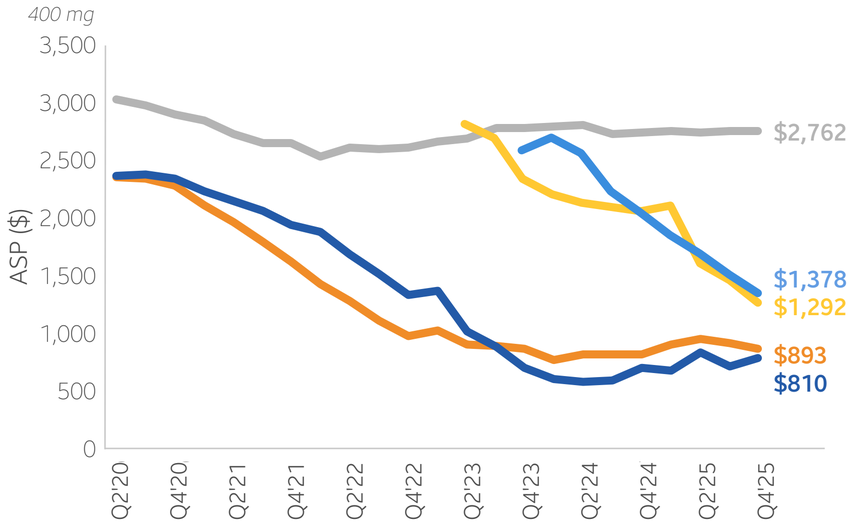


Figure 14. Bevacizumab ASP Trend[3]



Avastin Mvasi Zirabev Alymsys Vegzelma

Products are listed in legends in order of launch
ASP: Average Sales Price

Market Share and ASP Trends - Rituxan (Rituximab)

- As of Q2 2025, the biosimilar share of the rituximab market was 78% (+1% vs. last quarter).
- As of Q4 2025, the average ASP of all biosimilar products is $1,112 (-5% vs. last quarter).
- Since Q4 2024, Ruxience's ASP has shown a consistent upward trend, and in Q4 2025, it ranks as the second-highest among Rituximab biosimilars.

Figure 15. Rituximab Volume Market Share[4]

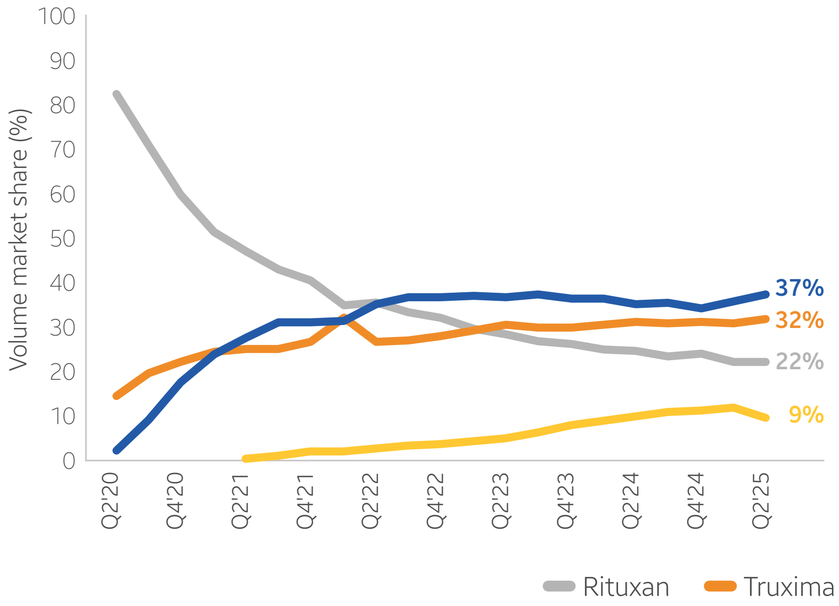
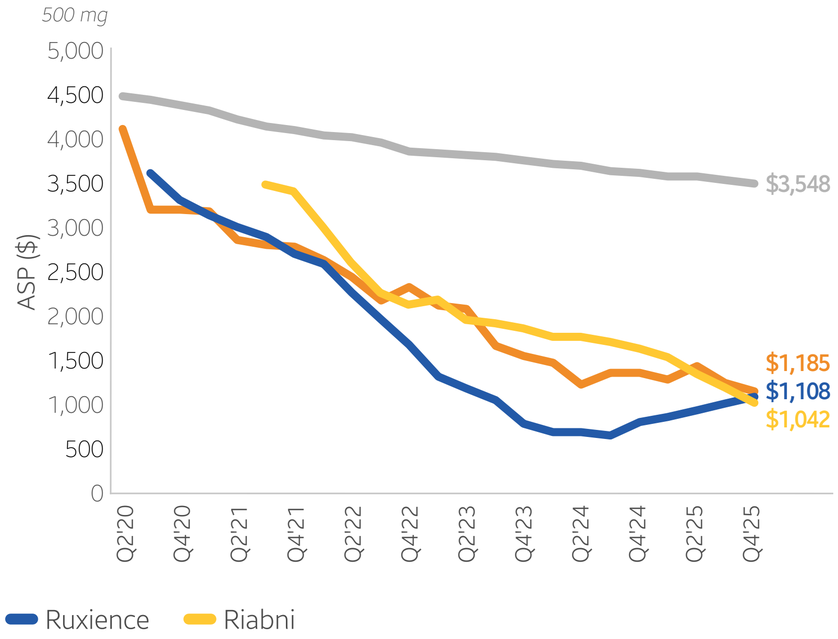


Figure 16. Rituximab ASP Trend[3]



Rituxan Truxima Ruxience Riabni

Products are listed in legends in order of launch
ASP: Average Sales Price

Market Share and ASP Trends - Neupogen (Filgrastim)

- As of Q2 2025, the biosimilar share of the filgrastim market has reached 75% (unchanged vs. last quarter).
- As of Q4 2025, the average ASP of all biosimilar products is $146 (+9% vs. last quarter).
- Despite being the latest to enter the market among filgratism biosimilars, Releuko has steadily increased its market share since its launch.

