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Biosimilar Market Report

10th Edition, Q3 2025

FOREWORD

We are pleased to share the 10th edition of the Biosimilar Market Report, marking an important milestone in our ongoing effort to provide timely, in-depth analysis of this evolving sector.

When we first launched this report in Q2 2023, the US market had seen the approval of 40 biosimilars, with 28 products commercially launched. As of this 10th edition, the numbers have risen to 75 approvals and 53 launches, reflecting the market's accelerating pace and growing complexity. As the biosimilar landscape continues to evolve at a rapid pace, our aim remains to provide clear, data-driven insights to help our readers navigate this increasingly dynamic environment.

This edition features two in-depth topics. The first examines the recently proposed Most-Favored-Nation (MFN) drug pricing and its potential implications for the biosimilar market. The second explores the critical roles of drug quality and supply stability in the pharmaceutical sector, highlighting the risks and consequences that may arise when these foundational standards are not adequately maintained. The complexity of today's global healthcare market has expanded the need to broaden product evaluations beyond the traditional clinical and pricing assessments.

We extend our sincere gratitude to our readers for continued interest and support, and we look forward to sharing further insights in future editions.

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

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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 June 2025, the FDA has approved a total of 75 biosimilars across 19 unique biological molecules. Of the 75 approvals, 53 biosimilars (71%) have launched in the US market.

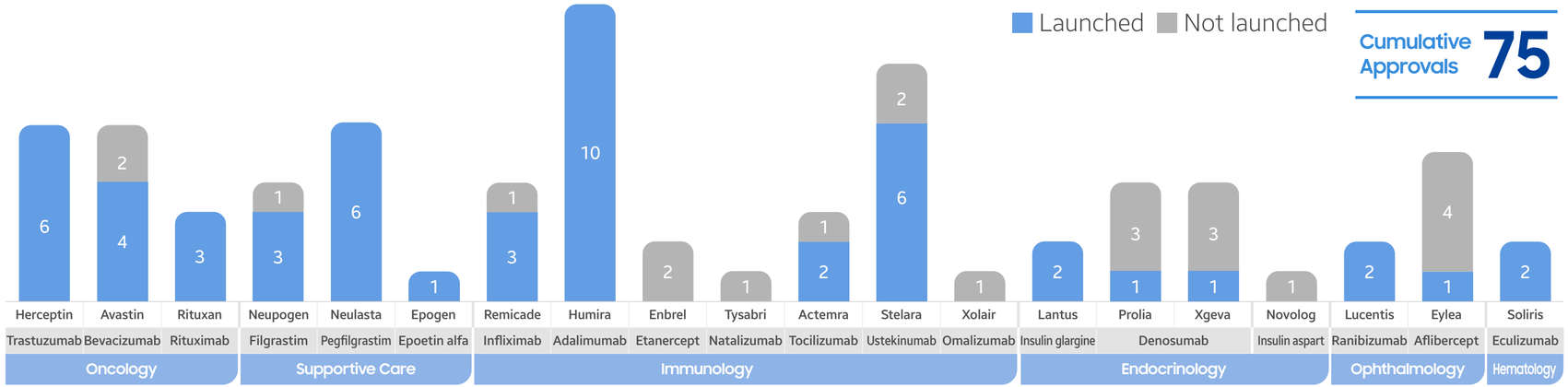
Figure 1-1. 10 FDA-approved Biosimilars in Q2`25

Reference Product	Biosimilar name	Biosimilar Manufacturer
Stelara	Starjemza	Bio-Thera
Avastin	Jobevne	Biocon

Figure 1-2. 7 Biosimilars Launched in the US Market in Q2`25

Reference Product	Biosimilar name	Biosimilar Manufacturer & Commercial Partner	Launch Date
Prolia	Jubbonti	Sandoz	Jun 2025
Xgeva	Wyost	Sandoz	Jun 2025
Soliris	Epysqli	Samsung Bioepis & Teva	Apr 2025
	Bkemv	Amgen	Apr 2025

Figure 2. Biosimilars Approval and Launch Status in the US[1*] (As of Jun 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 June 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				Yeintek (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 June 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		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	
					Pavblu (aflibercept-ayyh) Amgen 2024			Stimufend (pegfilgrastim-fpgk) Fresenius Kabi 2022	
								Fylnetra (pegfilgrastim-pbbk) Amneal&Kashiv 2022	

Launched Not launched

*Trade marks are not described to all brands

II. Biosimilar Price
(Medical Benefit & Pharmacy Benefit)

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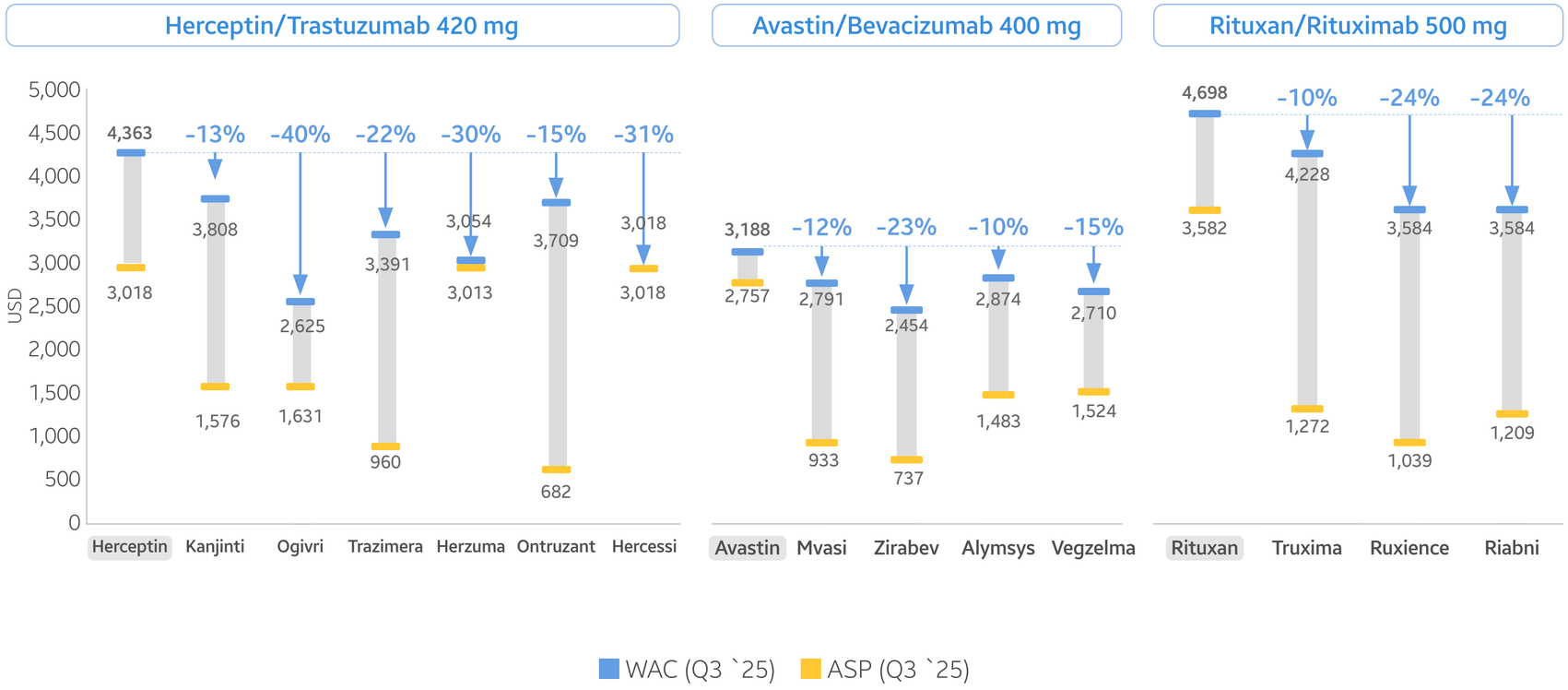
Oncology WAC and ASP – Q3 2025

- Across oncology biosimilars, WAC prices discounted between 10-40% compared to reference products.
- Biosimilar Q3 2025 ASP discounts as compared to the reference product's ASP average -40%, -58%, and -67%, and -65% for the trastuzumab, bevacizumab, and rituximab markets, respectively.

Figure 4. Q3 2025 WAC and ASP[2,3]

