Samsung Bioepis

Biosimilar Market Report

13th Edition, Q2 2026

SAMSUNG BIOEPIS

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

FOREWORD

We are pleased to share the 13th edition of our Biosimilar Market Report, providing updated analysis of US pricing and market share trends across biosimilar markets.

The regulatory environment for biosimilar approval continues to evolve. Over the past year, FDA has issued two notable draft guidance updates: an October 2025 draft indicating that comparative efficacy studies (CES) may no longer be routinely expected, and a March 2026 revision introducing additional flexibility in the use of non-US-licensed comparator data. Together, these updates reflect a broader shift toward greater emphasis on analytical and pharmacokinetic evidence in demonstrating biosimilarity.

In this quarter's report, we review these regulatory developments and assess the potential implications for biosimilar development and the US market. We also highlight perspectives from recent payer and provider market research to provide additional context on how these developments may be perceived across stakeholders.

We appreciate your continued readership and hope this edition serves as a valuable resource in navigating the evolving biosimilar landscape.

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

Table of Contents

I **US Biosimilar Approval & Launch Status**

II **Biosimilar Price**

- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

III **Biosimilar Market Dynamics**

- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends

- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

IV **Biosimilar Deep Dive**

V **Reference**

I. US Biosimilars Approval & Launch Status

FDA Approval and Launch Status of US Biosimilars

* As of March 2026, the FDA has approved a total of 92 biosimilars across 20 unique biological molecules. Of the 92 approvals, 67 biosimilars (73%) have launched in the US market.

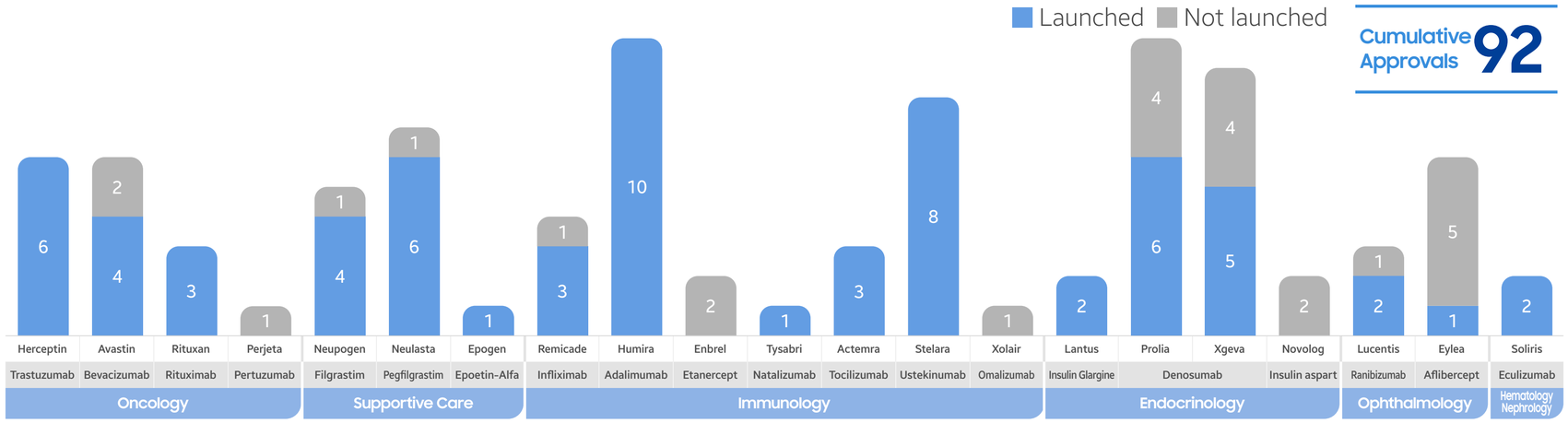
Figure 1-1. 2 FDA-approved Biosimilars in Q1`26

Reference Product	Biosimilar name	Biosimilar Manufacturer
Neupogen	Filkri	Accord BioPharma
Prolia	Ponlimsi	Teva Pharmaceuticals

Figure 1-2. 3 Biosimilars Launched in the US Market in Q1`26

Reference Product	Biosimilar name	Biosimilar Manufacturer & Commercial Partner	Launch Date
Prolia	Ospomyv	Samsung Bioepis	Dec 2025
Prolia	Enoby	Gedeon Richter & Hikma	Jan 2026
Xgeva	Xtrenbo	Gedeon Richter & Hikma	Jan 2026

Figure 2. Biosimilars Approval and Launch Status in the US[1*] (As of Mar 2026)



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

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

Biosimilar Deep Dive

Reference

Figure 3-1. Biosimilars Approval and Launch Status in the US[1*] (As of Mar 2026, with Suffix)

TA	Oncology				Immunology						
Molecule	Trastuzumab	Bevacizumab	Rituximab	Pertuzumab	Infliximab	Adalimumab	Etanercept	Natalizumab	Tocilizumab	Ustekinumab	Omalizumab
Reference Product	Herceptin (trastuzumab) Roche 1998	Avastin (bevacizumab) Roche 2004	Rituxan (rituximab) Genentech&Biogen 1997	Perjeta (pertuzumab) Genentech 2012	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	Poherdy (pertuzumab-dpzb) Henlius&Organon 2025	Inflectra (infliximab-dyyb) Celltrion&Pfizer 2016	Amjevita (adalimumab-atto) Amgen 2016	Erelzi (etanercept-szzs) Sandoz 2016	Tyruko (natalizumab-sztn) Sandoz 2023	Tofidence (tocilizumab-bavi) Bio-Thera&Organon 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

*Trade marks are not described to all brands

Continued on next page →

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

Biosimilar Deep Dive

Reference

Figure 3-2. Biosimilars Approval and Launch Status in the US[1*] (As of Mar 2026, with Suffix)

TA	Endocrinology				Ophthalmology		Hematology	Supportive Care		
Molecule	Denosumab	Denosumab	Insulin glargine	Insulin aspart	Ranibizumab	Aflibercept	Eculizumab	Filgrastim	Pegfilgrastim	Epoetin alfa
Reference Product	Prolia (denosumab) Amgen 2010	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 (denosumab-bbdz) Sandoz 2024	Wyost (denosumab-bbdz) Sandoz 2024	Semglee (insulin glargine-yfgn) Biocon 2021	Merilog (insulin aspart-szjj) Sanofi-Aventis 2025	Byooviz (ranibizumab-nuna) Samsung Bioepis & Harrow 2021	Opuviz (aflibercept-yszy) Samsung Bioepis 2024	Bkemv (eculizumab-aeeb) Amgen 2024	Zarxio (filgrastim-sndz) Sandoz 2015	Fulphila (pegfilgrastim-jmdb) Biocon 2018	Retacrit (epoetin alfa-epbx) Hospira&Pfizer 2018
	Ospomyv (denosumab-dssb) Samsung Bioepis 2025	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&Teva 2024	Nivestym (filgrastim-aafi) Hospira&Pfizer 2018	Udenyca (pegfilgrastim-cbqv) Coherus 2018	
	Stoboclo(denosumab-bmwo) Celltrion 2025	Osenvelt (denosumab-bmwo) Celltrion 2025			Nufymco (ranibizumab-leyk) Formycon&Zydus 2025	Ahzantive (aflibercept-mrbb) Formycon&Klinge 2024		Releuko (filgrstim-ayow) Amneal&Kashiv 2022	Ziextenzo (pegfilgrastim-bmez) Sandoz 2019	
	Conexxence (denosumab-bnht) Fresenius Kabi 2025	Bomyntra (denosumab-bnht) Fresenius Kabi 2025				Enzeevu (aflibercept-abzv) Sandoz 2024		Nypozi (filgrastim-txid) Tanvex&InvaGen 2024	Nyvepria (pegfilgrastim-apgf) Hospira&Pfizer 2020	
	Bildyos (denosumab-nxxp) Shanghai Henlius & Organon 2025	Bilprevda (denosumab-nxxp) Shanghai Henlius & Organon 2025				Pavblu (aflibercept-ayyh) Amgen 2024		Filkri (filgrastim-laha) Accord 2026	Stimufend (pegfilgrastim-fpgk) Fresenius Kabi 2022	
	Enoby(denosumab-qbde) Richter&Hikma 2025	Xtrenbo (denosumab-qbde) Richter&Hikma 2025				Eydenzelt (aflibercept-boav) Celltrion 2025			Fylnetra (pegfilgrastim-pbbk) Amneal&Kashiv 2022	
	Osvyrti (denosumab-desu) Accord 2025	Jubereq (denosumab-desu) Accord 2025							Armlupeg (pegfilgrastim-unne) Lupin&Valorum 2025	
	Boncresa (denosumab-mobz) mAbxience&Amneal 2025	Oziltus (denosumab-mobz) mAbxience&Amneal 2025								
	Ponlimsi (denosumab-adet) Teva 2026									

Launched Not launched

*Trade marks are not described to all brands

II. Biosimilar Price

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

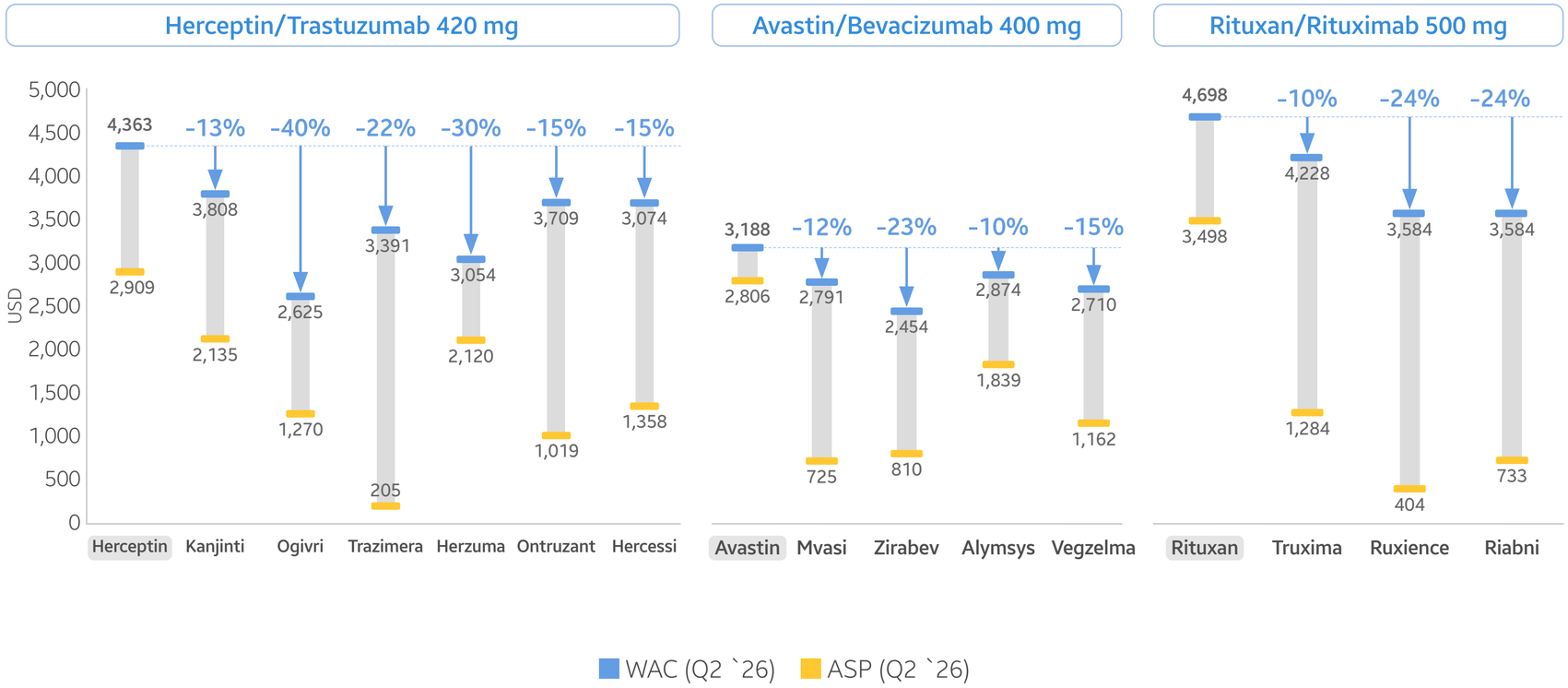
Biosimilar Deep Dive

Reference

Oncology WAC and ASP – Q2 2026

- Across oncology biosimilars, WAC prices discounted between 10-40% compared to reference products.
- Biosimilar Q1 2026 ASP discounts as compared to the reference product's ASP average -54%, -60%, and -77% for the trastuzumab, bevacizumab, and rituximab markets, respectively.