Figure 17. Filgrastim Volume Market Share[4]

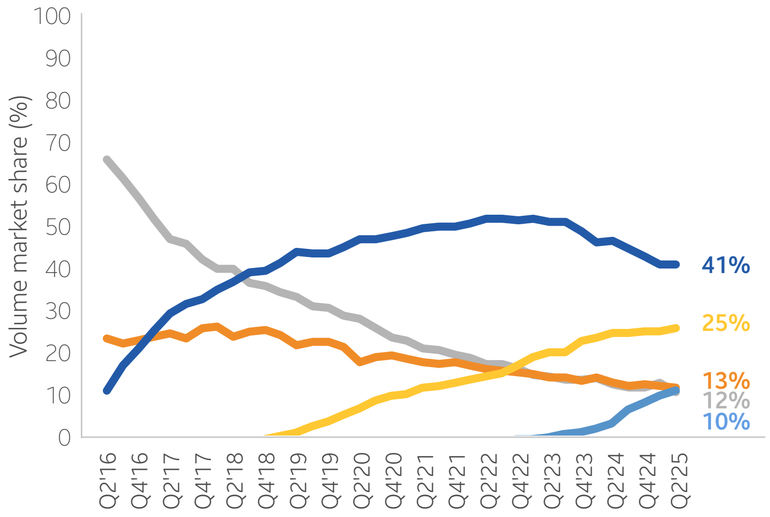
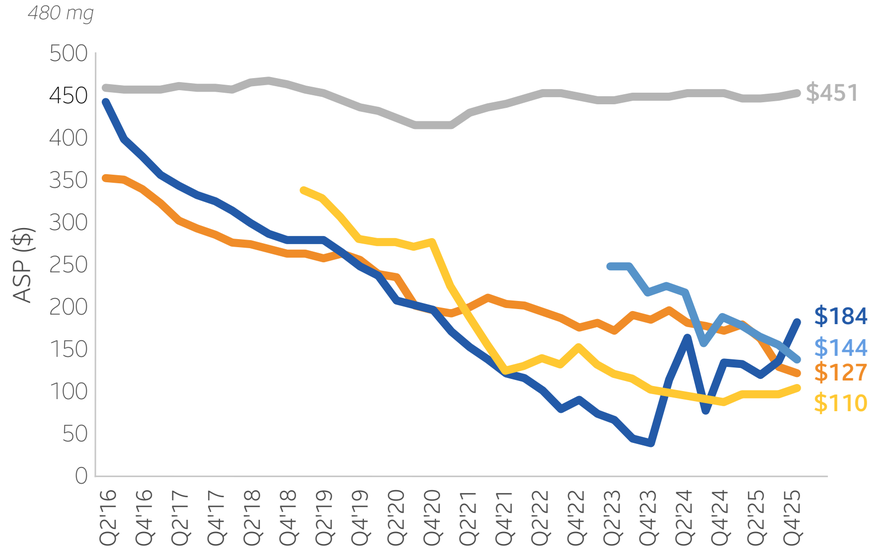


Figure 18. Filgrastim ASP Trend[3]



Neupogen Granix† Zarxio Nivestym Releuko

Legends are listed in order of launch
ASP: Average Sales Price
† Granix is not a biosimilar; it's approved under FDA, a new drug application pathway

Market Share and ASP Trends - Neulasta (Pegfilgrastim)

- As of Q2 2025, the biosimilar share of the pegfilgrastim market was 87% (+3% vs. last quarter).
- As of Q4 2025, the average ASP of all biosimilar products is $1,316 (-13% vs. last quarter).
- Udenyca has steadily regained market share lost in Q4 2024 due to supply shortages from third-party manufacturing constraints.

Figure 19. Pegfilgrastim Volume Market Share[4]

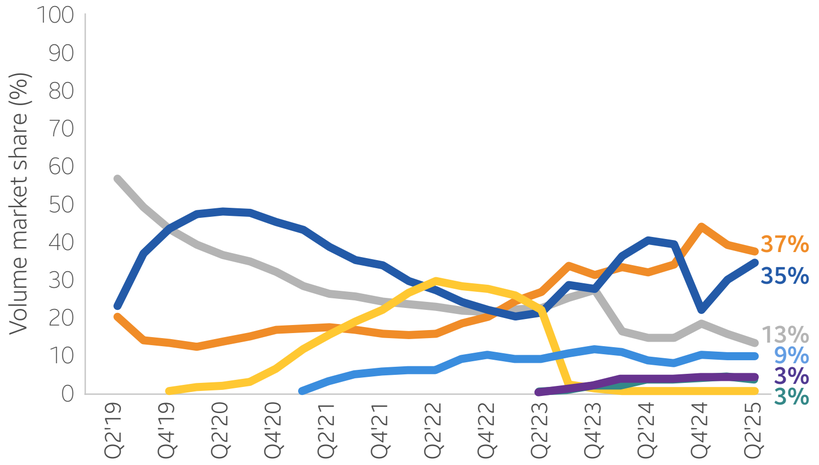
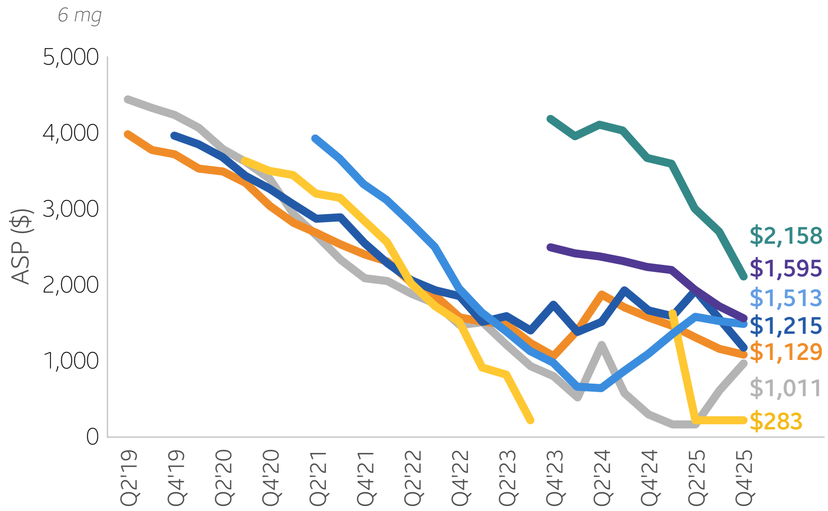


Figure 20. Pegfilgrastim ASP Trend[3]



Neulasta‡ Fulphila Udenyca Ziextenzo† Nyvepria Stimufend Fylnetra

Legends are listed in order of launch **ASP**: Average Sales Price
‡ Onpro is not included † Ziextenzo ASP republished in Q1 2025

Market Share and ASP Trends - Epogen/Procrit (Epoetin alfa)

* Retracrit, the only biosimilar of epoetin alfa, maintains more than a third of the epoetin alfa market share.
* By matching ASP, the two reference products (Epogen/Procrit) have maintained a combined share of approximately 63%.