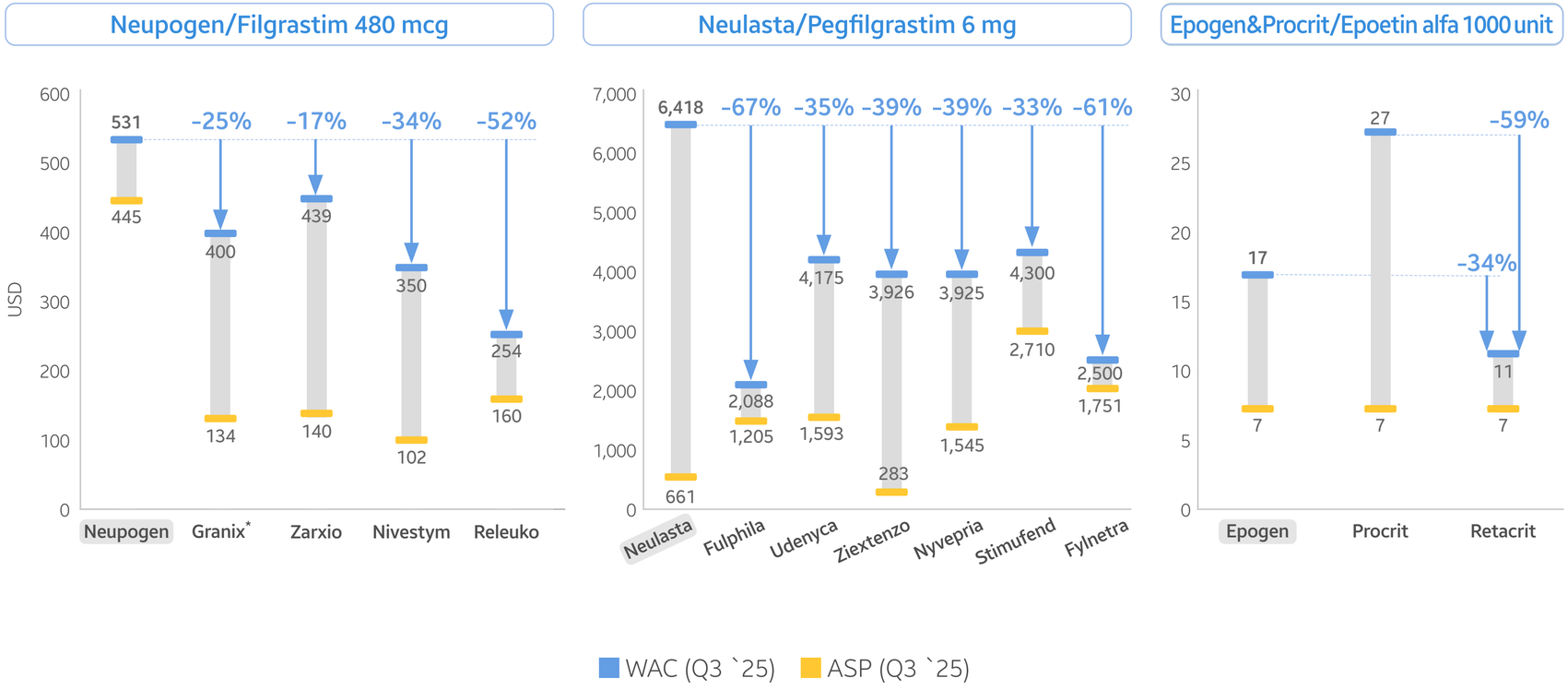


Products are listed in order of launch
ASP: Average Sales Price; **WAC**: Wholesale Acquisition Cost

Supportive Care WAC and ASP - Q3 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. Q3 2025 WAC and ASP[2,3]

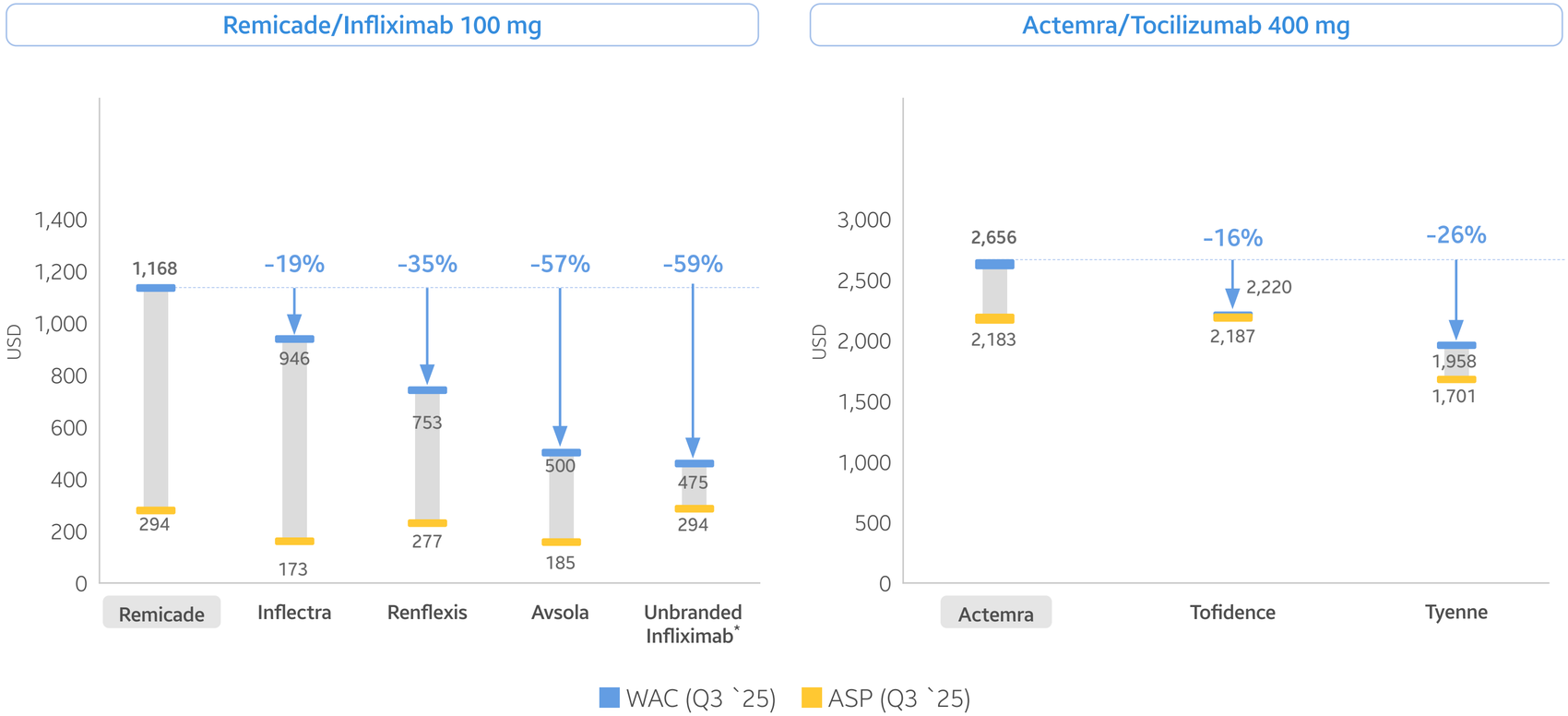


Products are listed in order of launch
ASP: Average Sales Price; **WAC**: Wholesale Acquisition Cost
*Granix is not a biosimilar; approved under the FDA's New Drug Application pathway

Immunology WAC and ASP - Q3 2025

- Infliximab biosimilars launched with progressively lower WACs, ranging from -19% to -59% in discounts.
- The two tocilizumab biosimilars have distinct ASP pricing strategies: Tofidence has an ASP 0.1% higher than the reference product, while Tyenne offers a significant discount of 22% compared to the originator.

Figure 6. Q3 2025 WAC and ASP[2,3]

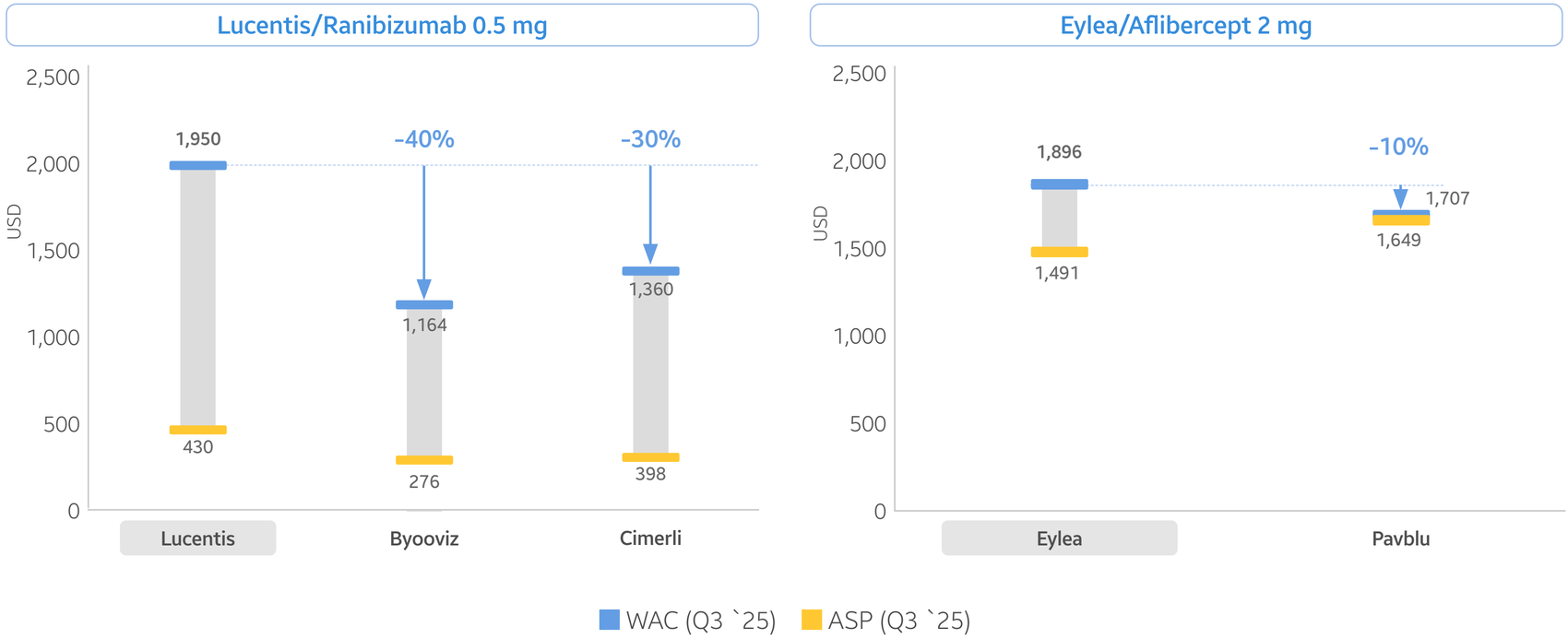


Products are listed in order of launch
ASP: Average Sales Price; **WAC**: Wholesale Acquisition Cost
*Janssen's Remicade without the brand name

Ophthalmology WAC and ASP – Q3 2025

- With only two competing biosimilars on the market, ranibizumab WACs represent -30% to -40% WAC discounts as compared to the reference product.
- Ranibizumab biosimilars are showing a continuous and steep decrease in average ASP, with a 39% decrease compared to last quarter.

