Samsung Bioepis

Biosimilar Market Report

14th Edition, Q3 2026

SAMSUNG BIOEPIS

Samsung Bioepis

Our mission

Samsung Bioepis is committed to improving patient access and expanding treatment options through the development and commercialization of high-quality biologic medicines.

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 present the 14th edition of our Biosimilar Market Report, offering our latest analysis of US pricing and market share dynamics across key biosimilar markets.

The US drug pricing landscape continues to shift toward greater transparency and accountability. Following our Q1 coverage of PBM reform, this edition turns to another policy development: the ongoing 340B Drug Pricing Program reform discussions. Health Resources and Services Administration (HRSA) is considering a transition from the current upfront discount model to a rebate-based model, which would introduce new reporting requirements and alter how 340B discounts flow between manufacturers and covered entities.

In this quarter's deep-dive section, we examine the 340B reform landscape and its potential implications for the biosimilar market. We explore how changes to 340B economics may influence biosimilar adoption dynamics and discuss both the opportunities and mitigating factors that biosimilar stakeholders should consider.

Thank you for your ongoing engagement with our reports. Our report continues to offer an in-depth perspective on current market trends, challenges, and strategic opportunities for stakeholders navigating this rapidly changing landscape.

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

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I. US Biosimilars Approval & Launch Status

FDA Approval and Launch Status of US Biosimilars

* As of June 2026, the FDA has approved a total of 96 biosimilars across 21 unique biological molecules. Of the 96 approvals, 71 biosimilars (74%) have launched in the US market.

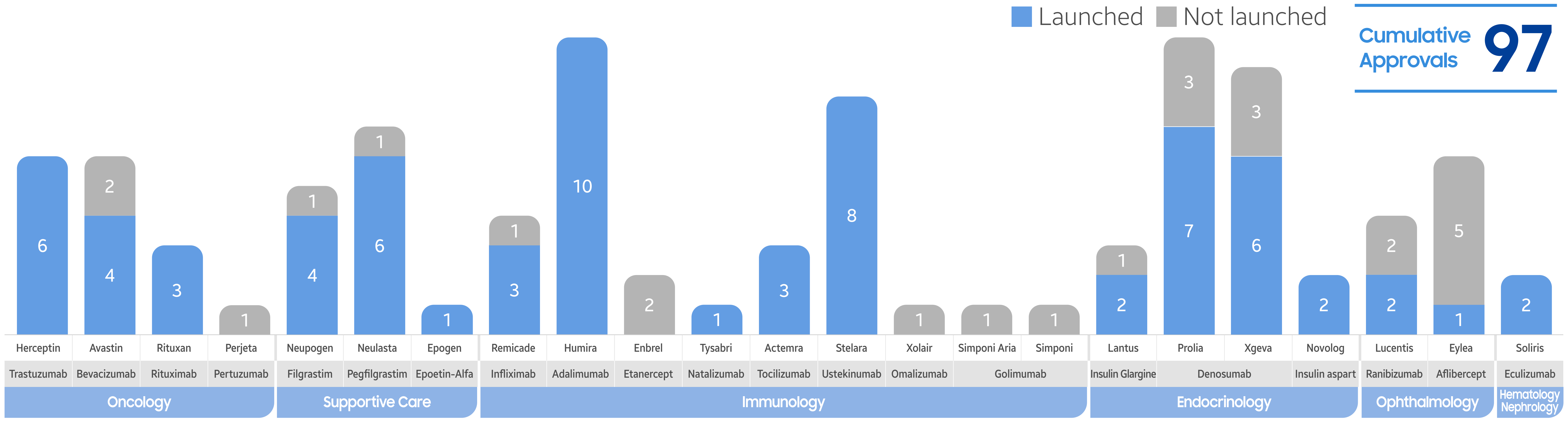
Figure 1-1. 5 FDA-approved Biosimilars in Q2`26

Reference Product	Biosimilar name	Biosimilar Manufacturer
Lantus	Langlara	Sunshine Lake Pharma
Neulasta	Ennumo	Accord
Simponi	Immgolis	Bio-Thera Solutions
Simponi Aria	Immgolis Intri	Bio-Thera Solutions
Lucentis	Ranluspec	Lupin

Figure 1-2. 2 Biosimilars Launched in the US Market in Q2`26

Reference Product	Biosimilar name	Biosimilar Manufacturer & Commercial Partner	Launch Date
Prolia	Bosaya	Biocon	Apr 2026
Xgeva	Aukelso	Biocon	Apr 2026