Figure21. Epoetin Alfa Volume Market Share[4]

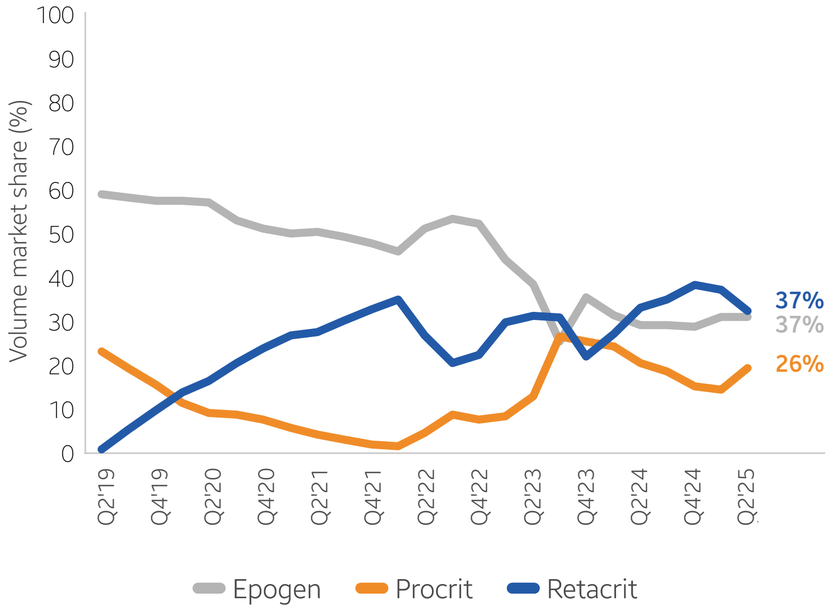
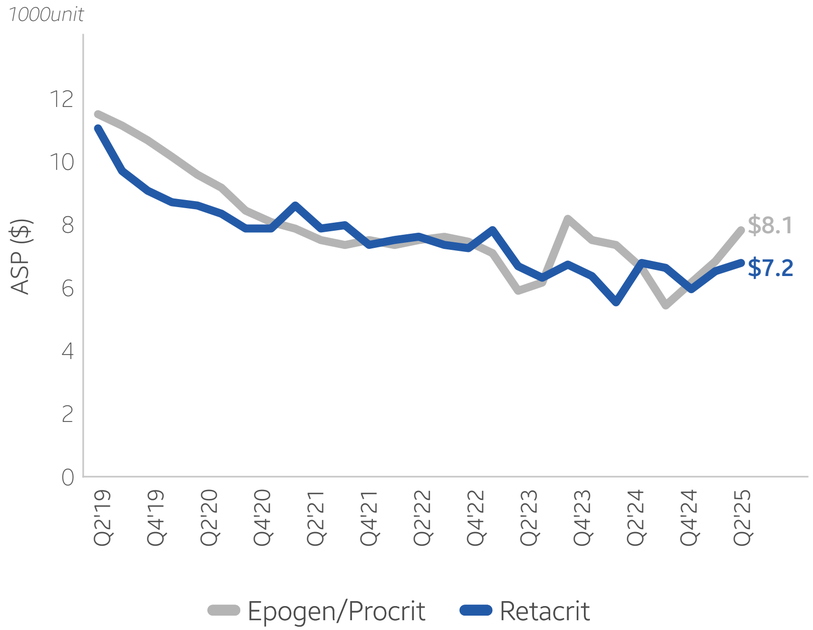


Figure 22. Epoetin Alfa ASP Trend[z]



Legends are listed in order of launch
ASP: Average Sales Price

Market Share and ASP Trends - Remicade (Infliximab)

- As of Q2 2025, infliximab biosimilar market share has reached 50% (unchanged vs. last quarter).
- As of Q4 2025, the average ASP of all biosimilar products is $201 (+3% vs. last quarter).
- Janssen's competitive ASP pricing and launch of unbranded infliximab of Remicade in Q4 2021 have allowed the reference product to hold onto the market leading position.

Figure 23. Infliximab Volume Market Share[4]