Figure 4. Q2 2026 WAC and ASP[2,3]



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

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

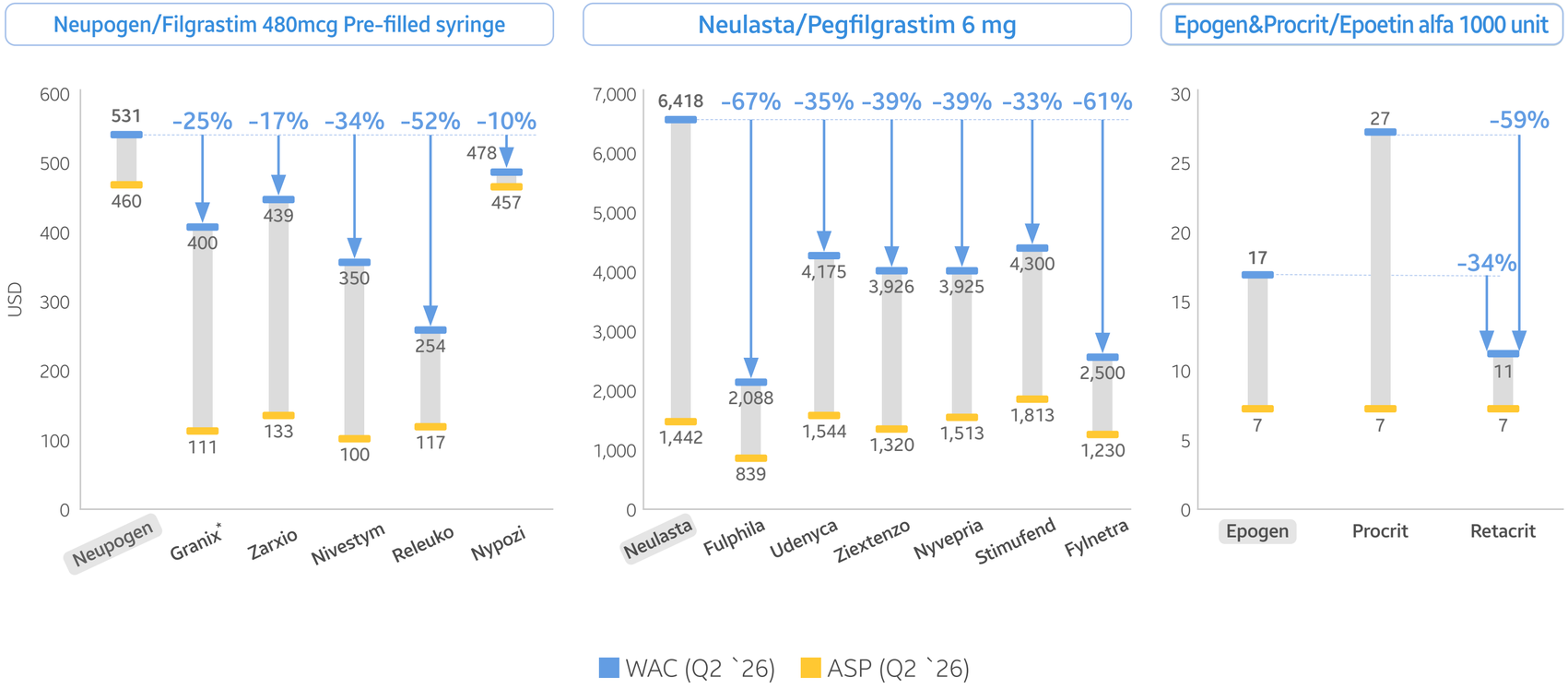
Biosimilar Deep Dive

Reference

Supportive Care WAC and ASP - Q2 2026

- Across supportive care biosimilars, WAC prices are 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. Q2 2026 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

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

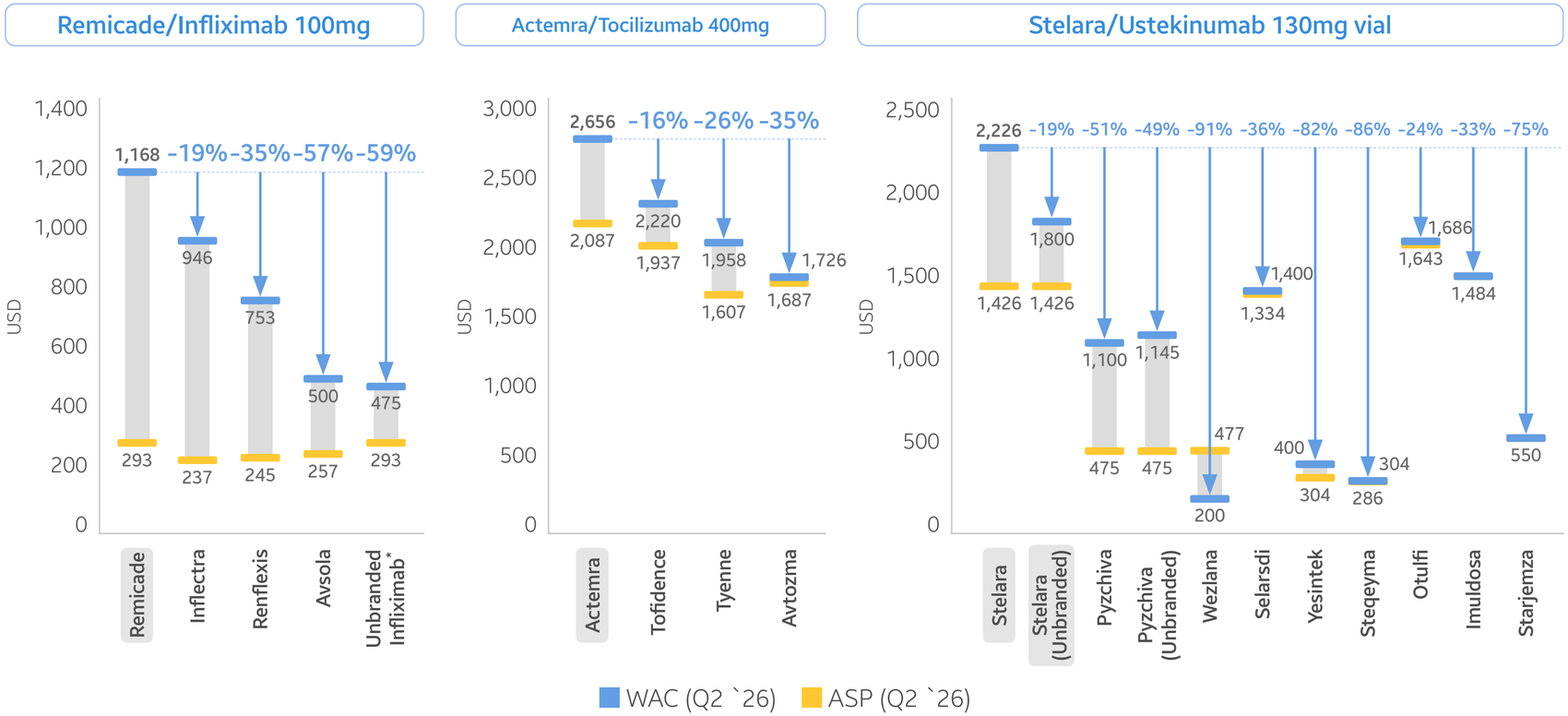
Biosimilar Deep Dive

Reference

Immunology WAC and ASP - Medical Benefit - Q2 2026

- Infliximab biosimilars launched with progressively lower WACs, ranging from -19% to -59% in discounts.
- Ustekinumab 130 mg vial pricing shows substantial variation across biosimilars, with both WAC and ASP spanning a wide range by product.

Figure 6. Q2 2026 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

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

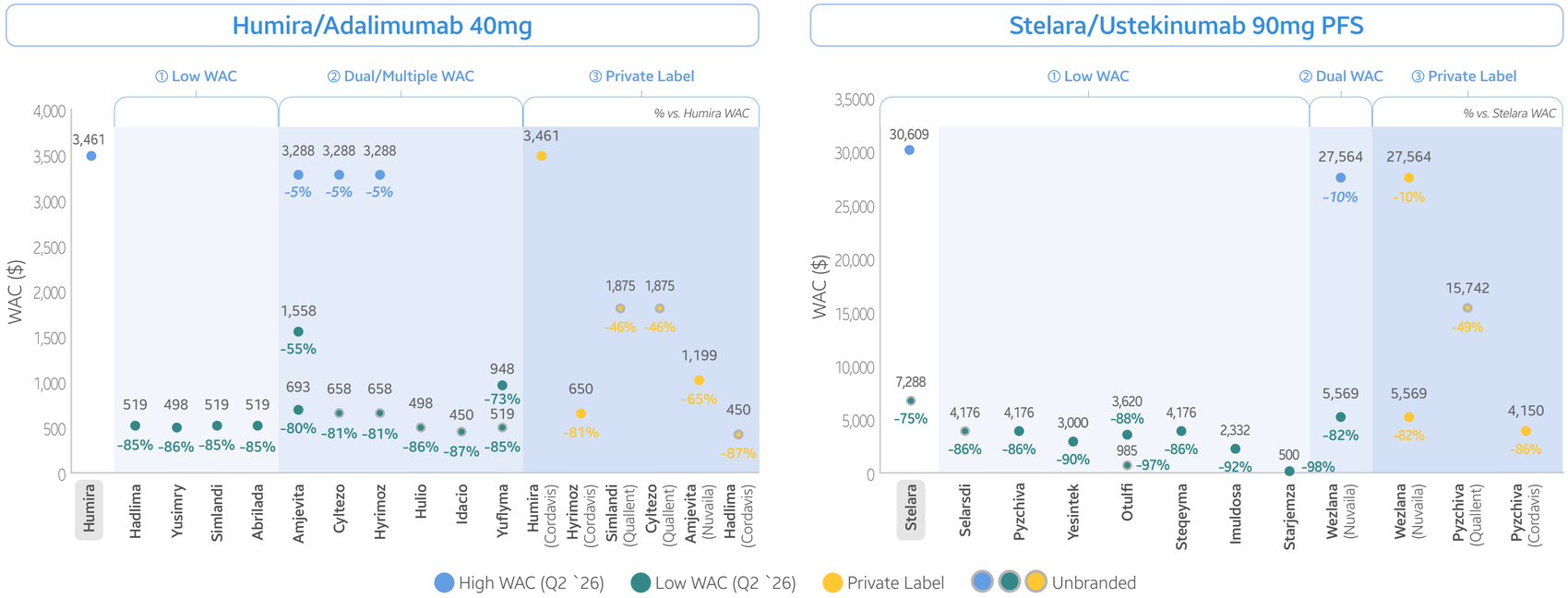
Biosimilar Deep Dive

Reference

Immunology WAC - Pharmacy Benefit - Q2 2026

- Adalimumab and subcutaneous ustekinumab 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 7. Q2 2026 WAC[2, 3]