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



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 Jun 2026, with Suffix)

TA	Oncology				Immunology								
Molecule	Trastuzumab	Bevacizumab	Rituximab	Pertuzumab	Infliximab	Adalimumab	Etanercept	Natalizumab	Tocilizumab	Ustekinumab	Omalizumab	Golimumab	
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) Abbvie 2002	Enbrel (etanercept) Amgen 2003	Tysabri (natalizumab) Biogen 2004	Actemra (tocilizumab) Genetech 2010	Stelara (ustekinumab) Janssen 2009	Xolair (omalizumab) Genentech&Novartis 2003	Simponi (golimumab) Janssen 2009	Simponi Aria (golimumab) Janssen 2013
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	Immgolis (golimumab-sldi) Bio-Thera Solutions 2026	Immgolis Intri (golimumab-sldi) Bio-Thera Solutions 2026
	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 Jun 2026, with Suffix)

TA	Endocrinology				Ophthalmology		Hematology	Supportive Care		
Molecule	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	Langlara (insulin glargine-aldy) Sunshine Lake Pharma 2026		Nufymco (ranibizumab-leyk) Formycon&Zydus 2025	Ahzantive (aflibercept-mrbb) Formycon&Klinge 2024		Releuko (filgrastim-ayow) Amneal&Kashiv 2022	Ziextenzo (pegfilgrastim-bmez) Sandoz 2019	
	Conexxence (denosumab-bnht) Fresenius Kabi 2025	Bomyntra (denosumab-bnht) Fresenius Kabi 2025			Ranluspec (ranibizumab-hkdz) Lupin&Sandoz 2026	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	
	Bosaya (denosumab-qbde) Biocon 2025	Aukelso (denosumab-qbde) Biocon 2025				Eydenzelt (aflibercept-boav) Celltrion 2025			Fylnetra (pegfilgrastim-pbbk) Amneal&Kashiv 2022	
	Enoby (denosumab-qbde) Richter&Hikma 2025	Xtrenbo (denosumab-qbde) Richter&Hikma 2025							Armlupeg (pegfilgrastim-unne) Lupin&Valorum 2025	
	Osvyrti (denosumab-desu) Accord 2025	Jubereq (denosumab-desu) Accord 2025							Ennumo (pegfilgrastim-pccg) Accord 2026	
	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

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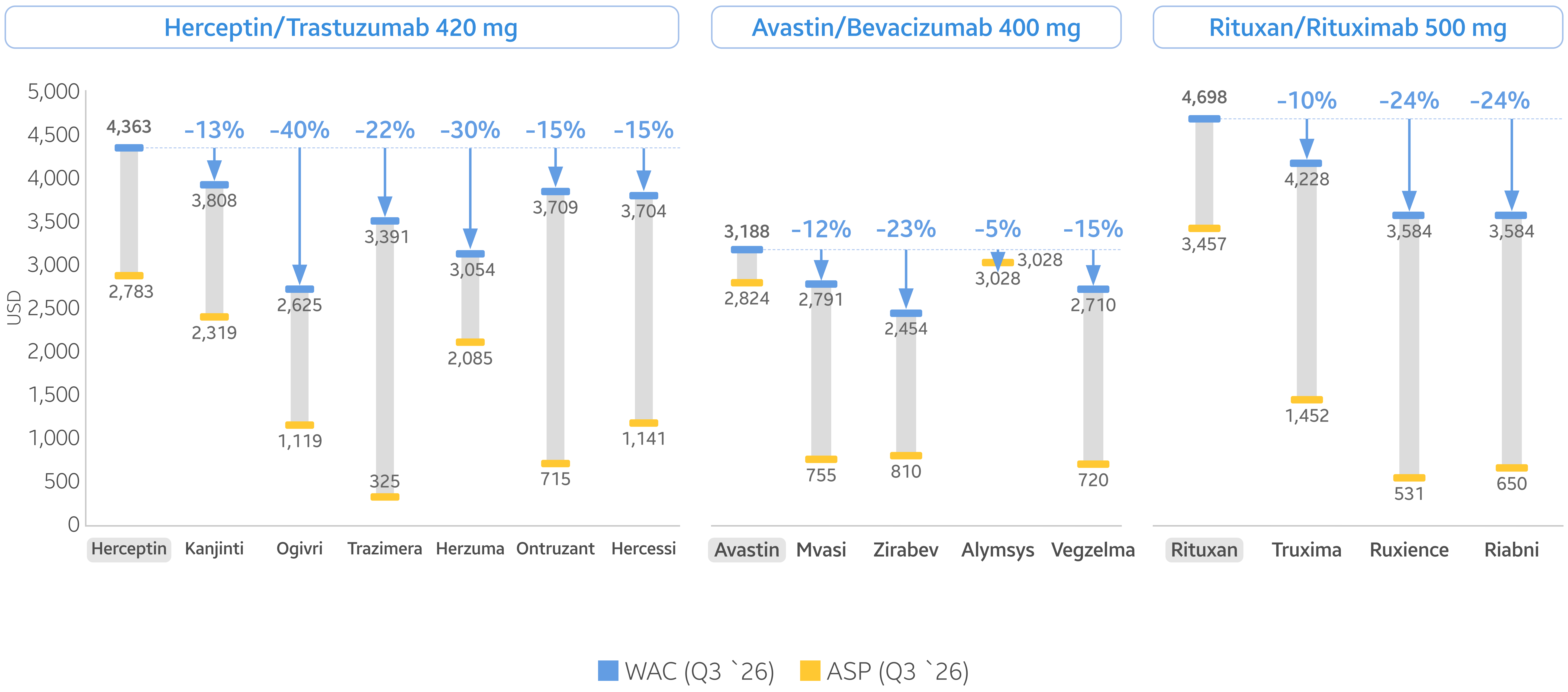
Oncology WAC and ASP – Q3 2026