Figure 7. Q3 2025 WAC and ASP[2,3]

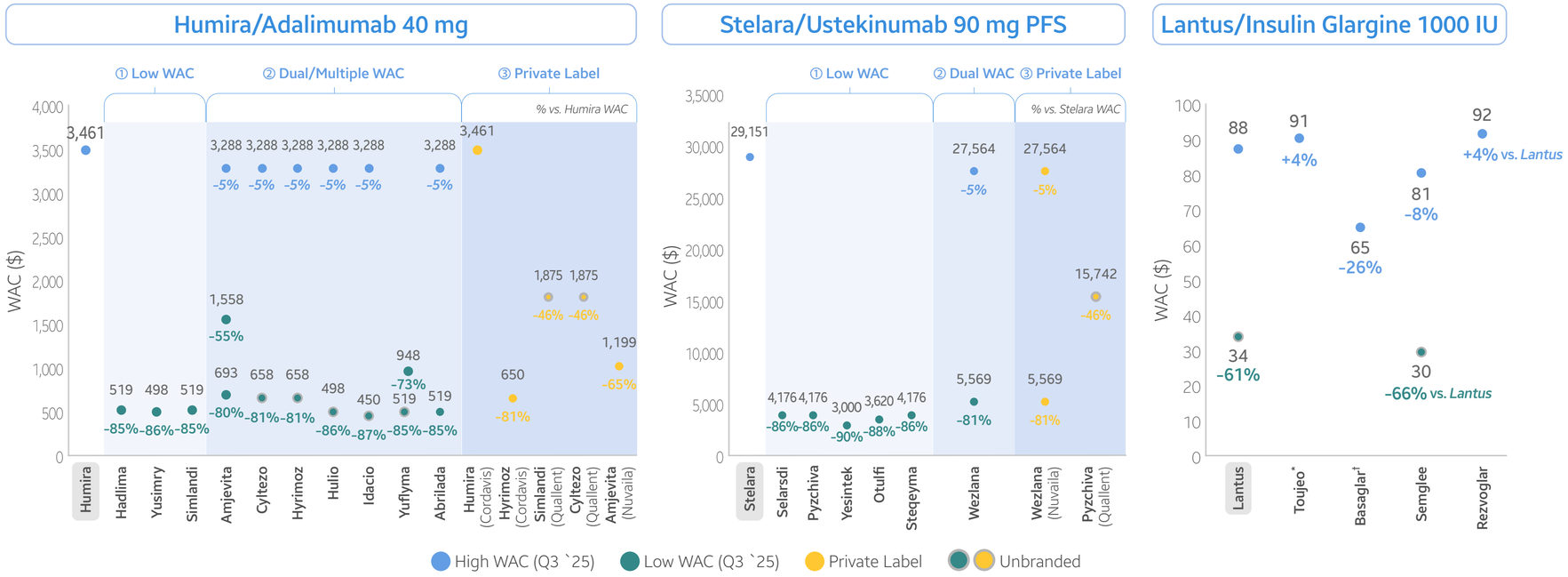


Products are listed in order of launch
ASP: Average Sales Price; **WAC**: Wholesale Acquisition Cost

Immunology & Endocrinology WAC – Q3 2025

- Adalimumab & 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.
- The beginning of 2025 marked the entrance of Stelara's biosimilar, ustekinumab; upon Stelara's loss of exclusivity, entrants provided steep WAC discounts of greater than 80%.

Figure 8. Q3 2025 WAC[2,12]



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

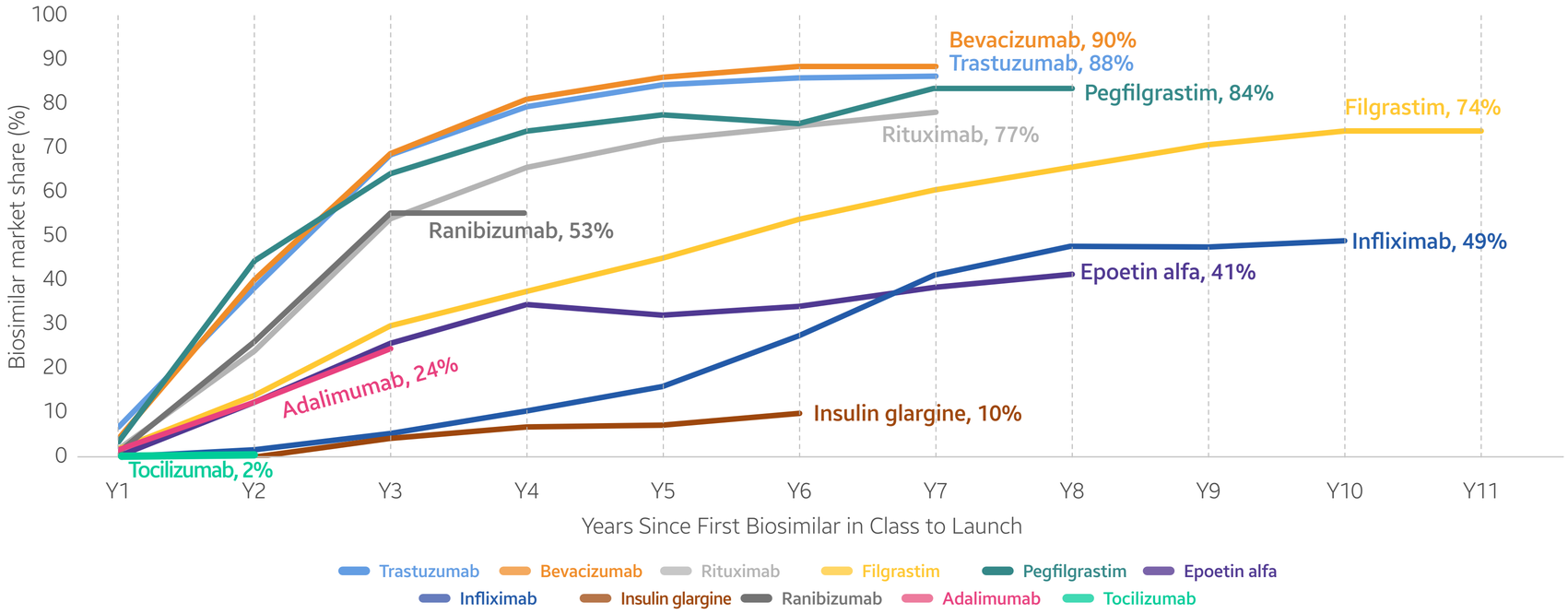
Biosimilar Volume Uptake Varies by Molecule

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§]

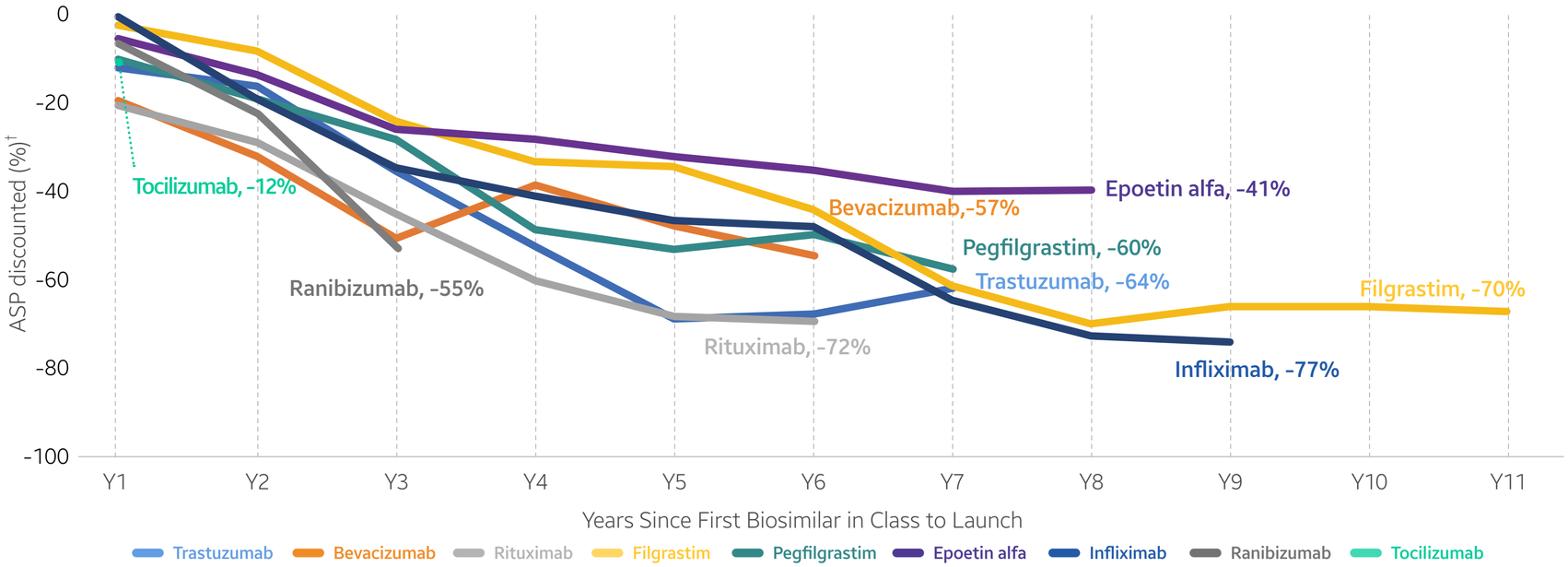


[*] Trastuzumab, bevacizumab, and rituximab [†] Averages include products that are 5 years or older [‡] Infliximab and adalimumab [§] Calculated based on calendar year

Biosimilars are Reducing Drug Costs across Multiple TAs by Lowering Prices

- Biosimilar launches have led to significant price decreases over time. On average, ASP decreased by 53% within five years of the first biosimilar launch, with more mature markets achieving even greater price reductions over time.
- Recently observed increases in ASP for some markets (e.g. trastuzumab, bevacizumab, pegfilgrastim and filgrastim) may be due to 1) artifacts of newly-launched, low-market share biosimilars with ASPs that reflect WAC pricing and 2) intentional ASP repositioning of some biosimilars.