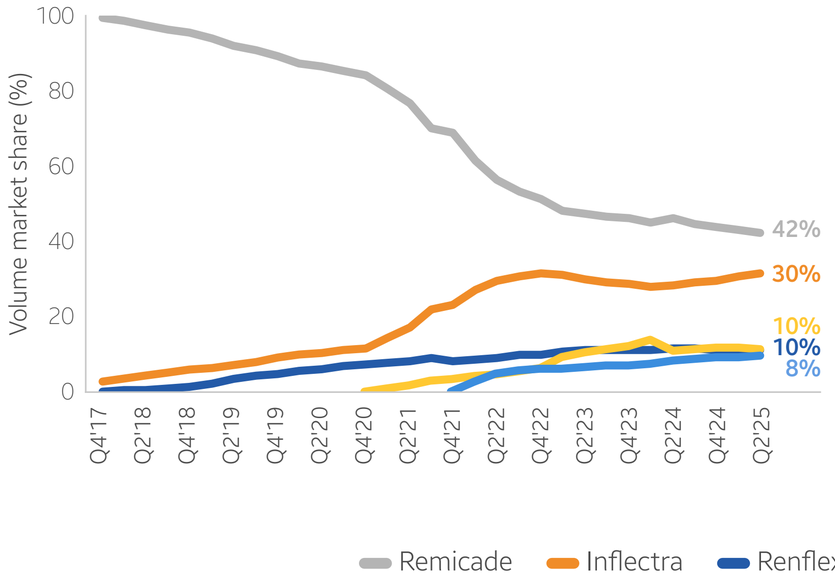
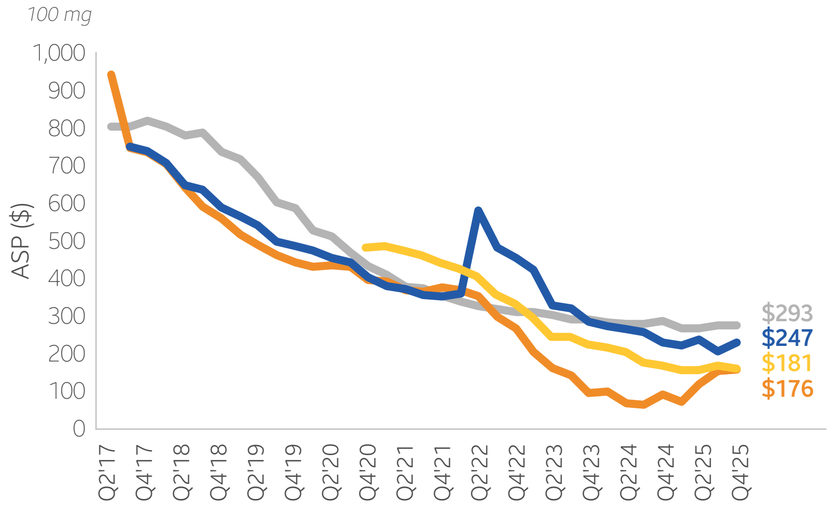


Figure 24. Infliximab ASP Trend[3]



Remicade Inflectra Renflexis Avsola Unbranded Infliximab†

Legends are listed in order of launch
ASP: Average Sales Price
†Janssen's Remicade without the brand name ‡Remicade and Unbranded Infliximab share a J code

Market Share and WAC Trends - Humira (Adalimumab)

- **Excluding Cordavis product dynamics, adalimumab biosimilars' market share has increased in 2025 as Humira's market share continues to slowly erode.**
- **Biosimilar brands have launched the market with diverse WAC pricing strategies.**
  1) Hadlima, Yusimry, and Simlandi offer a low WAC: ~85-86% less than Humira.
  2) Cyltezo, Amjevita, Hyrimoz, Yuflyma, and Abrilada offer dual/multiple pricing options (i.e. high and low WAC).
  3) OptumRx, CVS, and ESI contracted with select manufacturers to offer private label biosimilars available through their subsidiaries, Nuvaila, Cordavis, and Quallent, respectively.

Figure 25. Adalimumab Volume Market Share[5]

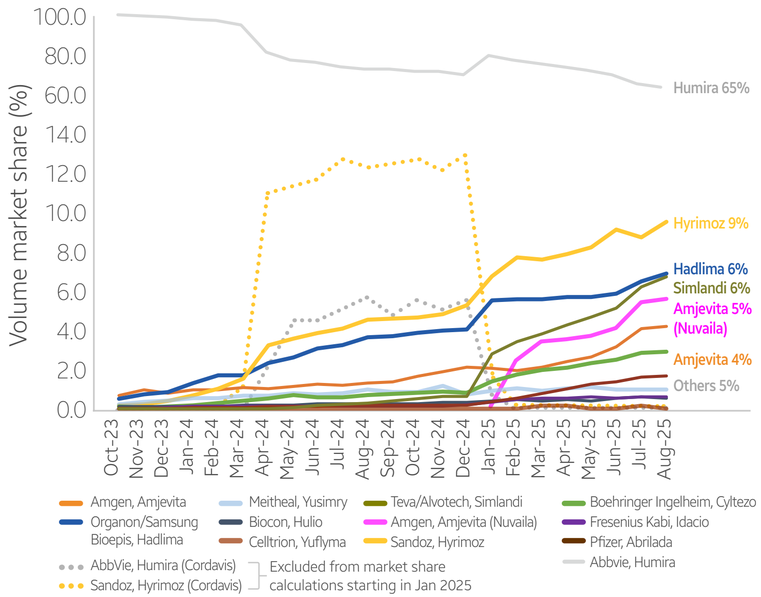
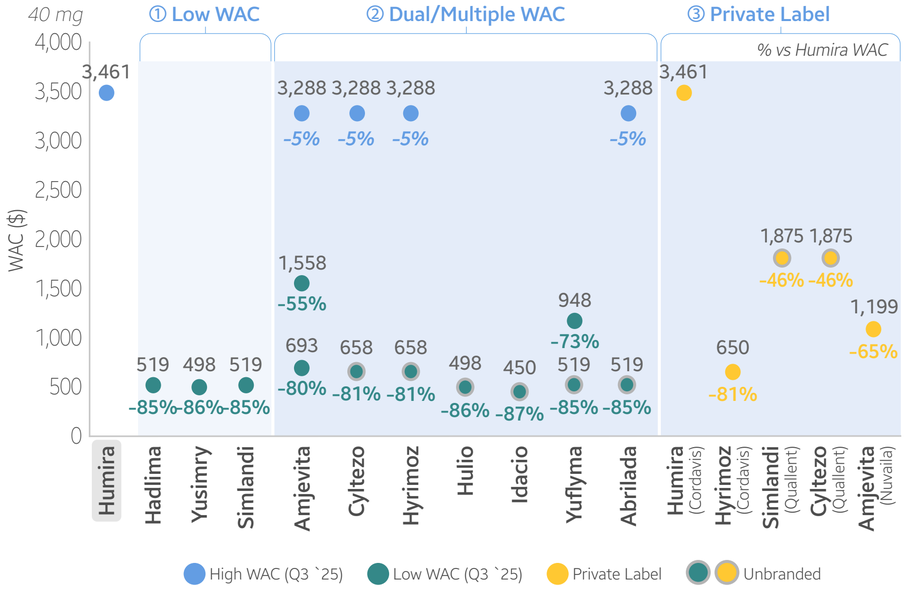


Figure 26. Adalimumab WAC Trend[7]



CVS Health's private label biosimilars, Humira (Cordavis) and Hyrimoz (Cordavis), do not have any published market share data available as of Jan 2025 and thus market share calculations do not reflect these two products.
WAC: Wholesale acquisition cost

Market Share and ASP Trends - Actemra (Tocilizumab)

- As of Q2 2025, tocilizumab biosimilars still hold a low market share, accounting for only 11.2% of the total market.
- As of Q4 2025, the average ASP of all biosimilar products is $1,818 (-6% vs. last quarter).
- Tyenne, the tocilizumab biosimilar with the higher ASP discount (26% lower than the reference product), has been consistently gaining market share.