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

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

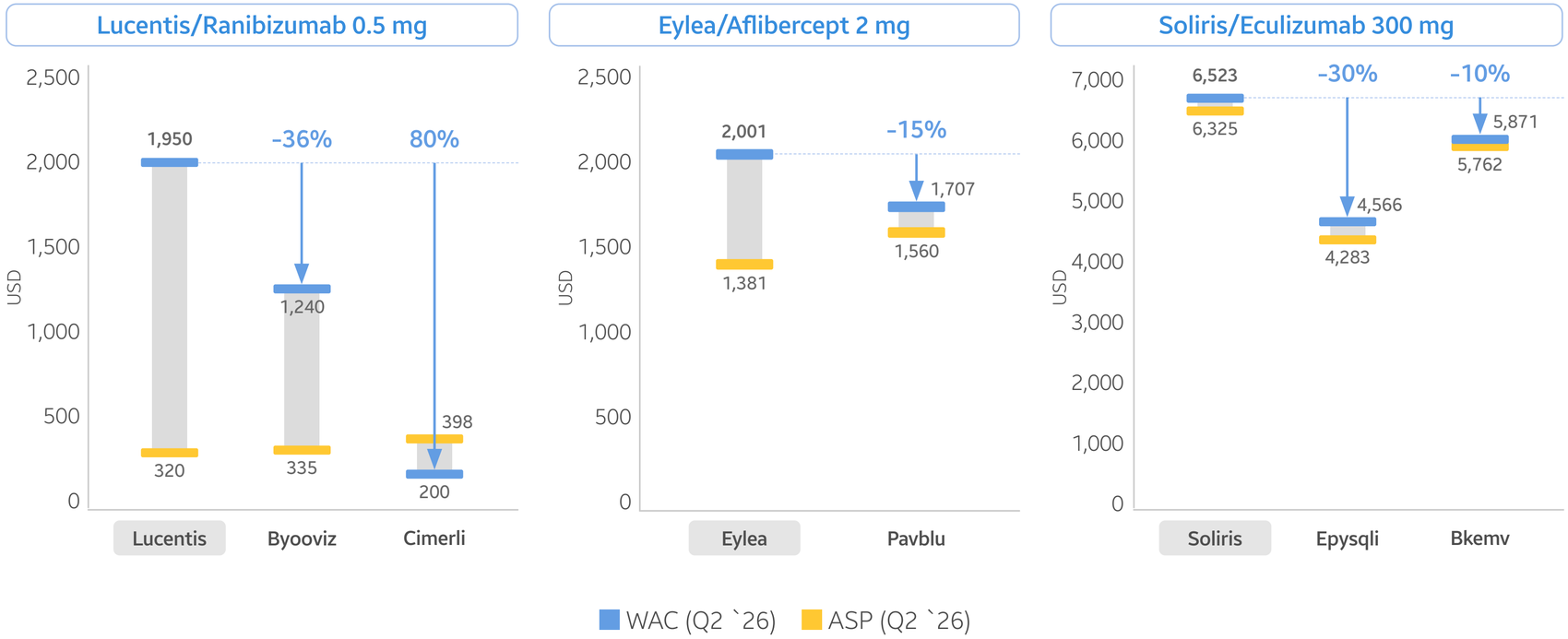
Biosimilar Deep Dive

Reference

Ophthalmology & Hematology WAC and ASP - Q2 2026

- Ranibizumab WACs represent -36% to -80% WAC discounts as compared to the reference product.
- The reference products in the ophthalmology market, Lucentis and Eylea, had lower ASPs than the biosimilar products.
- The two eculizumab biosimilars are priced 9-32% below the reference product's ASP, reflecting divergent pricing strategies.

Figure 8. Q2 2026 WAC and ASP[2,3]



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

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

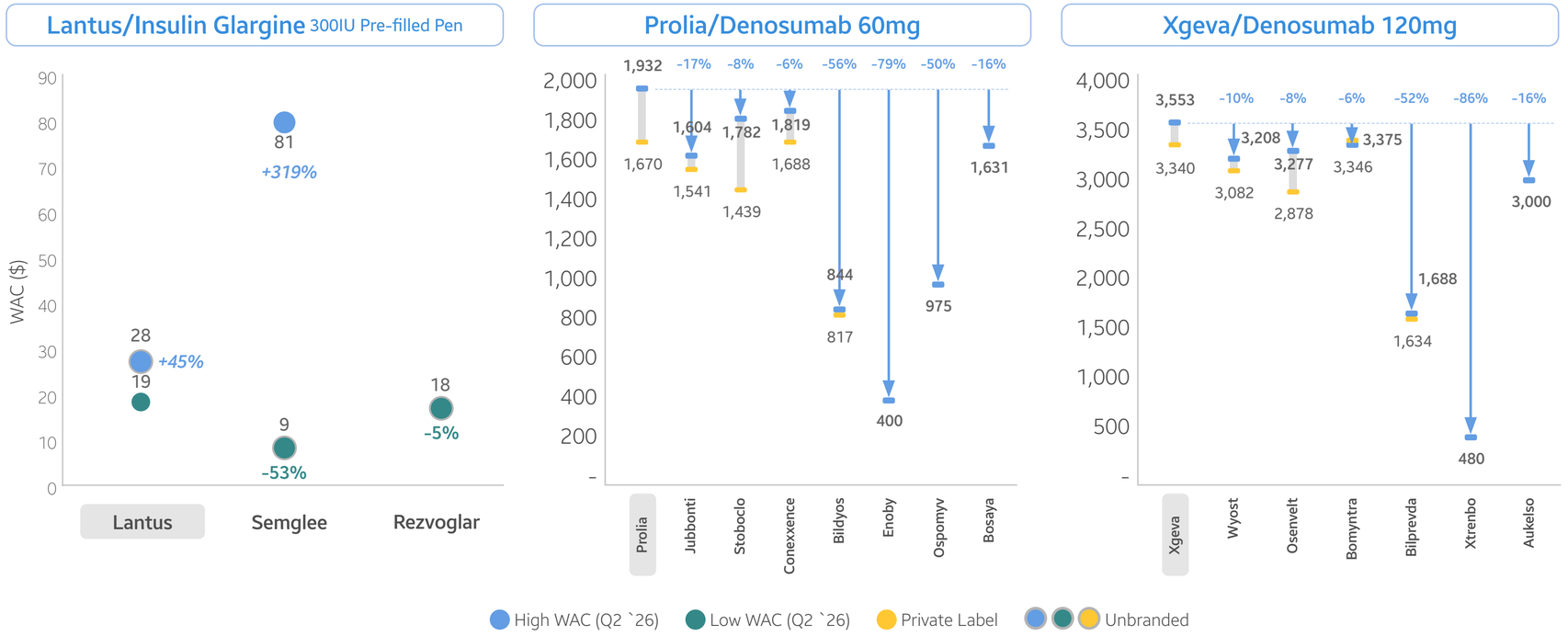
Biosimilar Deep Dive

Reference

Endocrinology WAC and ASP - Q2 2026

- Insulin glargine products reflect complex pricing practices such as multiple WAC options and unbranded biologics.
- Across denosumab biosimilars, WAC prices are discounted between 6-86% compared to reference products.

Figure 9. Q2 2026 WAC and ASP[2,3]



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

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

Biosimilar Deep Dive

Reference

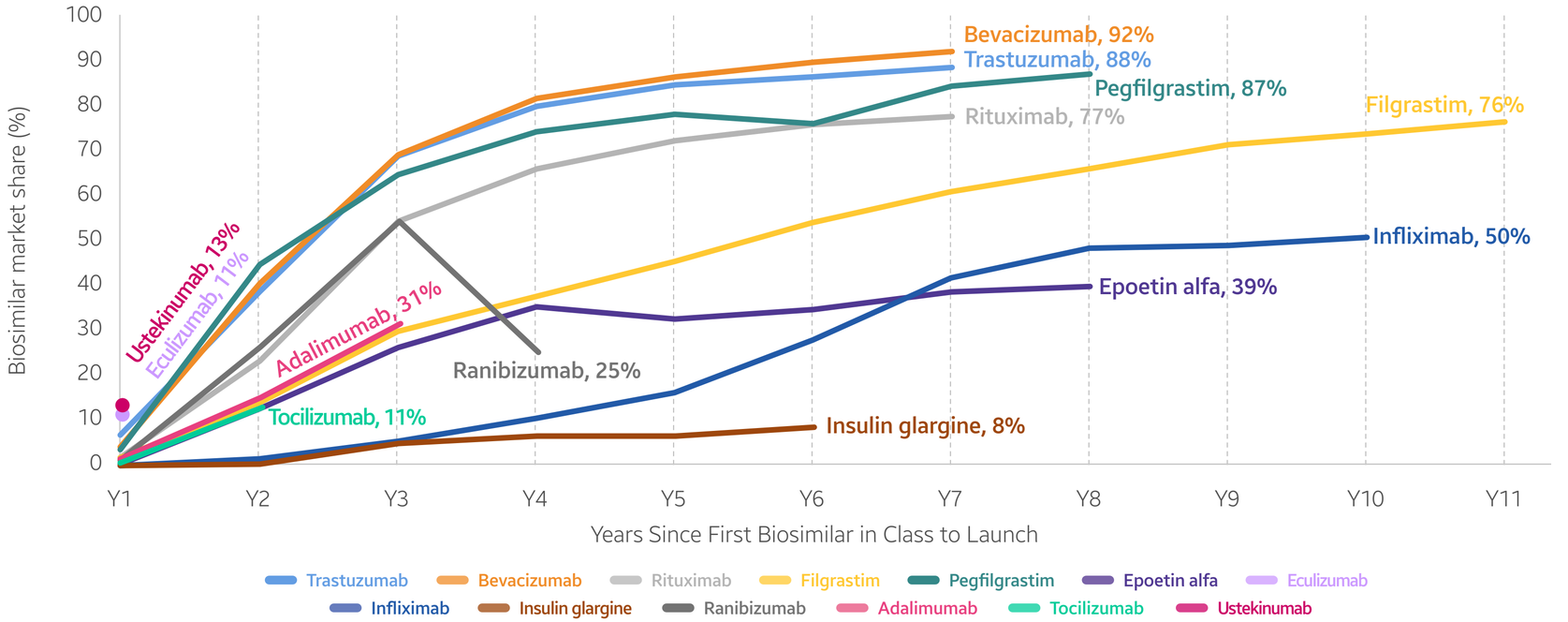
Biosimilar Volume Uptake Varies by Molecule

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 10. Biosimilar Market Share Post-Launch4[4§]



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

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

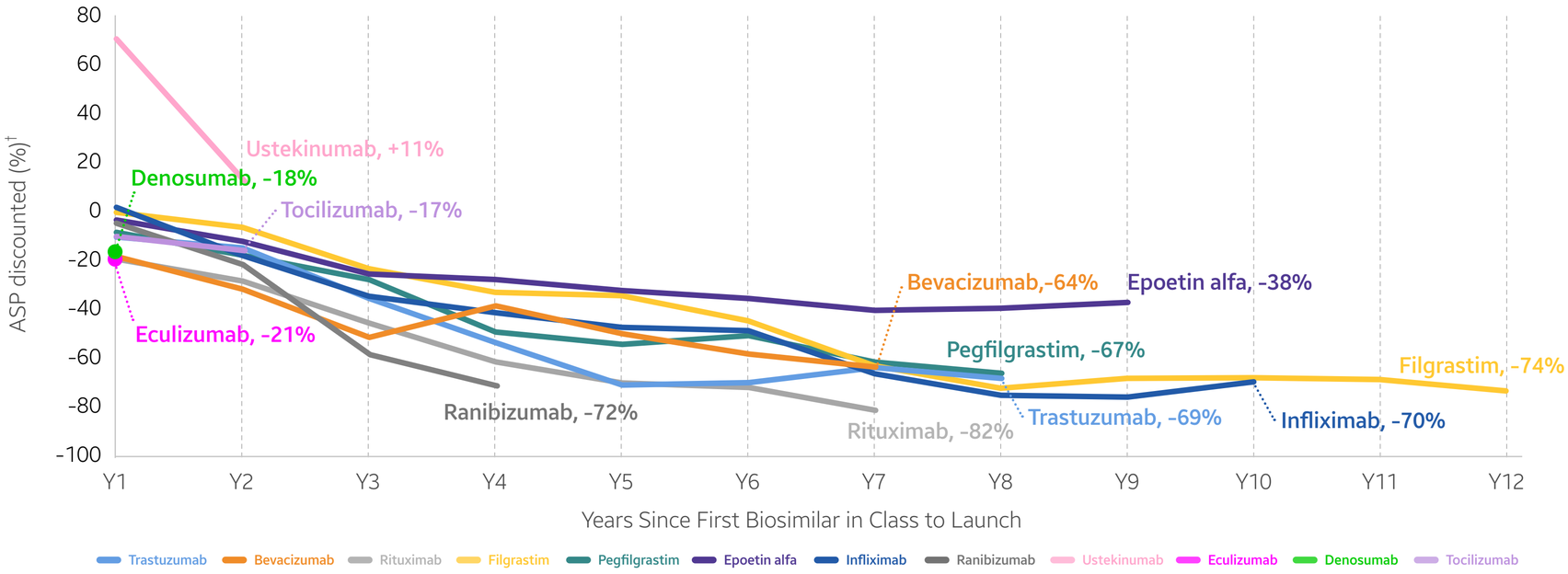
Biosimilar Deep Dive

Reference

Biosimilars are Reducing Drug Costs across Multiple TAs by Lowering Prices

- 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 82%).
- Declines in ASP within certain molecular markets do not always follow a consistent trend as they may be affected by intentional ASP repositioning, deliberate removal of products from the market, and a change in Medicare Part B payment calculation methodology.