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 Q1 2025, the biosimilar share of the trastuzumab market was 88% (+1% vs. last quarter).
- As of Q3 2025, the average ASP of all biosimilar products is $1,814, representing a +25% increase from last quarter driven by ASP increases across many trastuzumab products and Hercessi's market entrance.
- Ogivri's market share continues to grow, positioning it alongside other leading biosimilars, Kanjinti and Trazimera, and highlighting the intense competitiveness of the market.

Figure 11. Trastuzumab Volume Market Share[4]

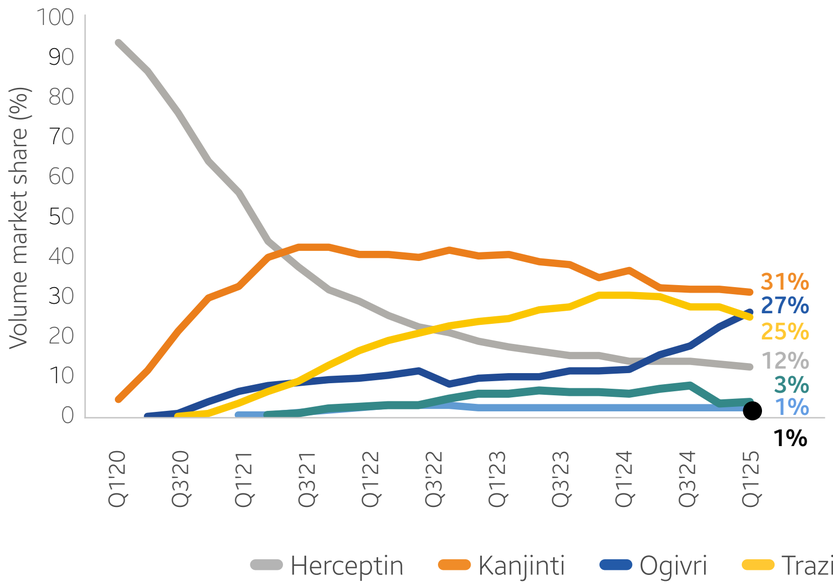
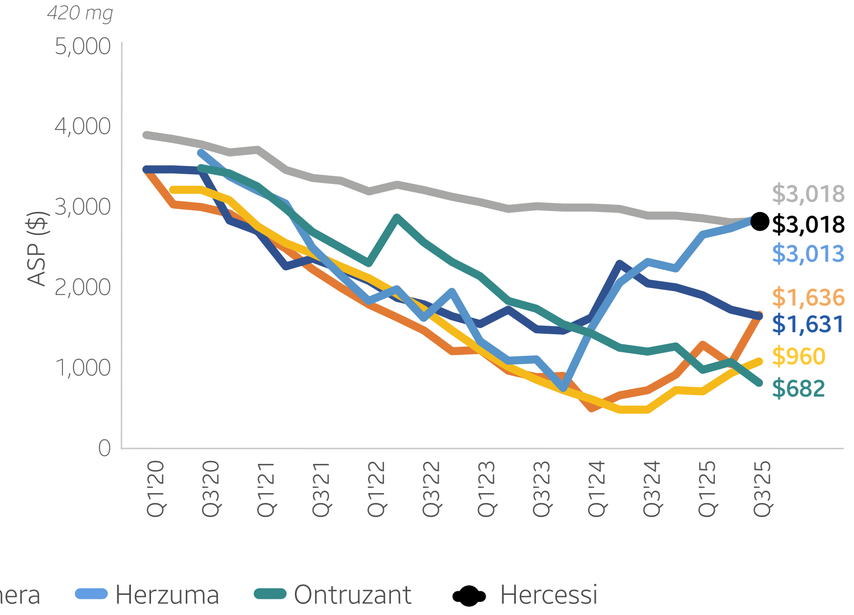


Figure 12. Trastuzumab ASP Trend[3]



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

Market Share and ASP Trends - Avastin (Bevacizumab)

- As of Q1 2025, the biosimilar share of the bevacizumab market was 90% (Unchanged vs. last quarter).
- As of Q3 2025, the average ASP of all biosimilar products is $1,169 (-9% vs. last quarter).
- Following the resolution of its recent shortage, Zirabev's market share partially recovered, increasing by approximately 4%.

Figure 13. Bevacizumab Volume Market Share[4]

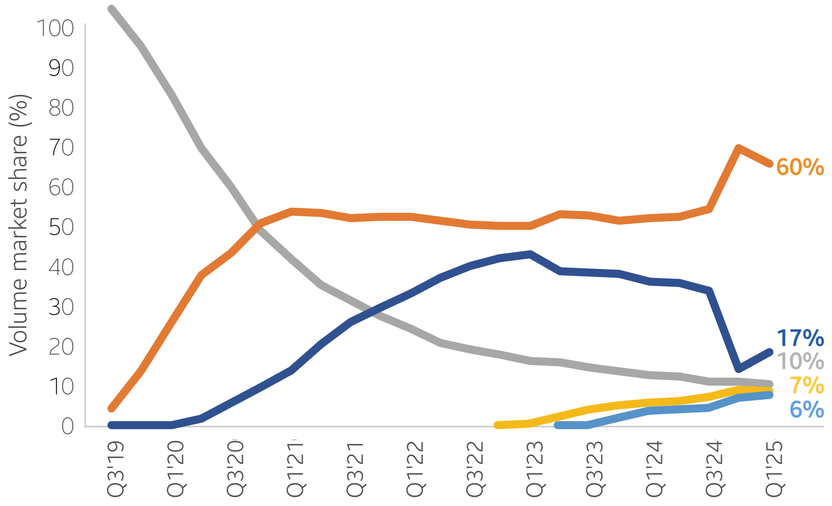
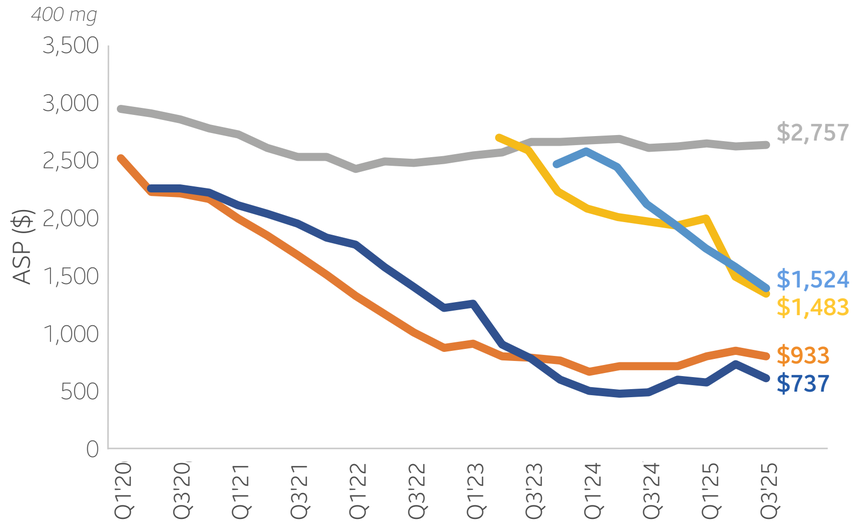


Figure 14. Bevacizumab ASP Trend[3]



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 Q1 2025, the biosimilar share of the rituximab market was 77% (+1% vs. last quarter).
- As of Q3 2025, the average ASP of all biosimilar products is $1,173 (-7% vs. last quarter).
- In the rituximab market, lower priced biosimilars are dominating the market. The most recent entrant, Riabni, continues to grow in market share while its ASP continues to trend downward.

Figure 15. Rituximab Volume Market Share[4]

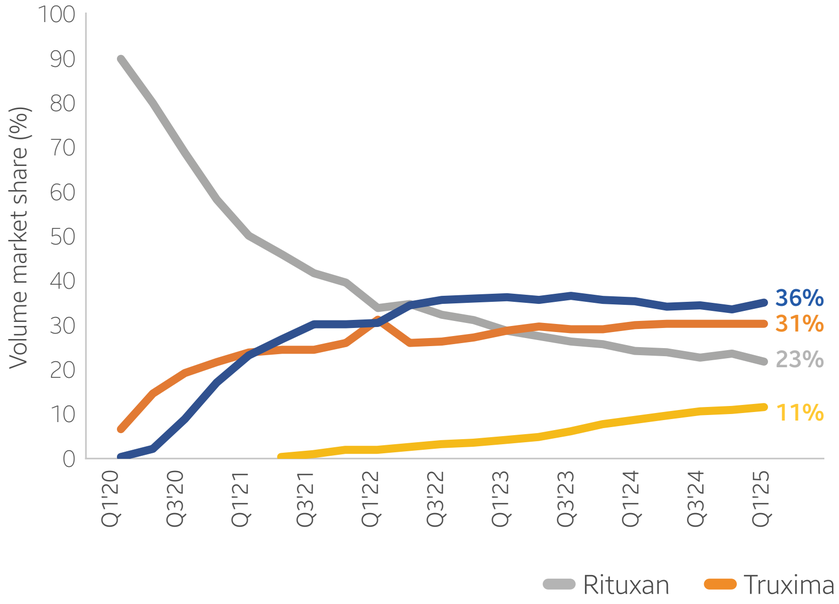
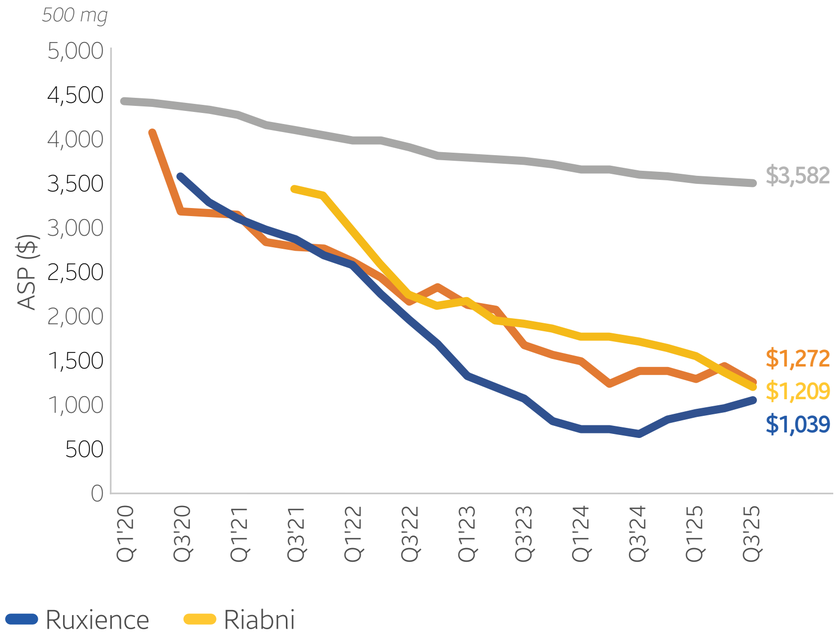