- Across oncology biosimilars, WAC prices discounted between 10-40% compared to reference products.
- Biosimilar Q3 2026 ASP discounts as compared to the reference product's ASP average -54%, -53%, and -75% for the trastuzumab, bevacizumab, and rituximab markets, respectively.

Figure 4. Q3 2026 WAC and ASP[2,3]



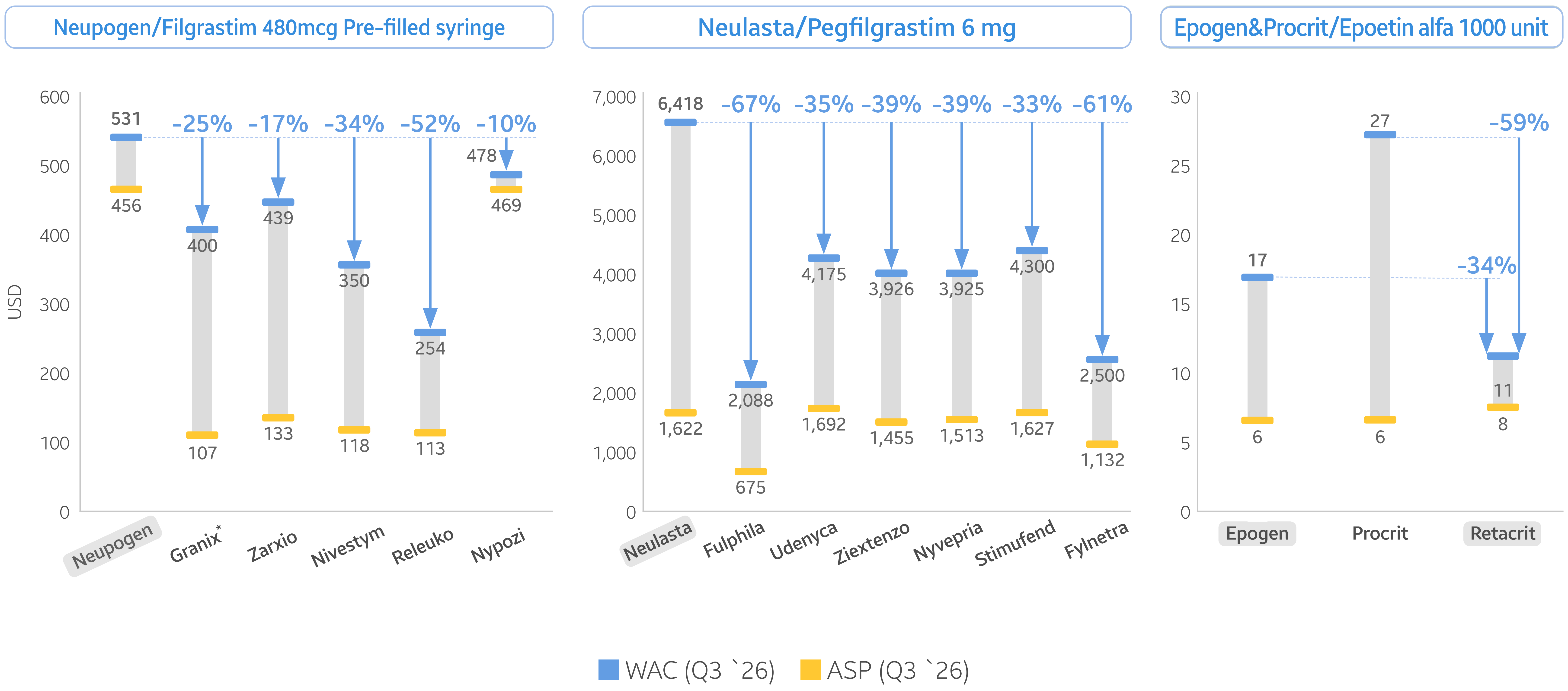
Products are listed in order of launch

ASP: Average Sales Price; WAC: Wholesale Acquisition Cost

Supportive Care WAC and ASP – Q3 2026

- Across supportive care biosimilars, WAC prices are discounted between 10-67% 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 2026 WAC and ASP[2,3]