Figure 27. Tocilizumab Volume Market Share[4]

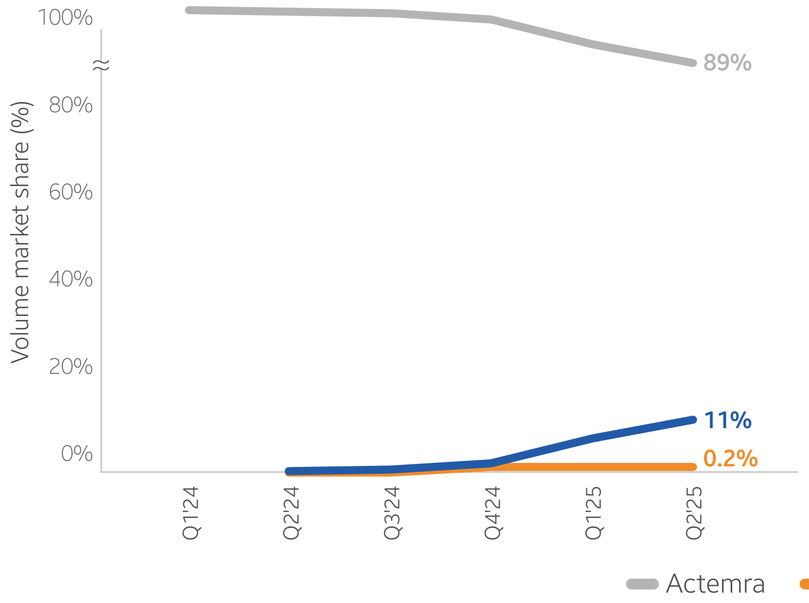
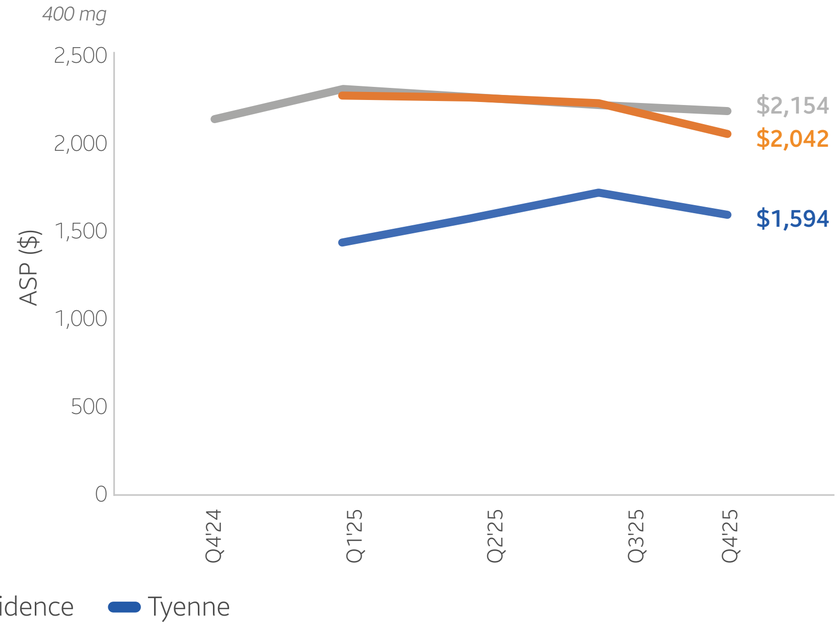


Figure 28. Tocilizimab ASP Trend[3]



WAC: Wholesale acquisition cost
*The WAC price of Actemra Subcutaneous Solution Prefilled Syringe 162 MG/0.9 ML and Subcutaneous Solution Auto-injector 162 MG/0.9 ML

Market Share and WAC Trends - Lantus (Insulin glargine)

Sanofi's dual pricing strategy and competitive rates have helped to maintain Lantus' position as the market leader.

Insulin Glargine Market Background

- Lantus (Sanofi): reference product, available unbranded
- Toujeo (Sanofi): higher dose insulin glargine product
- Rezvoglar (Eli Lilly): Lantus biosimilar, interchangeable
- Semglee (Biocon): Lantus biosimilar, available unbranded
- Basaglar (Eli Lilly): ISG product approved via New Drug Application pathway

Figure 29. Insulin Glargine Volume Market Share[4]