Figure 16. Rituximab ASP Trend[3]



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 Q1 2025, the biosimilar share of the filgrastim market has reached 74% (-1% vs. last quarter).
- As of Q3 2025, the average ASP of all biosimilar products is $134 (-4% vs. last quarter).
- The newest entrant, Releuko, shows a steep increasing market share trend. Also, it maintains the highest ASP among biosimilars.

Figure 17. Filgrastim Volume Market Share[4]

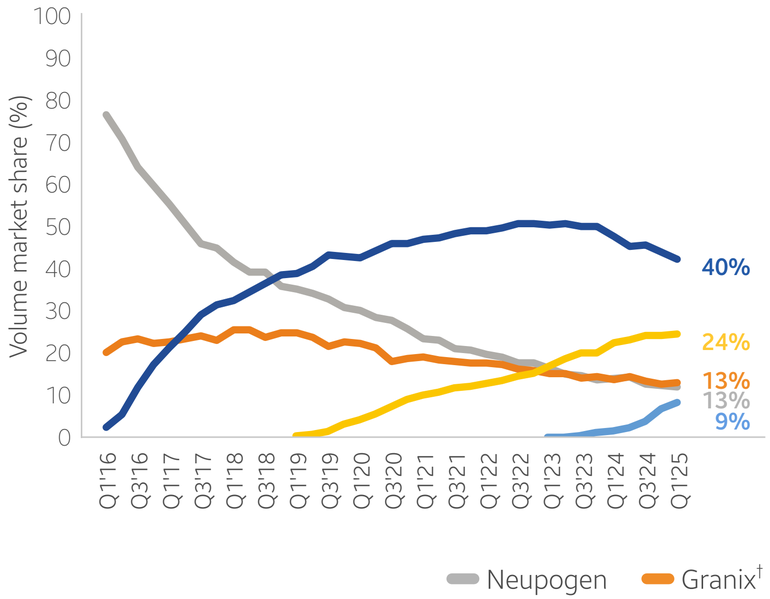
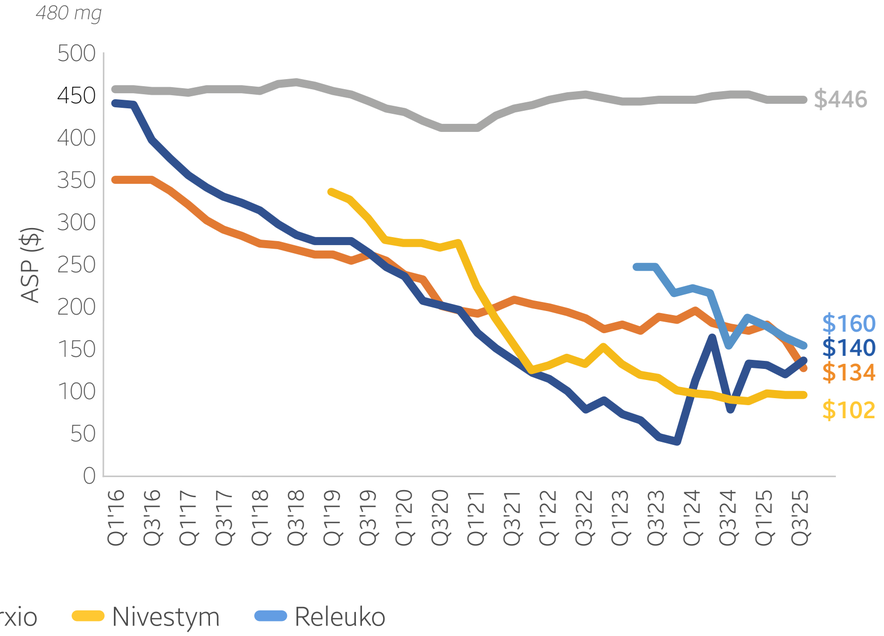


Figure 18. Filgrastim ASP Trend[3]



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 Q1 2025, the biosimilar share of the pegfilgrastim market was 84% (+2% vs. last quarter).
- As of Q3 2025, the average ASP of all biosimilar products is $1,514 (-10% vs. last quarter).
- Udenyca partially regained market share lost in Q4 2024 due to supply shortages from third-party manufacturing constraints.

Figure 19. Pegfilgrastim Volume Market Share[4]

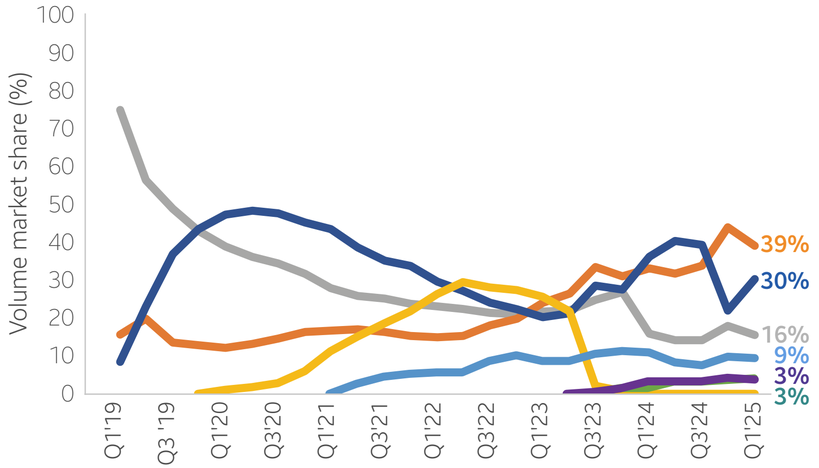
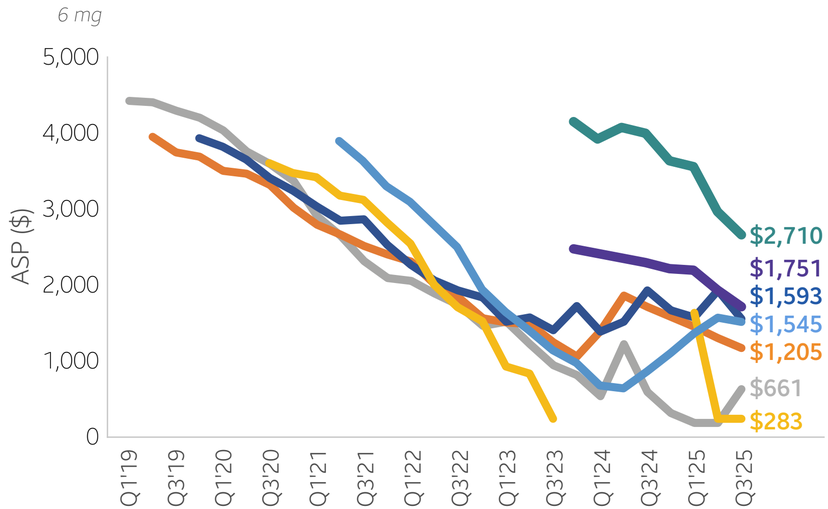


Figure 20. Pegfilgrastim ASP Trend[3]



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 60%.