Figure 11. ASP Trend by Molecule[3]



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

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

Biosimilar Deep Dive

Reference

Market Share and ASP Trends - Herceptin (Trastuzumab)

- As of Q4 2025, the biosimilar share of the trastuzumab market was 89% (+1% vs. last quarter).
- As of Q2 2026, average ASP of all biosimilar products is $1,351, representing a +5% from last quarter mainly driven by slight ASP increases across most biosimilar products.
- Since Q2 2025, Kanjinti's market share has remained relatively stable, while its ASP has continued to trend upward.

Figure 12. Trastuzumab Volume Market Share[4]

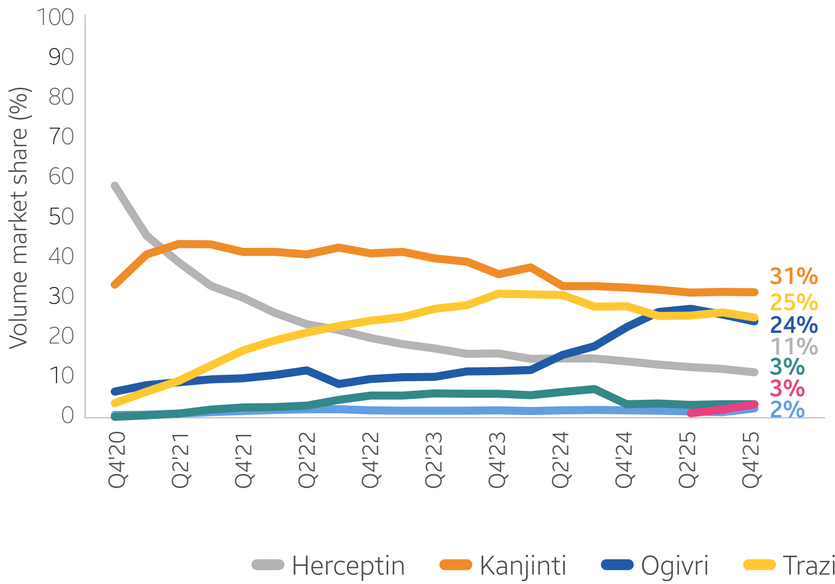
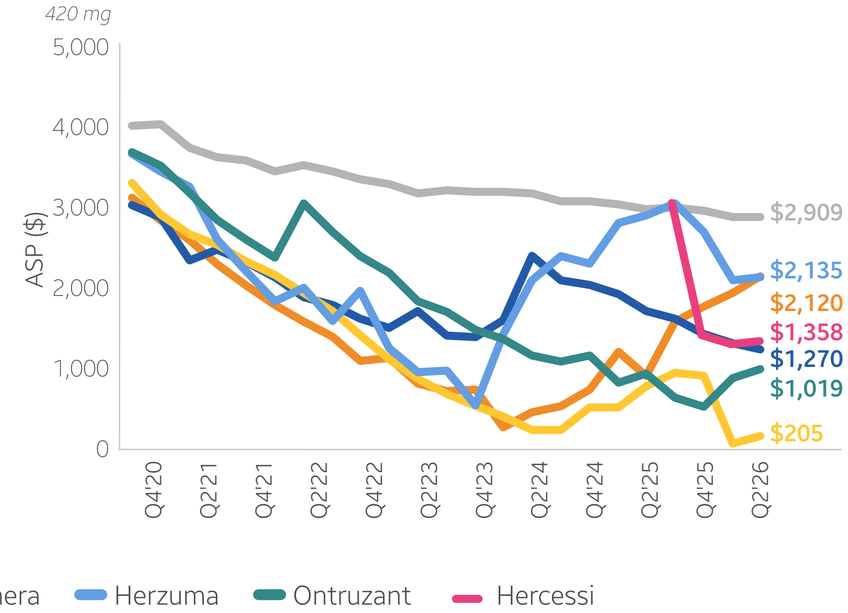


Figure 13. Trastuzumab ASP Trend[3]



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

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

Biosimilar Deep Dive

Reference

Market Share and ASP Trends - Avastin (Bevacizumab)

- As of Q4 2025, the biosimilar share of the bevacizumab market was 92% (unchanged vs. last quarter).
- As of Q2 2026, average ASP of all biosimilar products is $1,134 (+15% vs. last quarter), mainly driven by ASP increase of Alymsys.
- Earlier-to-market bevacizumab biosimilars with lower established ASPs continue to make up the majority of market share of 75%.

Figure 14. Bevacizumab Volume Market Share[4]

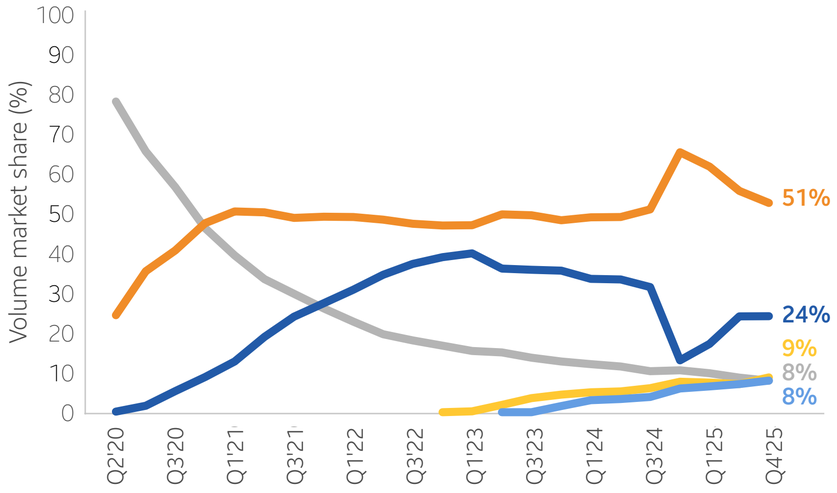
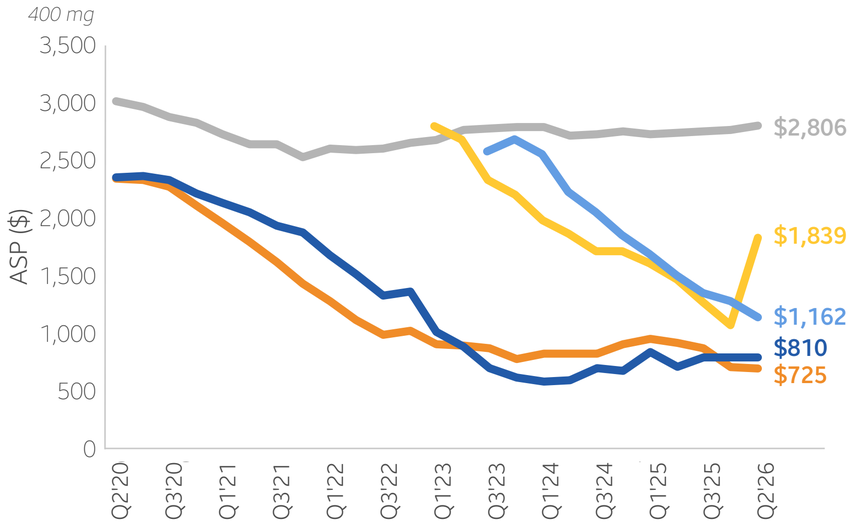


Figure 15. Bevacizumab ASP Trend[3]



Avastin Mvasi Zirabev Alymsys Vegzelma

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

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

Biosimilar Deep Dive

Reference

Market Share and ASP Trends – Rituxan (Rituximab)

- As of Q4 2025, the biosimilar share of the rituximab market was 77% (-1% vs. last quarter).
- As of Q2 2026, the average ASP of all biosimilar products is $807.
- The rituximab market appears bifurcated: The lower cost biosimilars make up 77% of the market while the reference product maintains a stable market share despite its high ASP.

Figure 16. Rituximab Volume Market Share[4]

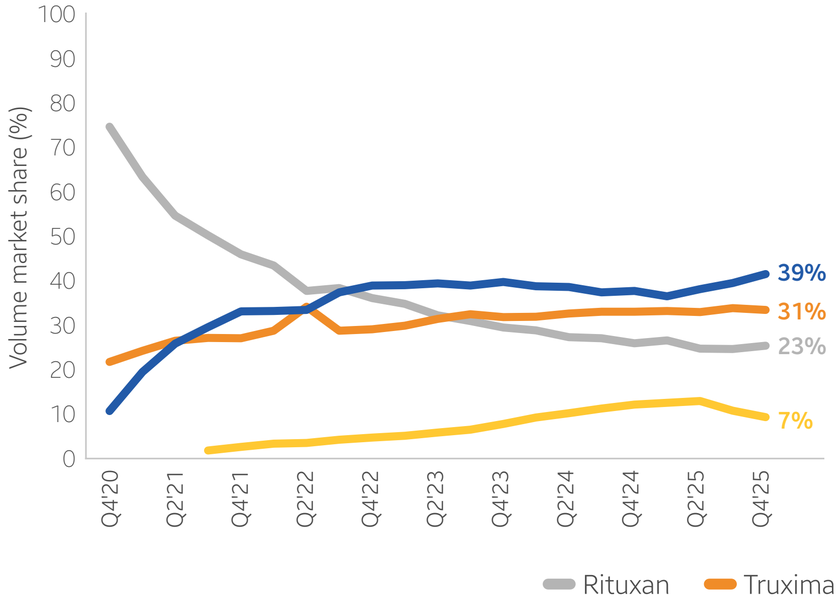
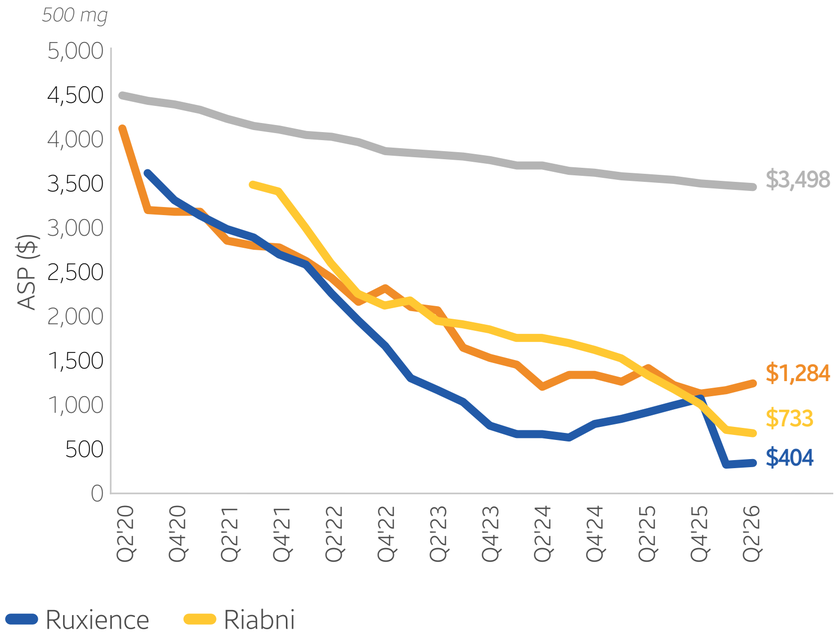


Figure 17. Rituximab ASP Trend[3]



Rituxan Truxima Ruxience Riabni

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

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

Biosimilar Deep Dive

Reference

Market Share and ASP Trends - Neupogen (Filgrastim)

- As of Q4 2025, the biosimilar share of the filgrastim market has reached 77% (Unchanged vs. last quarter).
- As of Q2 2026, the average ASP of filgrastim biosimilars is $202, influenced by the high ASP of Nypozi, the most recent market entrant.
- Despite being the later to enter the market among filgrastim biosimilars, Releuko has steadily increased its market share since its launch.