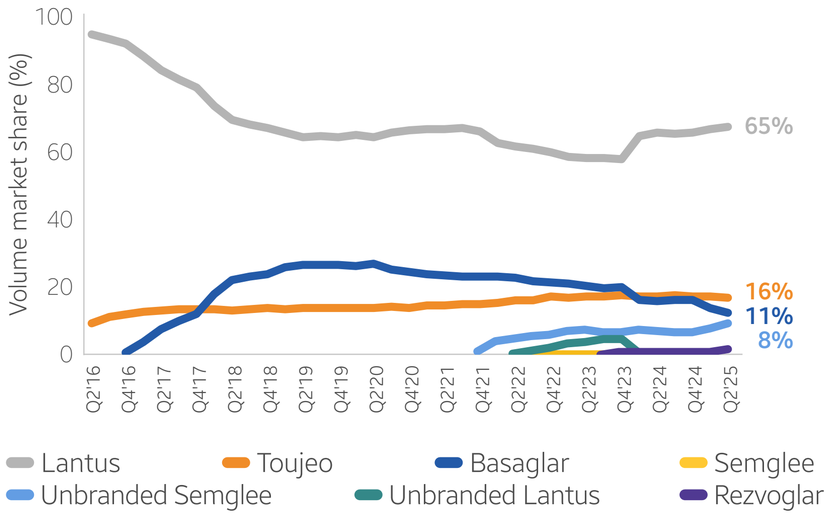
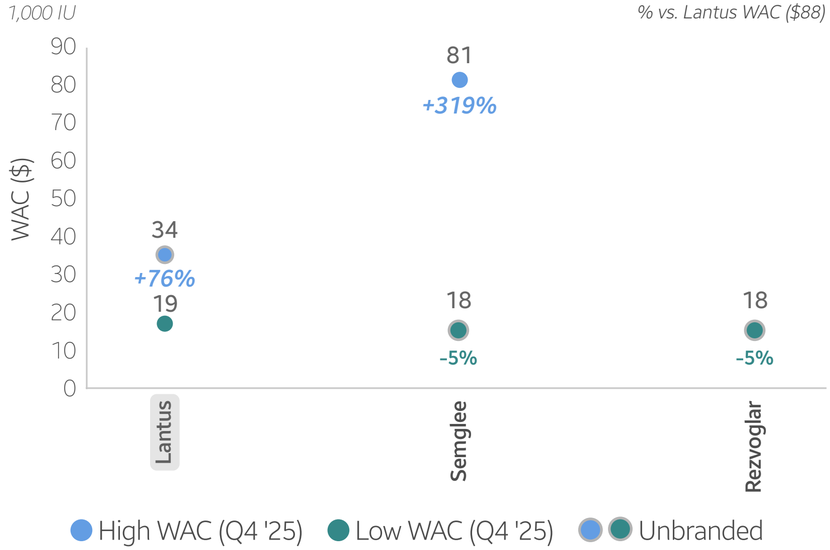


Figure 30. Insulin Glargine WAC Trend[2]



Legends are listed in order of launch
ISG: Insulin glargine; **WAC**: Wholesale Acquisition Cost

Market Share and ASP Trends - Lucentis (Ranibizumab)

- As of Q2 2025, ranibizumab biosimilar market share has reached 90% (+37% vs. last quarter).
- As of Q4 2025, the average ASP of all biosimilar products is $337 (Unchanged vs. last quarter).
- Cimerli market share dropped significantly in Q2 2025 following the pause on commercialization.

Figure 31. Ranibizumab Volume Market Share[4]

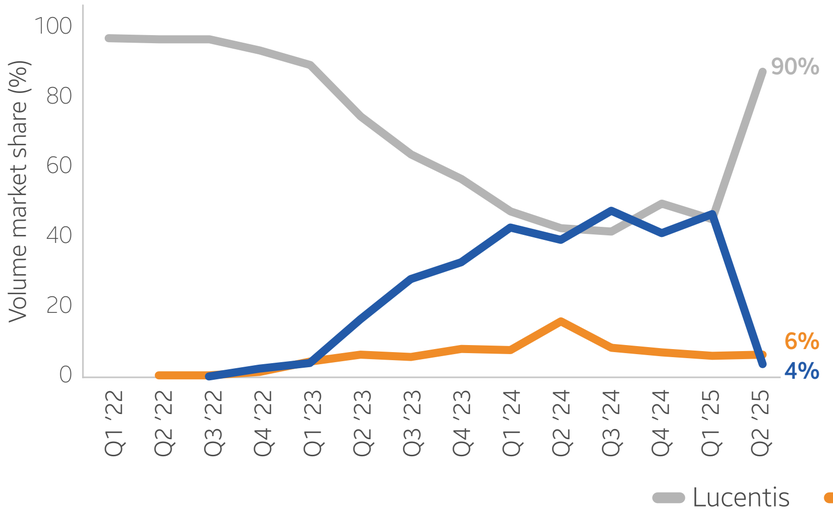
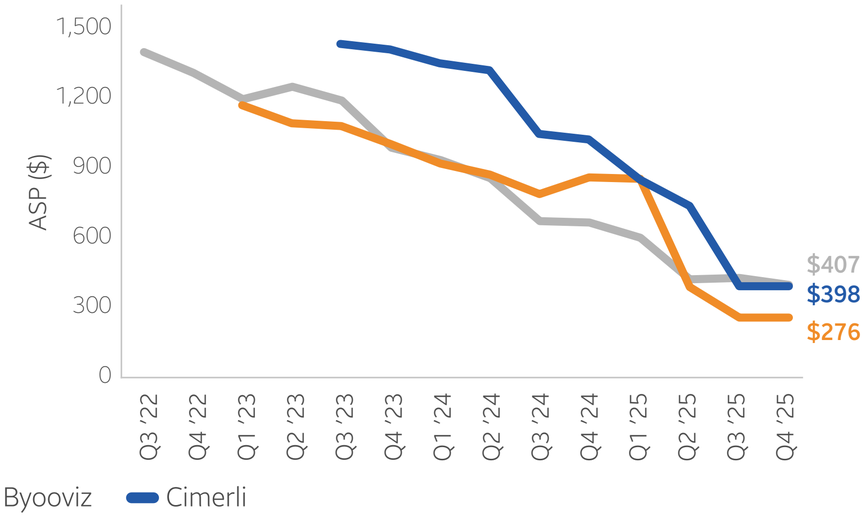


Figure 32. Ranibizumab ASP Trend[3]



Legends are listed in order of launch
ASP: Average Sales Price

IV. Biosimilar Deep Dive

Maximum Fair Price (MFP) Implementation in the US Biosimilar Market

Payer Spotlight: Interview with Former Senior Medicare Executive on MFP Implementation

The Inflation Reduction Act (IRA) introduces sweeping changes to drug pricing and reimbursement, with significant implications for payers, manufacturers, plan sponsors, and providers. One of the most consequential provisions, the Maximum Fair Price (MFP) policy, will take effect in just three months, on January 1, 2026, marking the first round of the U.S. centers for Medicare & Medicaid Services (CMS) negotiated prices for 10 selected drugs under Medicare Part D.