Figure21. Epoetin Alfa Volume Market Share[4]

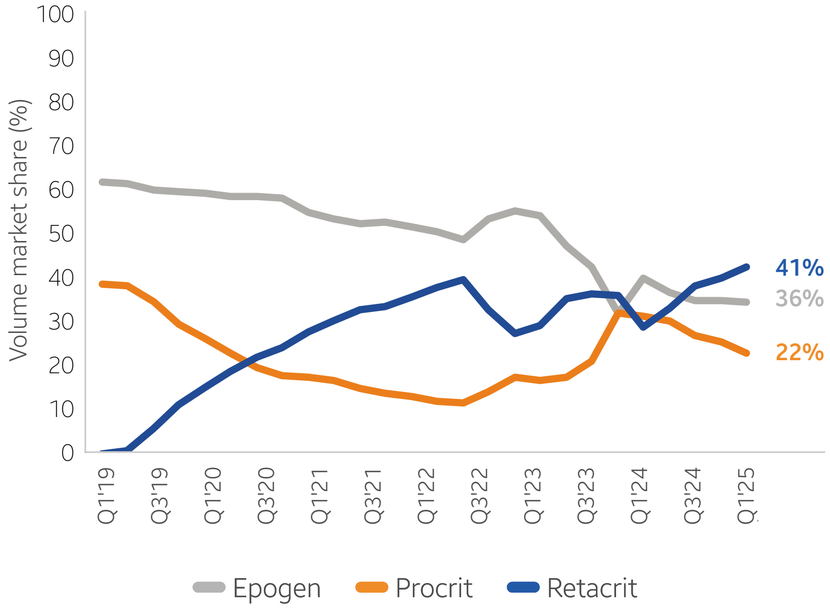
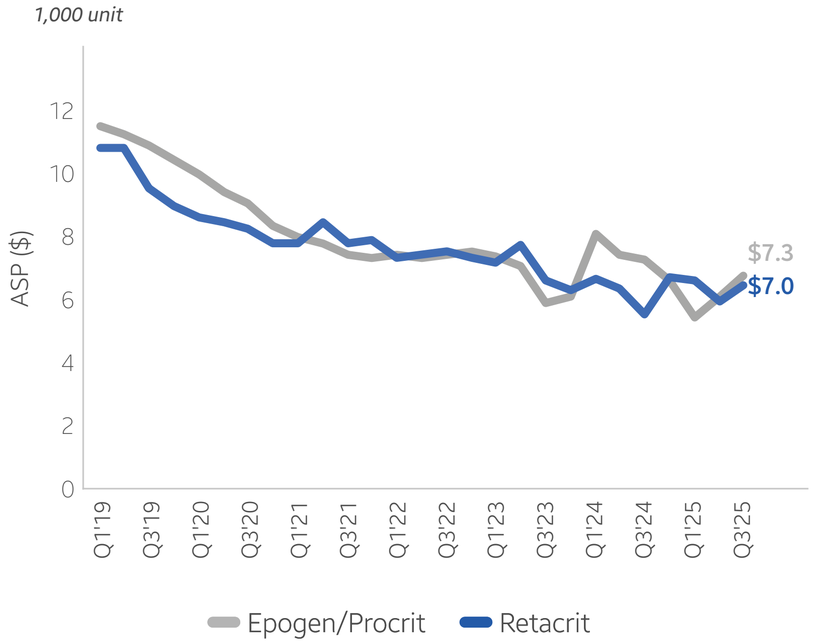


Figure 22. Epoetin alfa ASP Trend[3]



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

Market Share and ASP Trends - Remicade (Infliximab)

- As of Q1 2025, infliximab biosimilar market share has reached 50% (+1% vs. last quarter).
- As of Q3 2025, the average ASP of all biosimilar products is $189 (+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]

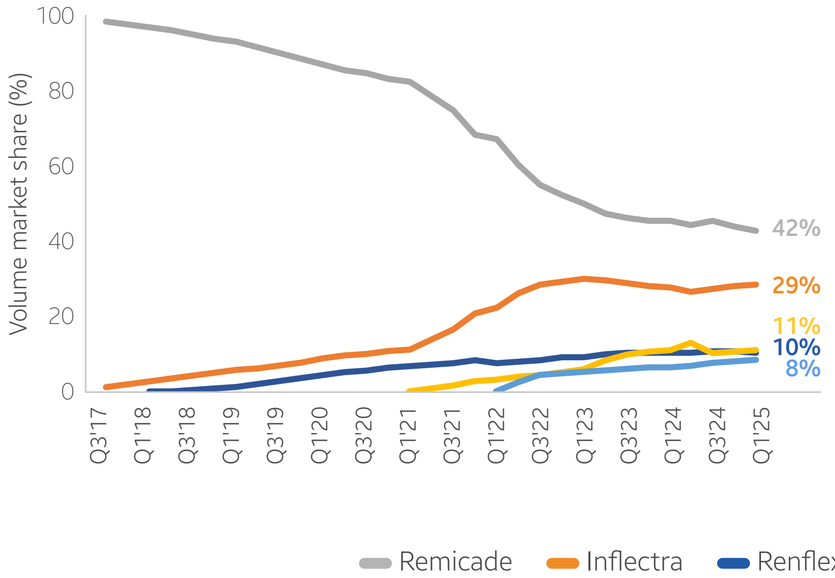
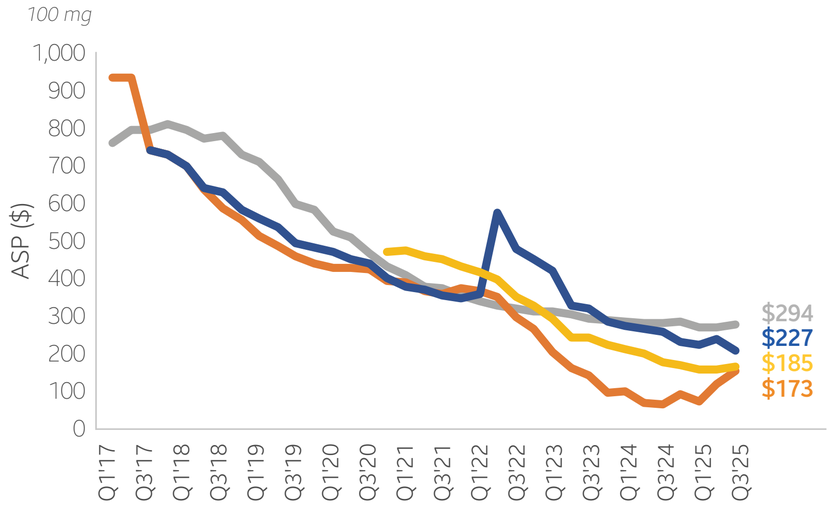


Figure 24. Infliximab ASP Trend[3]



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 modestly increased in 2025 as Humira's market share continues to slowly erode.**
- **Biosimilar brands have provided the market with diverse WAC pricing options.**
  1) Hadlima, Yusimry, and Simlandi offer a low WAC: ~85-86% less than Humira.
  2) Cyltezo, Amjevita, Hyrimoz, Hulio, Idacio, 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.
  4) Yuflyma, launched in November 2023 at a 5% discount to Humira, recently increased its WAC discount to ~71%.

Figure 25. Adalimumab Volume Market Share[5]

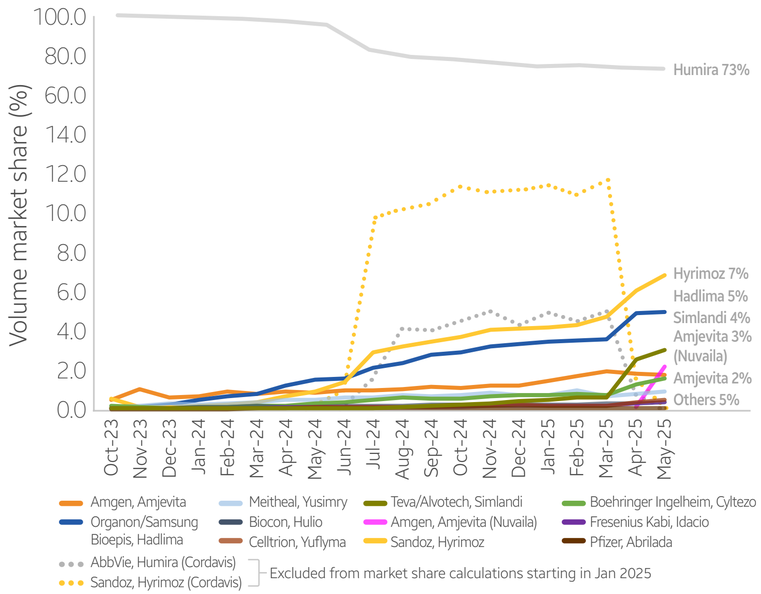
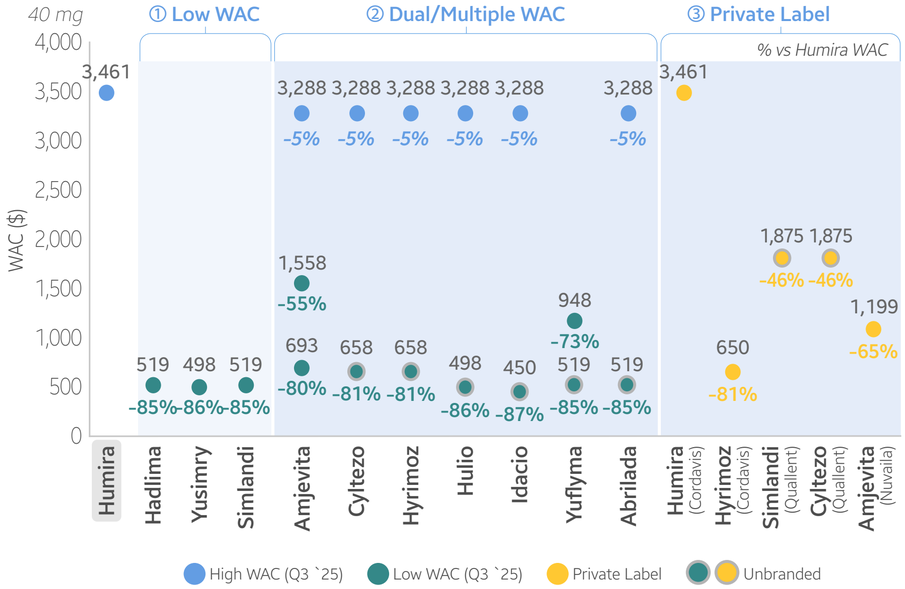


Figure 26. Adalimumab WAC Trend[2]



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 Q1 2025, tocilizumab biosimilars still hold a low market share, accounting for 7.2% of the total market. However, Tyenne, a tocilizumab biosimilar priced approximately 22% lower than the reference product (based on ASP), is beginning to gain traction and show notable growth in market share.
- As of Q3 2025, the average ASP of all biosimilar products is $1,944 (+3% vs. last quarter).