Figure 18. Filgrastim Volume Market Share[4]

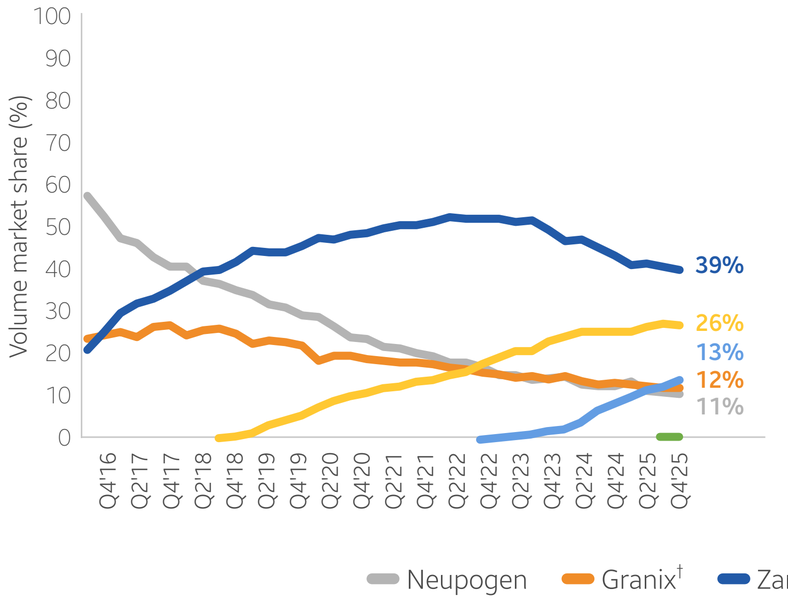
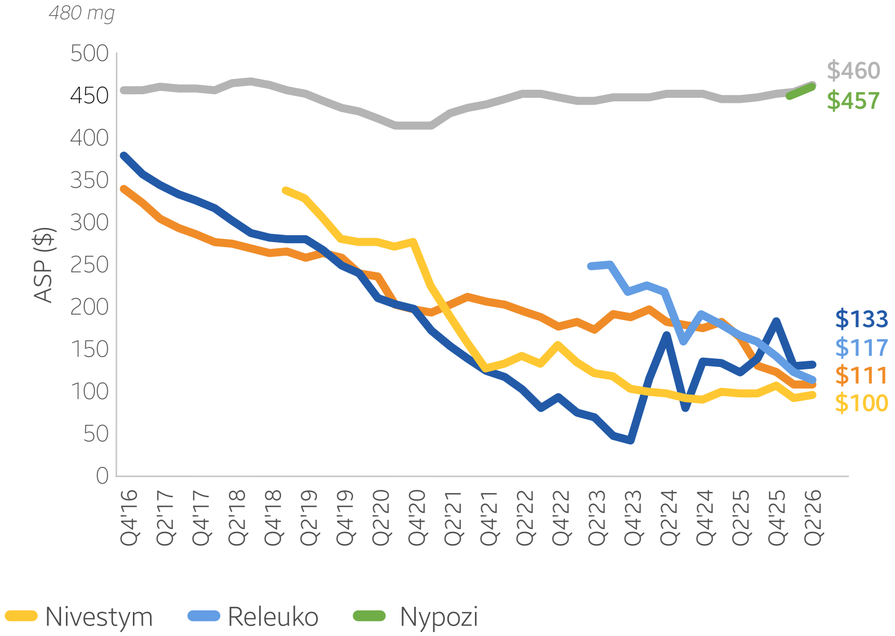


Figure 19. Filgrastim ASP Trend[3]



Neupogen | Granix† | Zarxio | Nivestym | Releuko | Nypozi

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

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

Biosimilar Deep Dive

Reference

Market Share and ASP Trends - Neulasta (Pegfilgrastim)

- As of Q4 2025, the biosimilar share of the pegfilgrastim market was 87% (-2% vs. last quarter).
- As of Q2 2026, the average ASP of all biosimilar products is $1,377 (-7% vs. last quarter), primarily reflecting ASP declines among the leading biosimilars by market share.
- Udenyca has exhibited fluctuations in market share over the past two years.

Figure 20. Pegfilgrastim Volume Market Share[4]

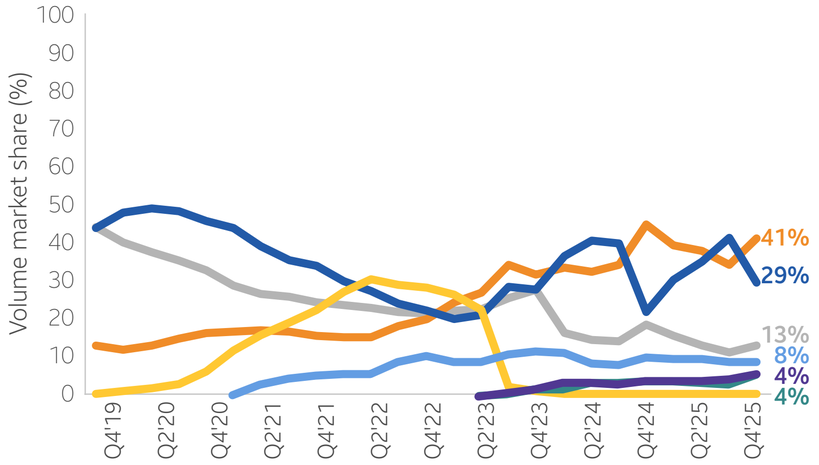
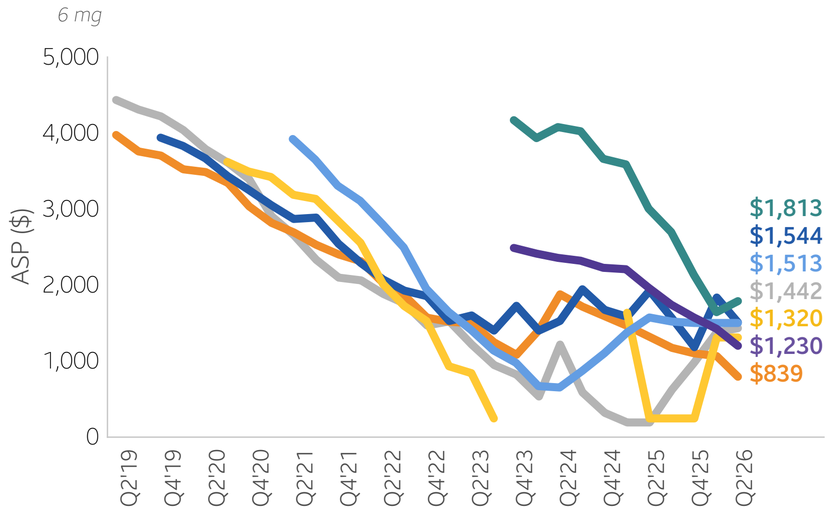


Figure 21 Pegfilgrastim ASP Trend[3]



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

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

Biosimilar Deep Dive

Reference

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

* Retacrit, the only biosimilar of epoetin alfa, maintains more than a third of the epoetin alfa market share.
* With only one biosimilar entrant, the reference product and the biosimilar have maintained similar ASPs in this market.

Figure 22. Epoetin Alfa Volume Market Share[4]

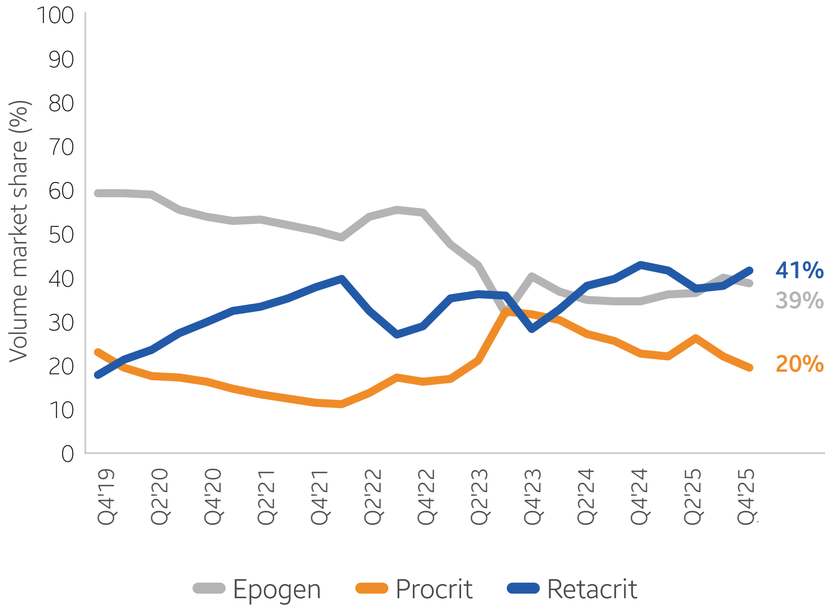
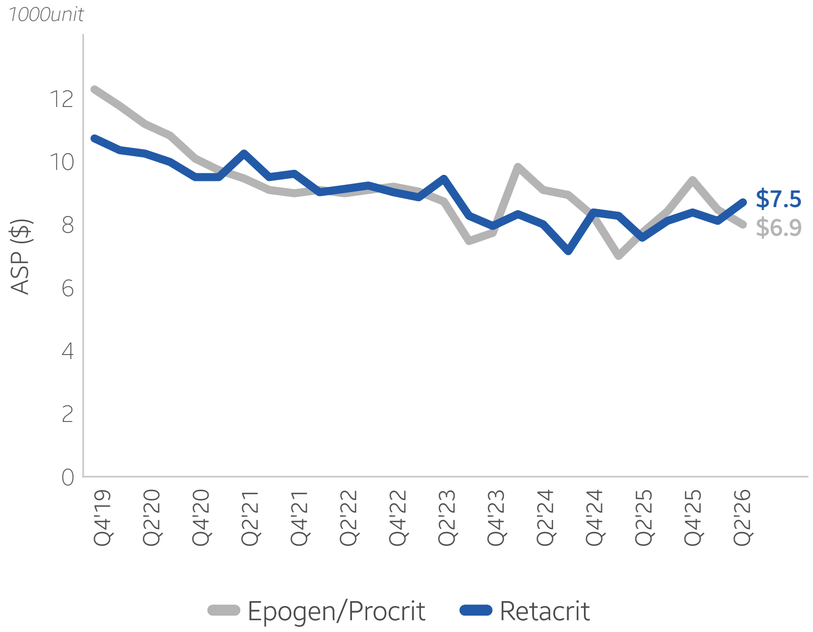


Figure 23. Epoetin Alfa ASP Trend[3]



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

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

Biosimilar Deep Dive

Reference

Market Share and ASP Trends - Remicade (Infliximab)

- As of Q4 2025, infliximab biosimilar market share has reached 51% (+1% vs. last quarter).
- As of Q2 2026, the average ASP of all biosimilar products is $246 (+8% vs. last quarter).
- Infliximab products demonstrated relatively limited ASP variability this quarter.