In this issue, we present insights from William Fleming, a former senior Medicare executive, on how payers are preparing for the upcoming implementation of the Maximum Fair Price (MFP) policy. Fleming dives into how MFP is reshaping formulary design, pricing negotiations, and the implications on the biosimilar market.

William K. Fleming, PharmD
Senior Advisor | **Petauri Health**

Dr. William K. Fleming is a seasoned healthcare executive with more than 30 years of leadership experience at Humana, where he held key roles across both the insurance and care delivery sides of the enterprise. Known for his strategic vision and operational depth, he led transformative initiatives across core healthcare services—including primary care, home health, and pharmacy—as well as across a wide range of insurance offerings, including Medicare, Medicaid, TRICARE, and commercial plans. His leadership delivered measurable improvements in clinical quality, member experience, and cost management.

Over the course of his career, Dr. Fleming held multiple C-suite positions and played a pivotal role in aligning Humana's insurance products with its expanding care delivery assets to create integrated, value-based care models. He also helped establish Humana as a national leader in pharmacy services, overseeing the growth of a high-performing pharmacy benefit manager and advancing pharmacy's role in driving better health outcomes.

Dr. Fleming has been deeply engaged in healthcare innovation, private equity partnerships, and board governance. He is a trusted advisor on business growth, healthcare policy, and the evolving payer-provider landscape. He is widely recognized as a policy expert, particularly in areas impacting Medicare, value-based care, and consumer access.

He holds a PharmD and BS in Pharmacy from the University of Kentucky and a BS from Transylvania University.

He is a Fellow of the Academy of Managed Care Pharmacy and currently serves on the boards of Petauri Health, CareShieldAI, and LifeGuides.

Inflation Reduction Act (IRA) Drug Price Negotiation Refresher

Effective Date:

- January 1, 2026

Key Concepts:

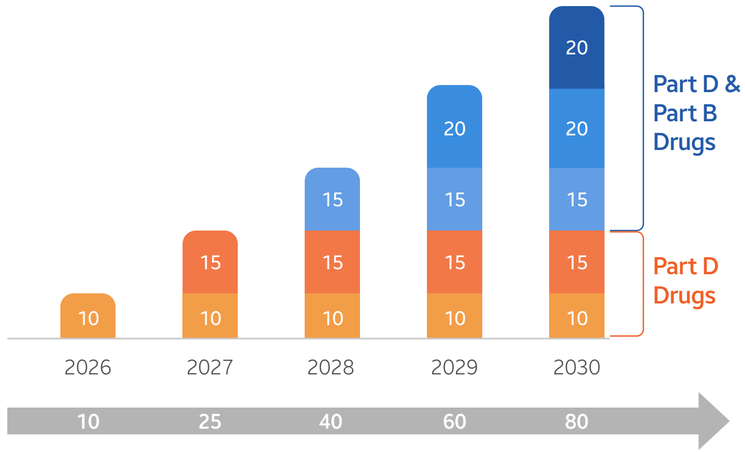
- In August 2023, CMS announced the first 10 drugs selected for Part D negotiation, whose "Maximum Fair Prices" will become effective in 2026.
- In March 2025, CMS announced the negotiated, "Maximum Fair Prices', for the first 10 drugs selected for Part D negotiation.
- By 2030, 70 more drugs from Part D and Part B will be selected.
- Drugs selected for negotiation represent drugs with the highest Medicare expenditures.
- Drugs that have been on the market for less than 9 years (small molecule drugs) or less than 13 years (biologic drugs) are excluded from price negotiation.
- Orphan drugs or drugs with actively launched biosimilar or generic products are also excluded from negotiation.
- The IRA requires all Part D plans to cover drugs with negotiated prices.

10 Drugs Selected for 2026 Part D 'Maximum Fair Price' Negotiation

Drug Name	Agreed to Negotiated Price for 30-day Supply for CY 2026	List Price for 30-day Supply for CY 2023	Discount of Negotiated Price from 2023 List Price %
Januvia	$113.00	$527.00	79%
Fiasp; Fiasp FlexTouch; Fiasp PenFill; Novolog; Novolog FlexPen; Novolog PenFill	$119.00	$495.00	76%
Farxiga	$178.50	$556.0	68%
Enbrel	$2,355.00	$7,106.00	66%
Jardiance	$197.00	$573.00	66%
Stelara*	$4,695.00	$13,836.00	66%
Xarelto	$197.00	$517.00	62%
Eliquis	$231.00	$521.00	56%
Entresto	$295.00	$628.00	53%
Imbruvica	$9,319.00	$14,934.00	38%

Bold: References products with biosimilars approved but not yet launched
**: References products with biosimilars that are approved and launched*

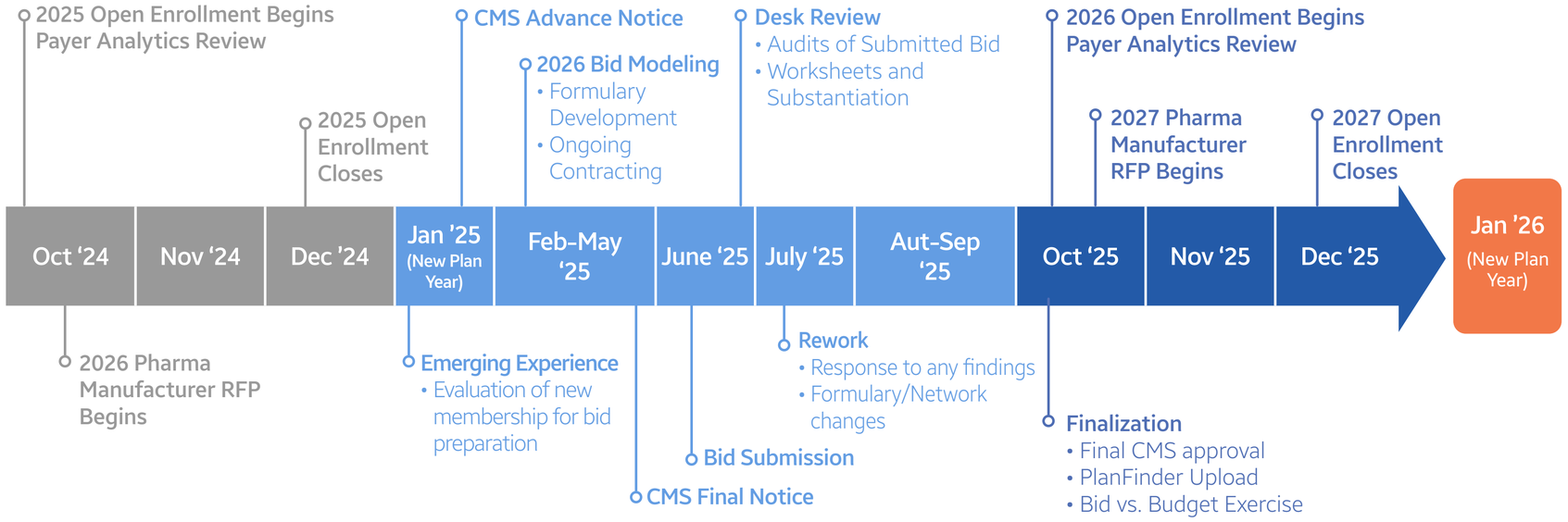
Maximum Number of Negotiated Drugs per Year