Figure 27. Tocilizumab Volume Market Share[4]

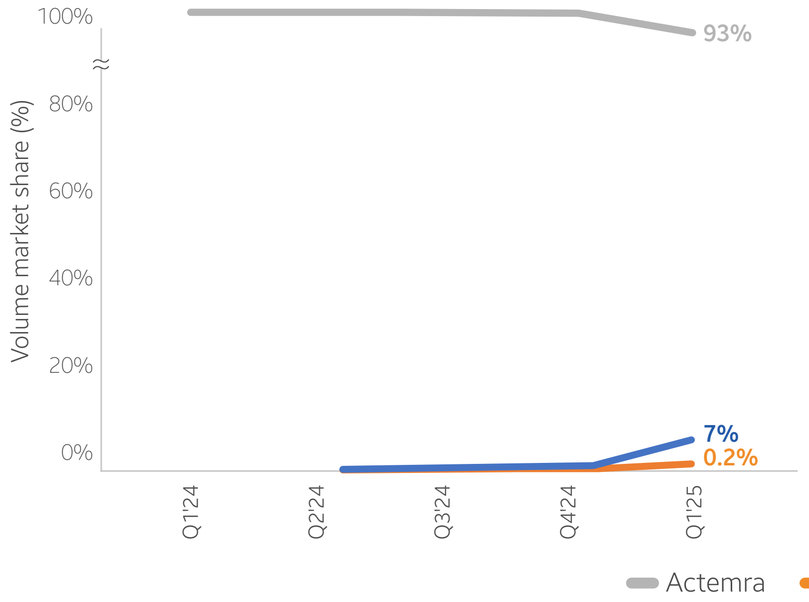
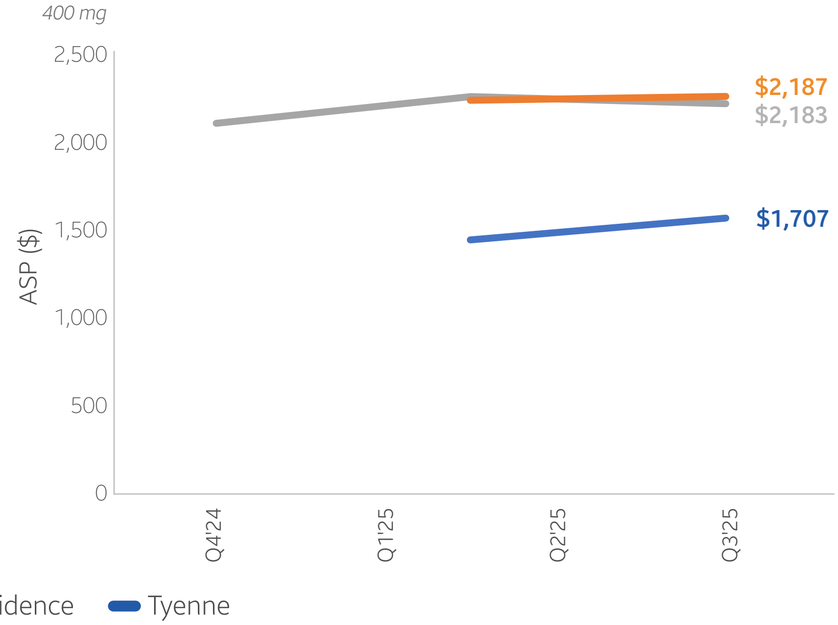


Figure 28. Tocilizimab ASP Trend[3]



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]

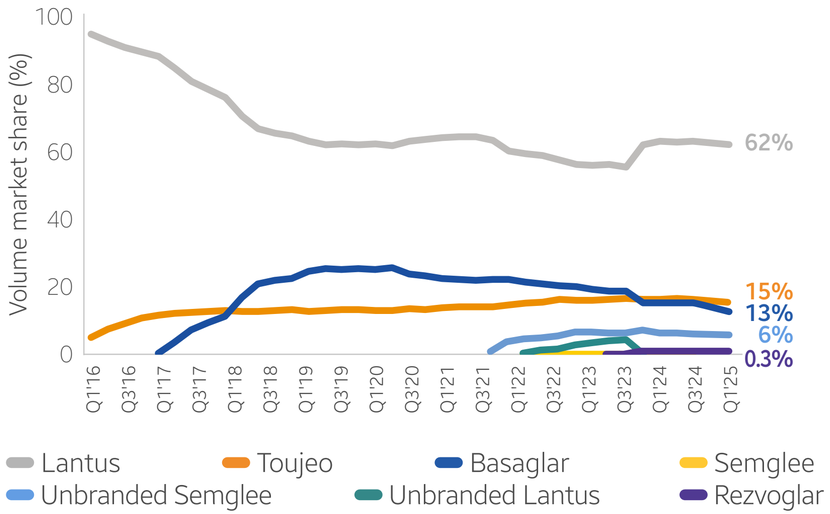
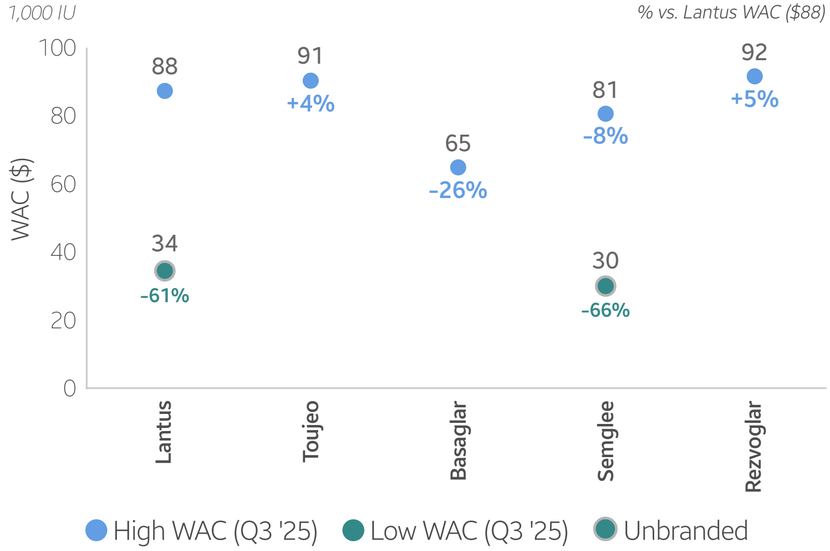


Figure 30. Insulin Glargine WAC Trend[2]



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

Market Share and ASP Trends - Lucentis (Ranibizumab)

* As of Q1 2025, ranibizumab biosimilar market share has reached 53% (+4% vs. last quarter).
* As of Q3 2025, the average ASP of all biosimilar products is $337 (-39% vs. last quarter).

Figure 31. Ranibizumab Volume Market Share[4]

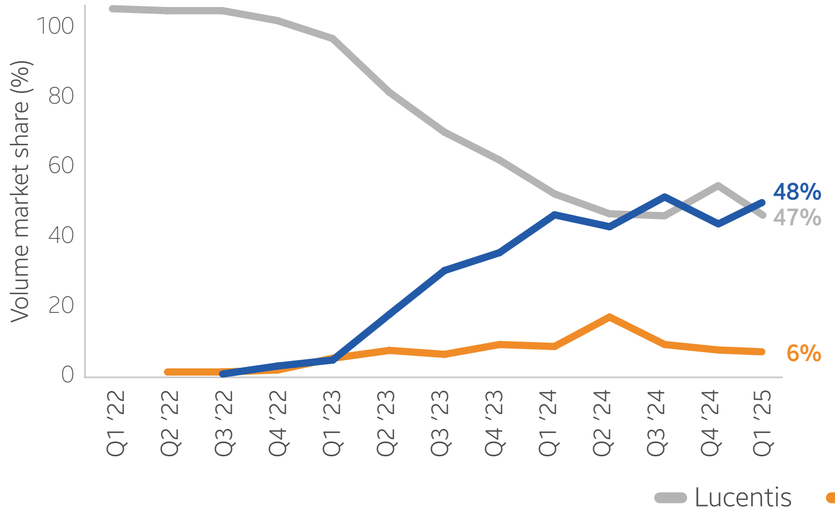
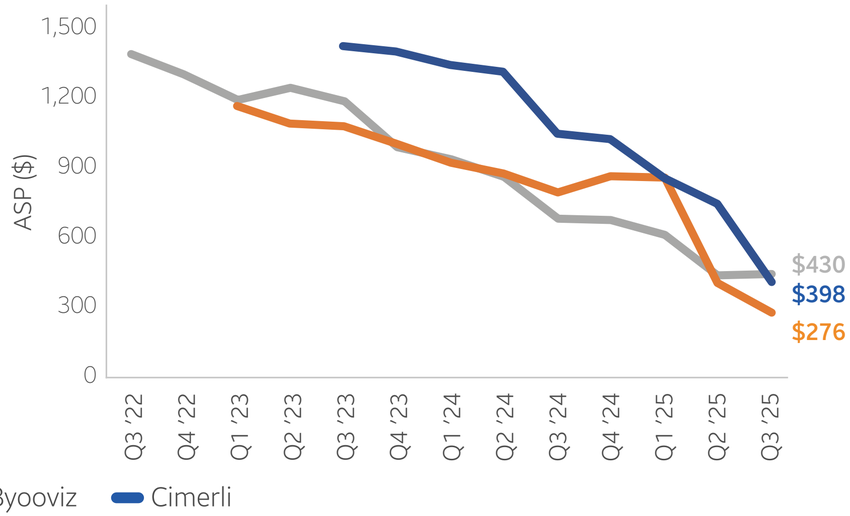


Figure 32. Ranibizumab ASP Trend[3]



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

IV. Biosimilar Deep Dive

1) Most-Favored-Nation (MFN) Drug Pricing

Understanding the Most-Favored-Nation (MFN) Policy

Policy Goals

- The MFN Policy, introduced by the Trump Administration, aims to reduce drug costs for Americans by ensuring that Americans have access to the lower prices typically paid by similar nations.
- The Executive Order (EO) reflects the administration's goal to address the fact that the US accounts for a much larger share of global pharmaceutical spending than its share of the world's population.