Figure 24. Infliximab Volume Market Share[4]

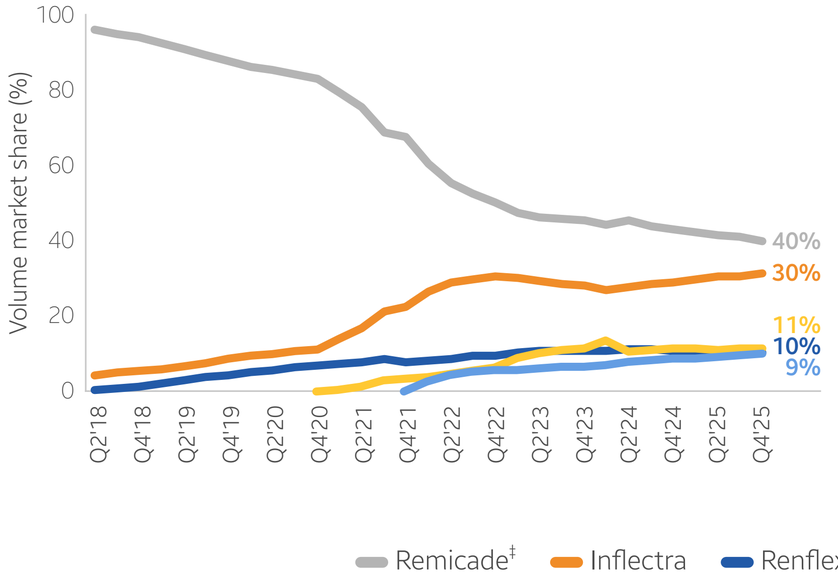
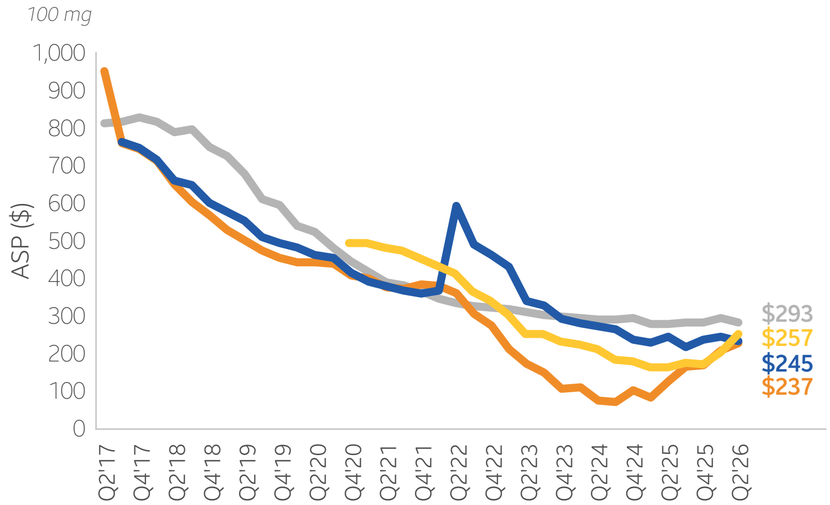


Figure 25. Infliximab ASP Trend[3]



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

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

Biosimilar Deep Dive

Reference

Market Share and WAC Trends - Humira (Adalimumab)

- **As of February 2026, biosimilar penetration increased to 60%, reflecting the inclusion of Quallent private label sales in market share calculations starting in 2026.**
- **Biosimilar brands have launched the market with diverse WAC pricing strategies.**
  1) Hadlima, Yusimry, Simlandi, and Abrilada offer a low WAC: ~85-86% less than Humira.
  2) Cyltezo, Amjevita, Hyrimoz, Hulio, Idacio, and Yuflyma 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 26. Adalimumab Volume Market Share[5]

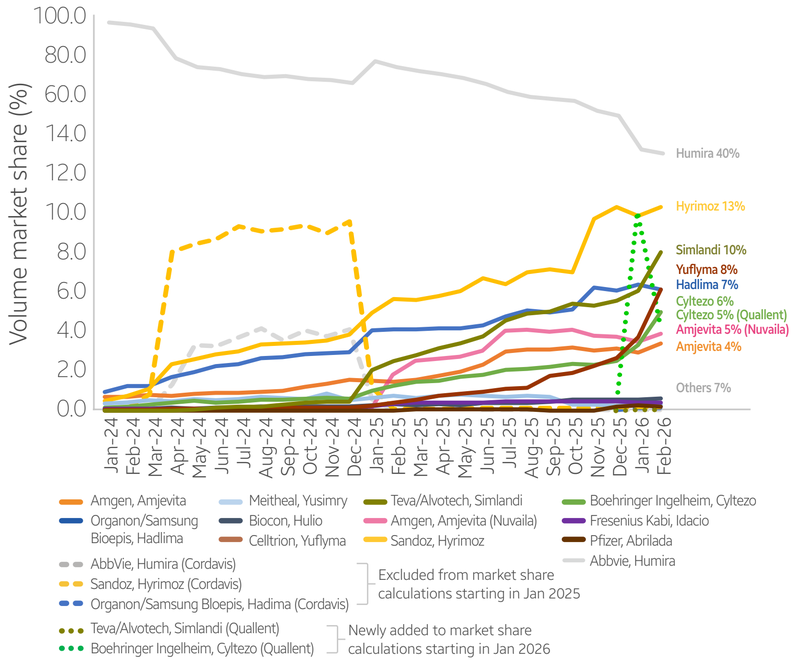
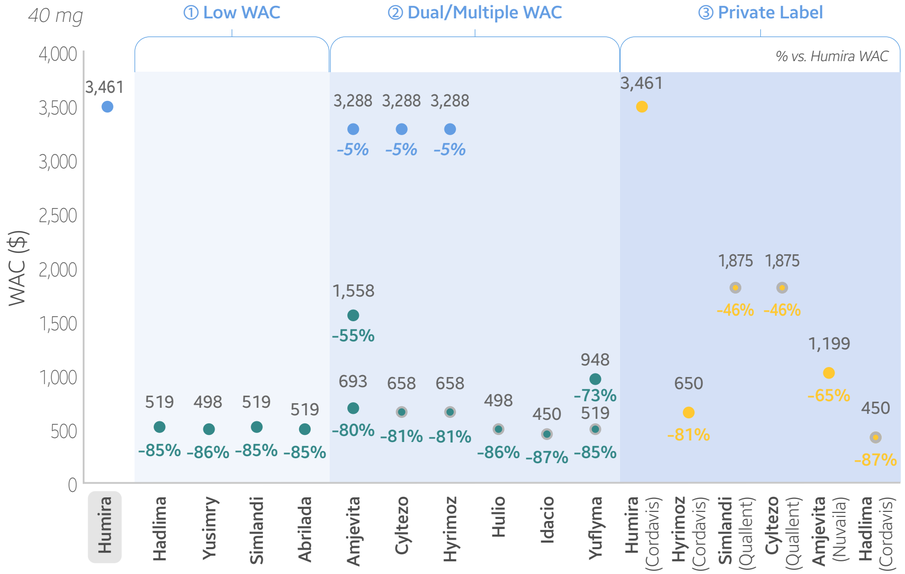


Figure 27. Adalimumab WAC Trend[z]



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

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

Biosimilar Deep Dive

Reference

Market Share and ASP Trends - Actemra (Tocilizumab)

- As of Q4 2025, tocilizumab biosimilars still hold a low market share, accounting for 18% of the total market.
- As of Q2 2026, the average ASP of all biosimilar products is $1,744 (-2% vs. last quarter).
- Tyenne, the tocilizumab biosimilar with the relatively higher ASP discount (23% lower than the reference product), has been consistently gaining market share.

Figure 28. Tocilizumab Volume Market Share[4]

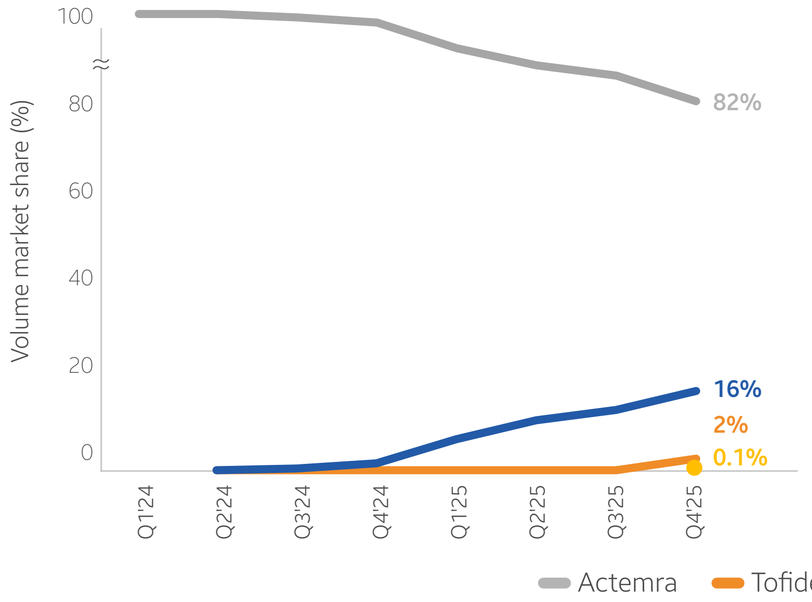
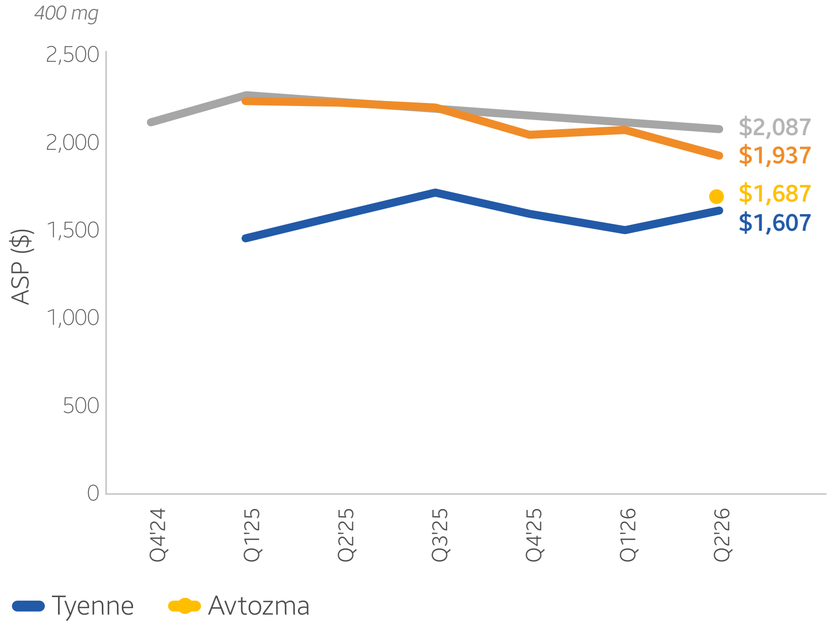


Figure 29. Tocilizimab ASP Trend[3]



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

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

Biosimilar Deep Dive

Reference

Market Share and WAC Trends - Stelara (Ustekinumab)

- As of Q4 2025, ustekinumab biosimilar market share has reached 27% (+8% vs. last quarter).
- As of Q2 2026, the average ASP of all ustekinumab biosimilar products is $753 (-73% vs. last quarter).
- ASPs of several ustekinumab biosimilars normalized in Q2 2026 following the exclusion of noncovered subcutaneous versions from the Medicare Part B payment calculation methodology.