Implementation Timeline for 2026 Medicare Plan Year

Timeline:

- Drug companies and the public had an opportunity to submit data and information on the selected drugs to CMS by October 2, 2023.
- During the Fall of 2023, CMS invited each participating drug company to engage in a meeting on its data submission. Additionally, CMS held public Patient-Focused Listening Sessions for each selected drug with patients and other interested parties.
- CMS sent an initial offer to the participating drug company reflecting CMS' proposal for a negotiated price and a concise justification of the initial offer on February 1, 2024. In developing an initial offer, CMS considered the factors set out by the statute, including evidence related to therapeutic alternatives as well as other factors, such as costs of research and development and production and distribution of the selected drug.
- The negotiation period ended on August 1, 2024.
- The negotiated 'Maximum Fair Price' were revealed in March 2025 and are set to be implemented on January 1, 2026.



Navigating MFP and Biosimilar Leverage in Part D Strategy

As the IRA begins reshaping the Medicare landscape, stakeholders across the pharmaceutical and payer ecosystem are grappling with the implications of the MFP policy. With implementation for Part D beginning in 2026, the biosimilar market stands at a critical inflection point. Insights from a former payer executive, William Fleming, reveal a complex, evolving strategy landscape where pricing dynamics, formulary design, and operational models are being reimagined.

Strategic Realignment: Modeling MFP and Biosimilar Leverage

"Payers began preparing for MFP implementation as early as fall 2024, submitting their 2026 bids amid significant uncertainty. Their strategies now hinge on two parallel tracks: modeling direct exposure to MFP for high-cost brands and evaluating biosimilars as cost-saving alternatives. The calculus is straightforward, compare the MFP reference price to the potential net cost of biosimilars. If biosimilars offer greater savings, they are likely to be prioritized on formularies." This strategic shift signals a departure from rebate-driven decision-making. As William noted, "Plans will likely prioritize biosimilars on formulary and negotiate accordingly, especially when biosimilars can undercut MFP thresholds."

Formulary Evolution: Net Price Focus

"With rebates on MFP products likely to disappear, formulary strategies are undergoing a transformation. Plans are expected to push biosimilars more aggressively, potentially reducing step therapy requirements and shifting focus to **absolute net price** rather than rebate optimization. However, this shift must be balanced against CMS requirements and the risk of adverse selection, particularly in the catastrophic coverage phase where plans now assume 60% of the liability." William emphasized that "plans will need to balance those savings against CMS requirements to ensure beneficiary access."

Market Dynamics: Mixed Signals for Biosimilar Uptake

The introduction of MFP is expected to produce a mixed impact on biosimilar adoption. "In some cases, lower negotiated prices for reference products may narrow the incentive to switch. However, biosimilars that maintain a pricing advantage or offer greater contracting flexibility could see accelerated uptake. Most likely, we may see a mixed picture with some categories where biosimilars thrive and others where MFP blunts their advantage," Fleming explained. This nuanced view underscores the importance of category-specific analysis and the evolving role of biosimilars in payer strategies.

Navigating MFP and Biosimilar Leverage in Part D Strategy

Operational Complexity: Forecasting in a Fog

"One of the most significant challenges for payers is the **uncertainty** surrounding MFP implementation. Variables such as product selection timing, biosimilar launch pricing, and shifting rebate structures complicate financial modeling," Fleming noted. Additionally, behavioral factors include how physicians and patients respond to pricing changes which add layers of unpredictability. "This complexity is compounded by broader industry trends, including a projected $300 billion in pharmaceutical pipeline costs over the next 3–5 years. As rebate economics fade, payers and PBMs are pivoting to alternative revenue models, such as administrative fees and data services."

Pharmacy Economics: A New Risk Landscape

Pharmacies may face financial strain if acquisition costs for MFP-capped products exceed reimbursement rates. "This could disrupt cash flows and require adjustments in payment terms or claims-level adjudication safeguards. Interestingly, biosimilars may offer a stabilizing force if their acquisition costs better align with reimbursement structures", noted Fleming.

Innovation at Risk: The Biosimilar Pipeline Challenge

While MFP aims to reduce costs for beneficiaries, it may inadvertently discourage investment in biosimilar development. If reference drug prices are capped too low, biosimilars lose their competitive edge, weakening the business case for innovation especially for smaller market products. "There's a real risk that if reference prices are capped too low, biosimilars lose their competitive edge," Fleming warned. This concern is amplified by the emergence of PBM-owned biosimilars, which could further disrupt traditional market dynamics.

Conclusion: A Market in Flux

The introduction of MFP is reshaping the biosimilar landscape in profound ways. While it offers opportunities for cost savings and formulary innovation, it also introduces new risks - financial, operational, and strategic. Stakeholders must navigate this evolving terrain with agility, balancing affordability with sustainability to ensure a robust biosimilar market in the years ahead.

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