Executive Order Details[6,7,9,13]

- The EO instructs the Secretary of the United States Department of Health and Human Services (HHS) to:
  - Communicate MFN price targets to pharmaceutical manufacturers
  - Establish a mechanism through which American patients can buy their drugs directly from manufacturers who sell to Americans at a "Most-Favored-Nation" price, bypassing Pharmacy Benefit Managers (PBMs)
  - If drug manufacturers fail to voluntarily offer MFN pricing, HHS shall: (1) propose rules that impose MFN pricing; and (2) take other aggressive measures to significantly reduce the cost of prescription drugs to the American consumer and end anticompetitive practices
- Per HHS, the MFN target price methodology will be based on the lowest price amongst Organization for Economic Co-operation and Development (OECD) countries with a GDP per capita of at least 60% of the US GDP per capita.
- Notably, MFN pricing would apply to all branded single source drugs.

Policy Timeline

May 12, 2025:
Executive Order signed by President Trump

May 20, 2025: HHS
communicates MFN price methodology

June - onwards:
Manufacturers to determine whether they will voluntarily comply with MFN prices

2H 2025:
Formal rule making and/or legislation likely to ensue

Future Uncertainty & Industry Reactions[8]

- The likelihood of MFN implementation is unknown at this time. Significant legal hurdles may exist for HHS rulemaking to fall within the legal authority granted to HHS by Congress, which will likely result in legal challenges from the industry.
- PhRMA, the lobbying association for manufacturers, repudiates the MFN executive order approach and instead highlights a new campaign "Balance the Scales" that recommends leveraging US trade negotiations to encourage other nations to pay their fair share. These recommendations center around forcing non-US countries to pay a minimum percentage of GDP per capita on innovative medicines along with US-based reforms related to 340B and PBM practices.

Potential Effects of MFN on the US Biosimilar Market

- Although there remains uncertainty regarding MFN implementation, widespread brand list price reductions may have significant considerable impact on the viability of the biosimilar market

Decreased Revenue for Brand Originators Shrinks Market Size

- MFN pricing reduces brand originators' revenue by enforcing lower drug prices aligned with international benchmarks.
- Lower revenue translates to a smaller overall market size.
- A smaller market reduces the commercial opportunity for biosimilars to enter and compete effectively.
- Reduced market attractiveness may discourage biosimilar manufacturers from investing in new biosimilar products.

Fixed High Development Costs for Biosimilars

- Biosimilar development requires substantial investment (estimated at ~$100-$300M).[11,12]
- These costs are relatively fixed and do not decrease with market price changes.
- When originator brand list prices are lowered by MFN policy, the price gap between brand and biosimilar narrows.

Narrowed Price Differential Limits Payer Incentives

- Smaller cost savings between brand and biosimilar reduce payers' motivation to implement step therapy or preferencing strategies favoring biosimilars
- Without strong payer incentives, biosimilar adoption rates remain limited.
- Limited adoption undermines the competitive pressure biosimilars can exert on the market.

The MFN policy's downward pressure on brand pricing risks undermining the economic viability and adoption of biosimilars, ultimately limiting competition and increasing costs in the biologics market.

Ⅳ. Biosimilar Deep Dive

2) The Role of Quality and Supply Stability in Pharmaceuticals

Importance of Quality Manufacturing and Supply Reliability in Biosimilar Markets

* In the growing landscape of biologic therapies, biosimilars represent a critical opportunity to enhance patient access and reduce healthcare costs. However, the success of biosimilars in clinical practice and payer formularies hinges on provider and patient trust and confidence in biosimilar therapies.

Quality Manufacturing Controls + **Supply Reliability** = ***Increased Trust & Confidence in Biosimilar Products***

Quality can be defined by many variables and issues may greatly vary by manufacturer, product, and region of production.

Supply reliability is influenced by factors such as production capacity, logistical efficiency, and regulatory compliance, which can differ significantly across manufacturers and regions.

The next two slides further explore how quality manufacturing and supply reliability underpin successful biosimilar partnerships and sustainable market integration.

High-Quality Manufacturing in Biosimilar Efficacy and Safety

- Biosimilars are complex molecules produced by living cells through a multistep manufacturing process. These molecules can vary due to post-translational modifications occurring in the cellular environment or during manufacturing.
- Ensuring limited variation in these modifications is crucial because they can impact the safety and efficacy of the biosimilar. The manufacturing process is fundamental in defining the final product's quality, making rigorous control and high standards essential[14].
- Payers consider the quality and consistency of biosimilars when making formulary decisions. Consistent, high-quality manufacturing controls reduces risks related to product variability, which is critical for establishing patient, provider, and payer trust in the product.
- Manufacturers emphasizing robust quality processes are better positioned as trusted partners for payers, supporting formulary inclusion and broader patient access.

Biosimilar manufactures can ensure high-quality manufacturing through process consistency, comprehensive and frequent quality controls, analytical rigor to control for batch variation, adherence to good manufacturing practices (cGMP), and a consistent track record for passing regulatory inspections.

Importance of Supply Management

- Assurance of a steady, uninterrupted supply is essential for biosimilar adoption and confidence.
- When making formulary decisions to prefer specific products, payers rely on consistent availability to ensure there is enough supply to accommodate their members.
- Supply disruptions to preferred formulary products can not only create administrative and clinical challenges, but risk patient care continuity and increase overall healthcare expenditures.
- In the biosimilar marketplace, this is especially important as patients and providers may be hesitant to switch from the originator. Once a patient undergoes the switch and becomes stabilized on the product, shortages can further undermine their confidence and perception of biosimilars.

Biosimilar manufacturers committed to prioritizing a consistent supply can improve trust and perceptions of biosimilars. Key strategies to ensure a consistent supply include diversifying manufacturing thru multiple production sites (multi-sourcing) and remaining committed to a track record of no major supply disruptions or safety issues.

Reference

1. Biosimilar Product Information. FDA. (Jun 2025). Retrieved Jun 2025 from https://www.fda.gov/drugs/biosimilars/biosimilar-product-information
2. HCPCS Unit WAC Price. Buy and Bill. (Jun 2025). Retrieved Jun 2025 from https://buyandbill.com
3. Medicare part B Drug Average Sales Price. CMS. (Jun 2025). Retrieved Jun 2025 from https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files
4. SMART Global MIDAS. IQVIA. (Jan 2017-Mar 2025). Retrieved Jun 2025.
   Based on internal analysis by SAMSUNG BIOEPIS CO., LTD. using data from the following source: IQVIA MIDAS® in Standard Units for the period Jan 2017 – Mar 2025 reflecting estimates of real-world activity. Copyright IQVIA. All rights reserved.
5. Weekly Sales Perspectives. IQVIA. (Jan 2023-May 2025). Retrieved Jun 2025.
   Based on internal analysis by SAMSUNG BIOEPIS CO., LTD. using data from the following source: IQVIA Weekly Sales Perspectives® for the period Jan 2023 – May 2025 reflecting estimates of real-world activity. Copyright IQVIA. All rights reserved.
6. Delivering Most-Favored-Nation Prescription Drug Pricing to American Patients. Executive Orders from The White House. (May 12, 2025). Retrieved Jun 2025 from https://www.whitehouse.gov/presidential-actions/2025/05/delivering-most-favored-nation-prescription-drug-pricing-to-american-patients
7. Fact Sheet: President Donald J. Trump Announces Actions to Put American Patients First by Lowering Drug Prices and Stopping Foreign Free-riding on American Pharmaceutical Innovation. The White House. (May 12, 2025). Retrieved Jun 2025 from https://www.whitehouse.gov/fact-sheets/2025/05/fact-sheet-president-donald-j-trump-announces-actions-to-put-american-patients-first-by-lowering-drug-prices-and-stopping-foreign-free-riding-on-american-pharmaceutical-innovation
8. New “Balance the Scales” Campaign Highlights Why Americans Pay More for Prescription Medicines. PhRMA. (May 21, 2025). Retrieved Jun 2025 from https://phrma.org/blog/new-balance-the-scales-campaign-highlights-why-americans-pay-more-for-prescription-medicines
9. Most Favored Nation (MFN) Drug Pricing Proposal Reintroduced in 2025. Medicare Nationwide. (Jun 2025). Retrieved Jun 2025 from https://medicarenationwide.com/most-favored-nation-mfn-drug-pricing-2025
10. The Trump Most Favored Nation Pricing Proposal: Bad News for Biosimilars. Biosimilars Review & Report. (May 20, 2025). Retrieved Jun 2025 from https://biosimilarsrr.com/2025/05/20/the-trump-most-favored-nation-pricing-proposal-bad-news-for-biosimilars/
11. An Inflection Point for Biosimilars. McKinsey. (Jun 07, 2021). Retrieved Jun 2025 from https://www.mckinsey.com/industries/life-sciences/our-insights/an-inflection-point-for-biosimilars
12. The Economics of Biosimilars. Article from American Health & Drug Benefits. (Sep 06, 2013). Retrieved Jun 2025 from https://pmc.ncbi.nlm.nih.gov/articles/PMC4031732/
13. Most-Favored-Nation Prescription Drug Pricing Executive Order: Legal Issues. Library of Congress. (Jun 05, 2025). Retrieved Jun 2025 from https://www.congress.gov/crs-product/LSB11319
14. The Process Defines the Product: What Really Matters in Biosimilar Design and Production?. Article from Rheumatology (Oxford, England). (Aug 30, 2017). Retrieved Jun 2025 from https://pmc.ncbi.nlm.nih.gov/articles/PMC5850795/

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