Figure 30. Ustekinumab Volume Market Share[4]

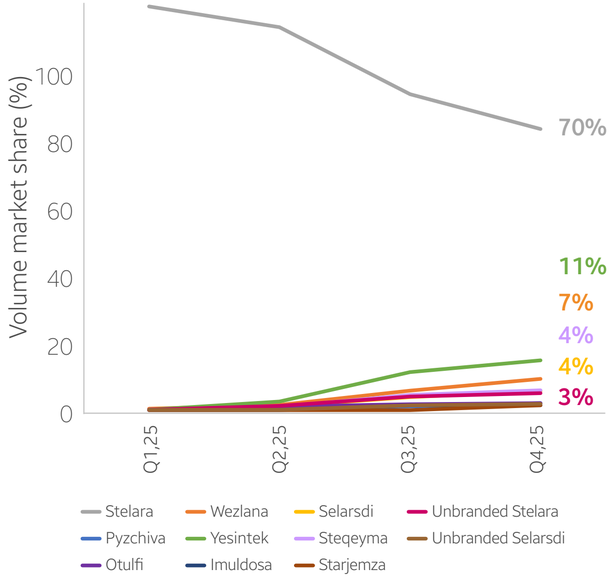
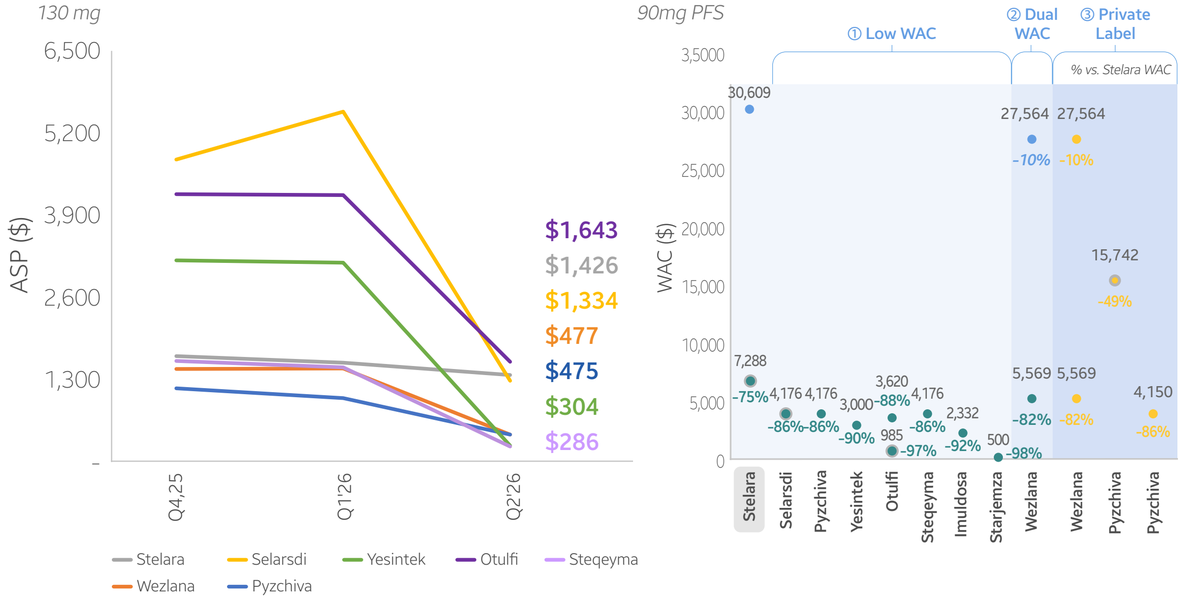


Figure 31. Ustekinumab ASP Trend & WAC



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

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

Biosimilar Deep Dive

Reference

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 32. Insulin Glargine Volume Market Share[4]

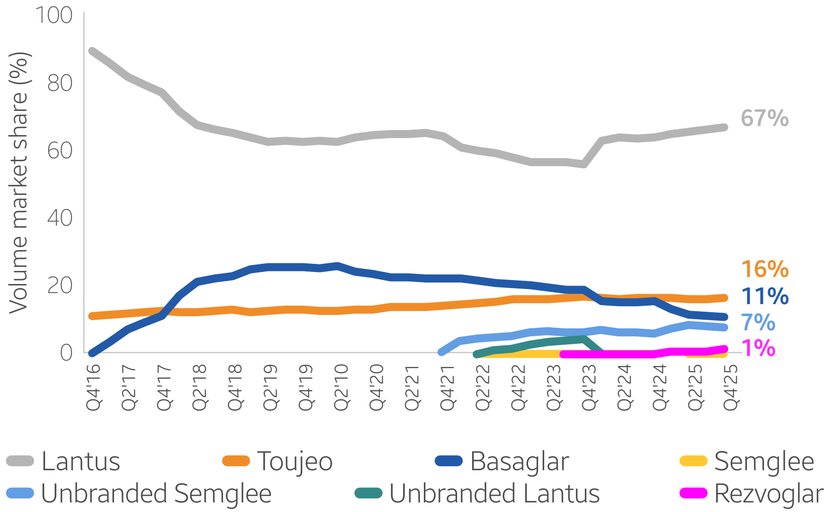
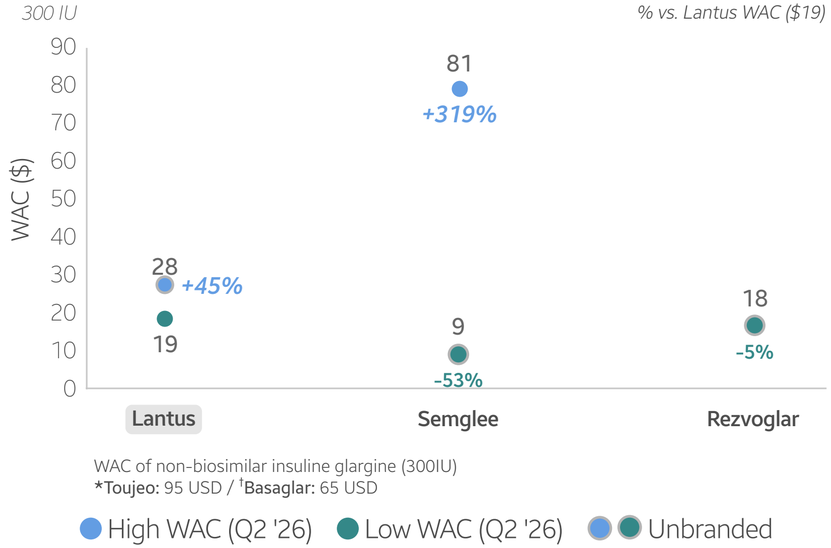


Figure 33. Insulin Glargine WAC Trend[2]



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

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

Biosimilar Deep Dive

Reference

Market Share and ASP Trends - Lucentis (Ranibizumab)

- As of Q4 2025, ranibizumab biosimilar market share has reached 2% (-4% vs. last quarter).
- As of Q2 2026, the average ASP of all biosimilar products is $367 (+9% vs. last quarter).
- Cimerli's volume market share declined to below 1% following a temporary pause in commercialization.

Figure 34. Ranibizumab Volume Market Share[4]

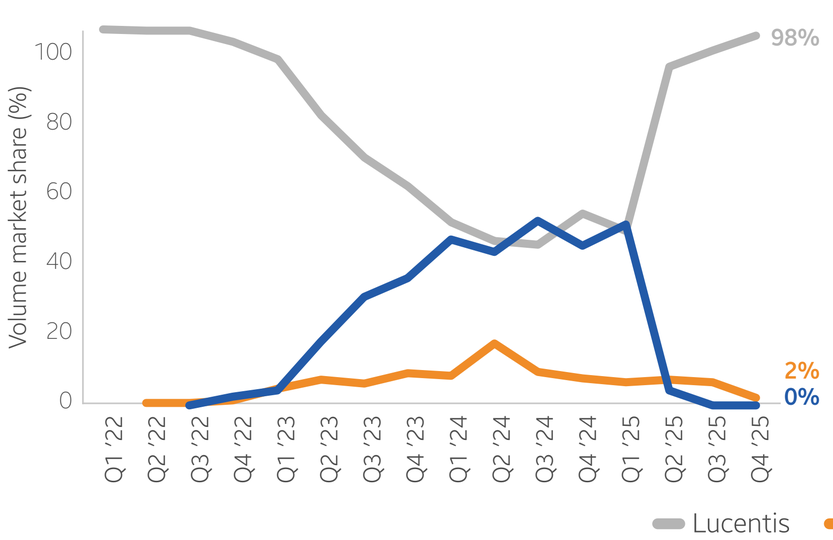
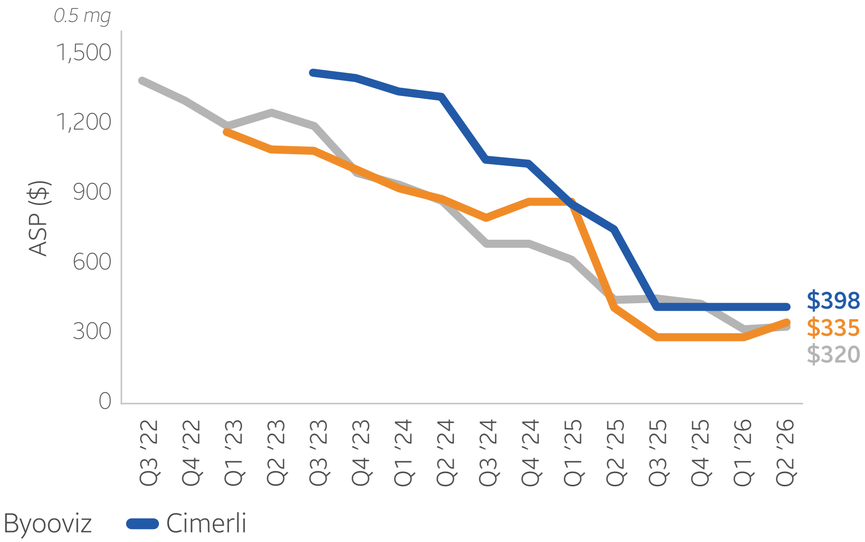


Figure 35. Ranibizumab ASP Trend[3]



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

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

Biosimilar Deep Dive

Reference

Market Share and ASP Trends – Soliris (Eculizumab)

- As of Q4 2025, eculizumab biosimilar market share has reached 22% (+13% vs. last quarter).
- As of Q2 2026, the average ASP of all biosimilar products is $5,023 (-0.4% vs. last quarter).
- Epysqli, an eculizumab biosimilar with ASP priced 32% lower than the reference product, is beginning to gain traction and show notable growth in market share.

Figure 36. Eculizumab Volume Market Share[4]

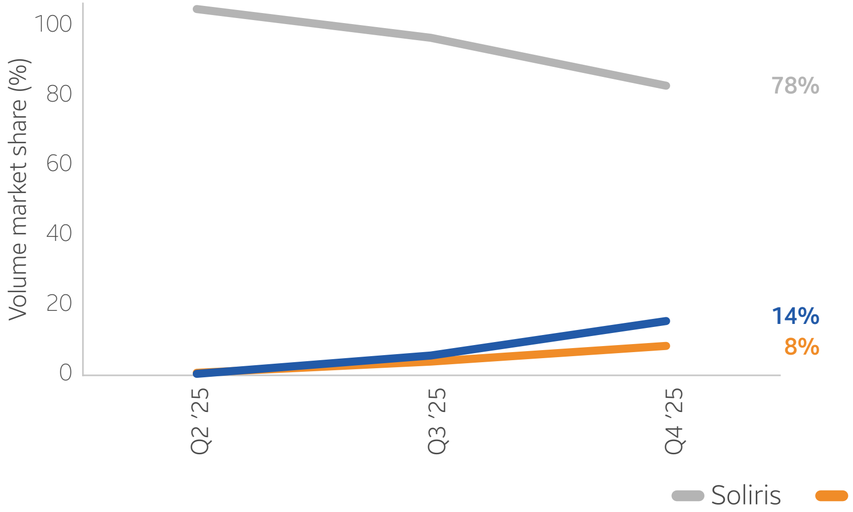
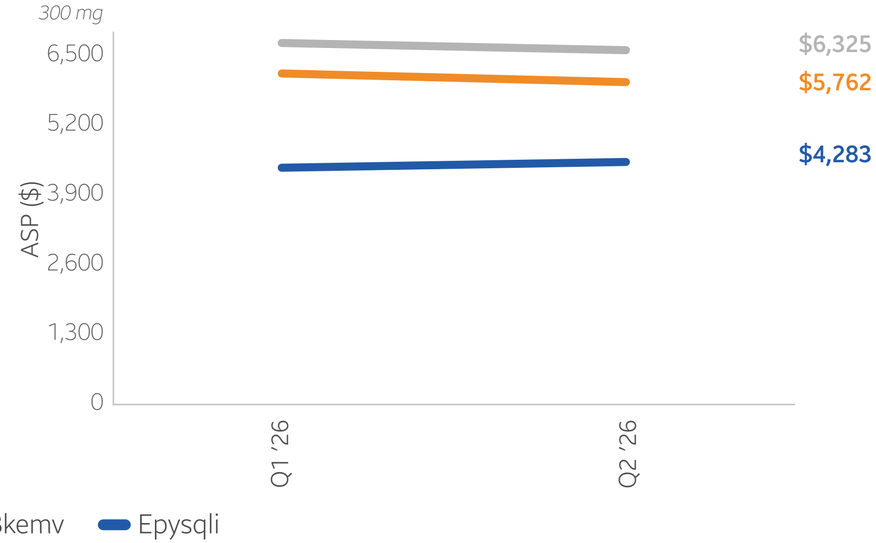


Figure 37. Eculizumab ASP Trend[3]



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

Ⅳ. Biosimilar Deep Dive

FDA Moves to Streamline Biosimilar Development: Key Regulatory Updates and Market Implication

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

Biosimilar Deep Dive

Reference

FDA will No Longer Require Routine Comparative Clinical Efficacy Studies (CES)

The FDA increasingly emphasizes the fundamental role of analytical and functional data

- FDA historically framed biosimilar approval as a step-wise, risk-based evaluation, where evidence is generated to resolve uncertainty at each stage of development before progressing. The agency now recognizes that certain steps run concurrently.
- Advanced analytical characterization (structure, function, post-translational modifications), functional studies and comparative pharmacokinetic (PK) studies are widely considered the most sensitive tools for detecting clinically meaningful differences.
- Analytical, functional and PK data are expected to be sufficient to demonstrate high similarity in many cases, and FDA has issued updated guidance indicating that CES is no longer expected by default.

Evolution in the use of Analytical and Functional Studies make routine CES unnecessary

- Modern analytical and bioassay technologies can detect minor molecular and functional differences that clinical efficacy endpoints may not reliably capture, particularly in well-characterized biologics such as monoclonal antibodies.
- FDA has indicated that CES may no longer be necessary as a matter of routine, while retaining the option to require such studies when there is an outstanding question critical to a regulatory decision that cannot be answered by other means.

The FDA positions CES as no longer routine or foundational

Comparative clinical efficacy studies may still be relevant (e.g., if PK studies are not feasible or not likely to be informative).
Sponsors must still engage with FDA on the need for CES, although such studies are considered unnecessary for most biosimilars.

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

Biosimilar Deep Dive

Reference

March 9 Revision Introduces Additional Flexibility in Biosimilar Development

FDA clarified greater flexibility in sourcing reference product material

- In the March 9 revision, FDA clarified that clinical data generated using a non-US-licensed comparator product may be used to support a US biosimilar application, provided sufficient scientific justification is established.
- Sponsors remain responsible for providing adequate scientific justification for the use of non-US-licensed comparator data, including analytical, regulatory, and manufacturing considerations.

Additional bridging studies may not be required in certain circumstances

- Historically, sponsors often conducted three-way PK bridging studies when using non-US comparator data.
- Under the revised draft guidance, sponsors may be able to justify the use of foreign comparator data through scientific rationale and analytical evidence without conducting a three-way PK study, where sufficient comparability can be demonstrated.

Core biosimilar approval standards remain unchanged

- The statutory standard for biosimilar approval remains unchanged, including the requirement to demonstrate high similarity and no clinically meaningful differences.
- Robust analytical, functional, and PK evidence continues to be required, consistent with FDA's totality-of-evidence approach.

What's changed since this time last year?

CES is no longer routinely expected; the need is assessed on the basis of residual uncertainty (October 2025 draft guidance)

Additional bridging studies (e.g., three-way PK bridging) may not be required in certain circumstances when using non-US comparator products (March 2026 revision)

Updated draft guidance reflects FDA's evolving approach to biosimilar development

What has not changed?

Statutory biosimilarity standard under 351(k) unchanged — high similarity and no clinically meaningful differences in safety, purity, and potency still required

Biosimilar sponsors must continue to provide a scientifically rigorous justification for their development strategy

FDA retains discretion to request additional data if uncertainty remains

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

Biosimilar Deep Dive

Reference

Lower Development Barriers may Increase Competition While Maintaining Quality Expectations

Impact on biosimilar development

- Reduced reliance on CES and increased flexibility in comparator sourcing may lower development cost and complexity
- Development strategies are likely to continue shifting toward front-loaded analytics and PK/PD studies.
- These changes may enable development across a broad set of reference products, particularly in later-wave or smaller markets.

Impact on market dynamics

- Lower development barriers may support increased market participation, potentially intensifying competition and contributing to pricing pressure over time.
- Limited change is expected in payer evidence requirements, which are primarily driven by pricing and access considerations.

Regulatory flexibility does not alter the fundamental standards for biosimilar approval

- Notwithstanding the regulatory flexibility introduced, the scientific and quality standards underpinning biosimilar approval remain fully intact.
- Biosimilar approval continues to require rigorous demonstration of similarity based on analytical, functional, and PK/PD evidence, evaluated under FDA's totality-of-evidence approach.
- Manufacturing and quality standards (e.g., cGMP) remain unchanged.

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

Biosimilar Deep Dive

Reference

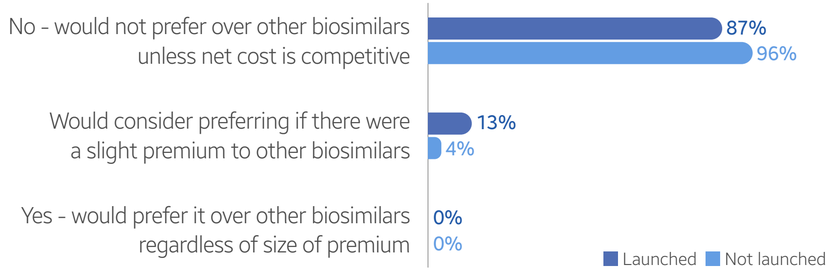
Reduced Reliance on Comparative Efficacy Studies (CES) is Unlikely to Materially Change Payer or Provider Decision Drivers

Payers and health systems view FDA approval as definitive

KEY FINDINGS (2026 Primary Market Research)

- Reduced reliance on CES is unlikely to materially impact coverage or formulary positioning, as FDA approval is viewed as the threshold for equivalence.
- Panelists emphasized that once the FDA determines analytical and PK/PD data are adequate, they consider all approved biosimilars clinically equivalent without requiring additional comparative efficacy data (as evidenced by their willingness to cover different biosimilars year to year, without interchangeability considerations).
- Decisions are primarily driven by net cost, and extra trials are not perceived to provide incremental clinical value.
- Provider behavior is unlikely to shift, as comparative efficacy data are rarely a key factor in real-world treatment decision-making.

IF ONE BIOSIMILAR MANUFACTURER WERE TO FOLLOW THE CURRENT, MORE RIGOROUS STUDY REQUIREMENTS EVEN AFTER THESE FDA POLICY CHANGES OCCURRED, WOULD YOUR ORGANIZATION PREFER THAT BIOSIMILAR OVER OTHER BIOSIMILARS THAT DO NOT CONDUCT SWITCHING STUDIES OR PHASE 3 TRIALS?



Payers

*"**I really do not think it would make much of a difference. If anything, it would streamline the whole process.** It sounds like what the FDA is attempting to do is make biosimilars more available without requiring all of these comparative studies. **Those studies just slow everything down and make it harder.** In a way, that protects the originator. I do not know if that was the intent, but that is what it did. It allowed the originator to have a longer runway. If they move away from that approach, that would be better and more ideal"*

*"**No, the [removal of phase 3 trial requirements] won't do anything.** Whatever speeds them to market will be fine. You've got PK/PD data; combine that with the number of biosimilars we've had out, provider experience, and how comfortable they are with them. I think it's going to be okay"*

*"Those additional studies don't meaningfully change our clinical confidence once the FDA has updated its requirements. **If the FDA determines that robust analytical, functional, and PK/PD data are sufficient for approval, then all biosimilars meeting that standard are clinically equivalent from our perspective.** Extra clinical trials may make a manufacturer feel differentiated, but they don't translate into added clinical value or justify a higher price. Our decisions are ultimately driven by net cost, operational feasibility, and the ability to deliver savings to clients. So, while we respect manufacturers who choose to exceed the requirements, it wouldn't influence our preference unless the economics remain aligned with our overall strategy"*

Payers

"Two or three years ago, I'd say yes, 100%. We were fielding questions and concerns about skinny labels and looking at the trial data to say, 'You didn't study this.' When I look at adalimumab, that was a big one. We had four or five hundred patients established just in our self-insured employee population, so you're moving a large portion of the population. It was a big discussion item at that point, including labeling and concerns around whether we could do this and whether it was off-label. We saw that, then moved on to ustekinumab and tocilizumab. ***Since then, I don't recall hearing a single comment in clinician meetings or discussions where a Phase 3 trial was brought up. The key questions have been: Has it been approved? Is it interchangeable, if that remains a thing? And how does it compare? How do I order it? So, I think pharmacists may still be watching that closely, but I don't think it's significantly impacting providers' appetite for accepting biosimilars"***

"These changes wouldn't significantly alter my (or the industry's) overall perception of FDA-approved biosimilars. We generally trust the FDA's review process, and adoption would continue to be driven more by real-world experience, provider comfort, and clinical outcomes than by the specific regulatory pathway used for approval. ***Based on the conversations that I've been a part of, the studies demonstrating comparative effectiveness haven't been discussed/referenced much at all*** *and interchangeability is looked at as more of an operational challenge (not something that demonstrates "better" results for one product vs another)"*

US Biosimilars Approval & Launch Status

Biosimilar Price
- Oncology
- Supportive Care
- Immunology
- Ophthalmology & Hematology
- Endocrinology

Biosimilar Market Dynamics
- Biosimilar Market Adoption & Price Erosion

Market Share & Price Trends
- Oncology
- Supportive Care
- Immunology
- Endocrinology
- Ophthalmology
- Hematology

Biosimilar Deep Dive

Reference

Reference

1. Biosimilar Product Information. FDA. (Dec 2025). Retrieved Dec 2025 from https://www.fda.gov/drugs/biosimilars/biosimilar-product-information
2. HCPCS Unit WAC Price. Buy and Bill. (Dec 2025). Retrieved Dec 2025 from https://buyandbill.com
3. Medicare part B Drug Average Sales Price. CMS. (Dec 2025). Retrieved Dec 2025 from https://www.cms.gov/medicare/payment/part-b-drugs/asp-pricing-files
4. SMART Global MIDAS. IQVIA. (Jan 2017-Sep 2025). Retrieved Dec 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 – Sep 2025 reflecting estimates of real-world activity. Copyright IQVIA. All rights reserved.
5. Weekly Sales Perspectives. IQVIA. (Jan 2023-Nov 2025). Retrieved Dec 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 – Nov 2025 reflecting estimates of real-world activity. Copyright IQVIA. All rights reserved.
6. FDA Takes Further Steps to Streamline Biosimilar Development and Make Medicines More Affordable. FDA. (Mar 2026). Retrieved Mar 2025 from
   https://www.fda.gov/news-events/press-announcements/fda-takes-further-steps-streamline-biosimilar-development-and-make-medicines-more-affordable
7. Do the Outcomes of Clinically Efficacy Trials Matter in Regulatory Decision-making for Biosimilars?. BioDrugs. (Nov 2023). Retrieved Mar 2025 from Do the Outcomes of Clinical Efficacy Trials Matter in Regulatory Decision-Making for Biosimilars? | BioDrugs | Springer Nature Link
8. Scientific Considerations in Demonstrating Biosimilarity to a Reference Product: Updated Recommendations for Assessing the Need for Comparative Efficacy Studies. FDA. (Oct 2025). Retrieved Mar 2025 from https://www.fda.gov/media/189366/download
9. Primary Market Research Conducted by Petauri. (Mar 2025).

SAMSUNG BIOEPIS

76, Songdogyoyuk-ro, Yeonsu-gu, Incheon, Republic of Korea
E-mail: bioepisinfo@samsung.com
For more information, please visit: www.samsungbioepis.com

© 2026 Samsung Bioepis Co., Ltd. All Rights Reserved. 04/2026 [C_US_202604_001_260427]