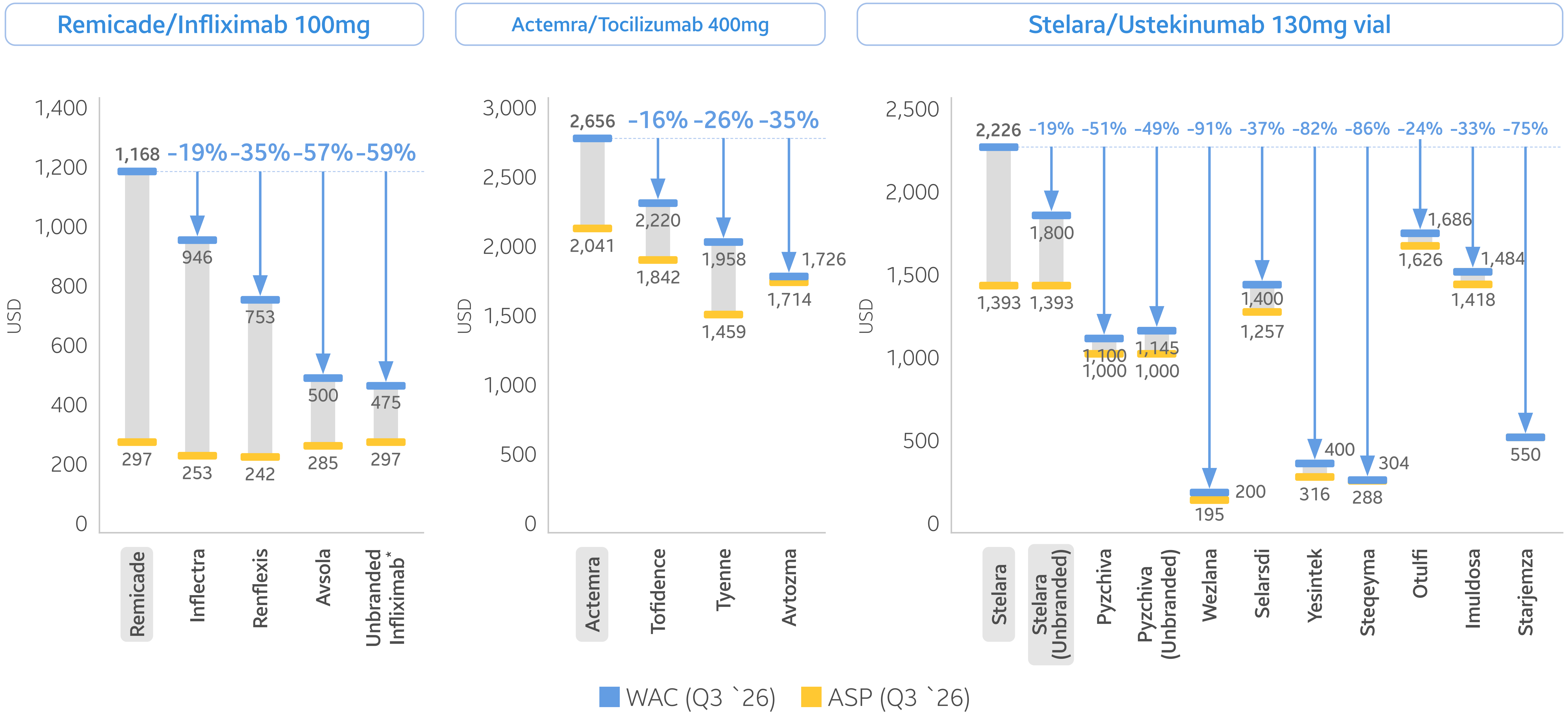


Products are listed in order of launch
ASP: Average Sales Price; **WAC**: Wholesale Acquisition Cost
*Granix is not a biosimilar; approved under the FDA's New Drug Application pathway

Immunology WAC and ASP (1) - Q3 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. Q3 2026 WAC and ASP[2,3]

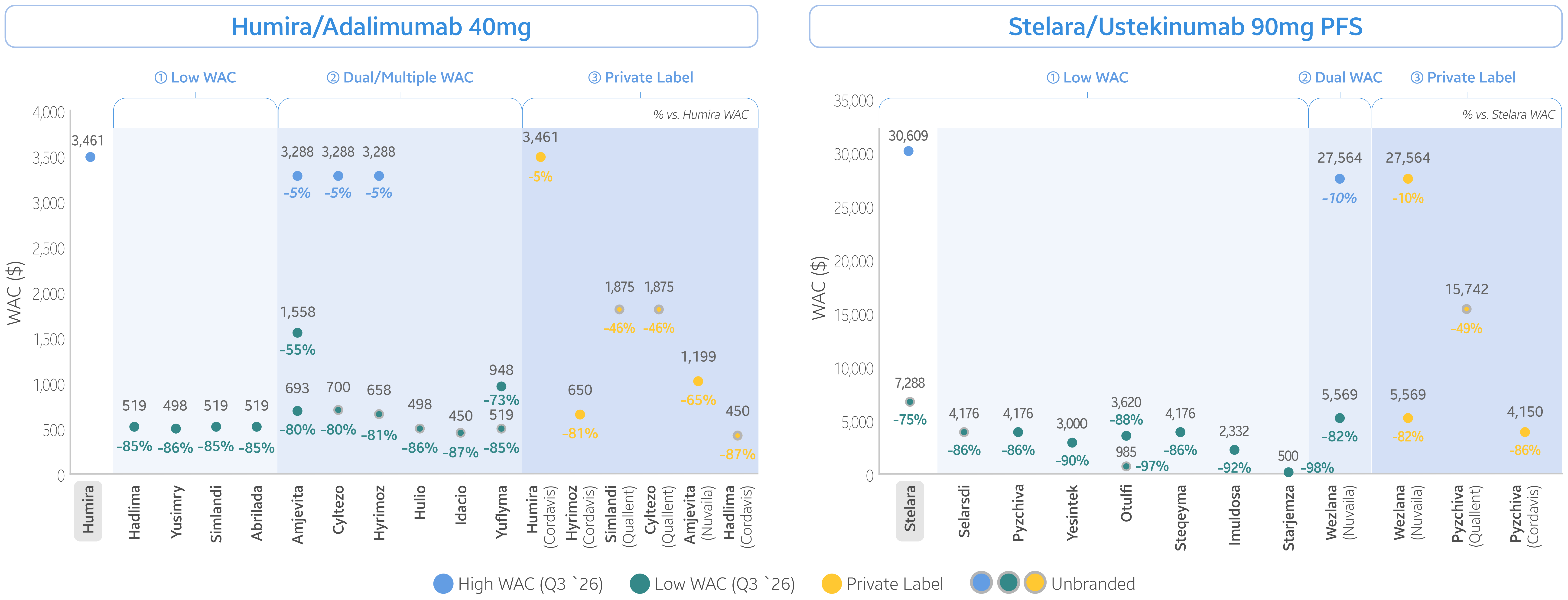


Products are listed in order of launch
ASP: Average Sales Price; **WAC**: Wholesale Acquisition Cost
*Janssen's Remicade without the brand name

Immunology WAC and ASP (2) – Q3 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.
- Most ustekinumab biosimilars did not adopt a dual or high WAC strategy as compared to the adalimumab market.

Figure 7. Q3 2026 WAC[2, 3]

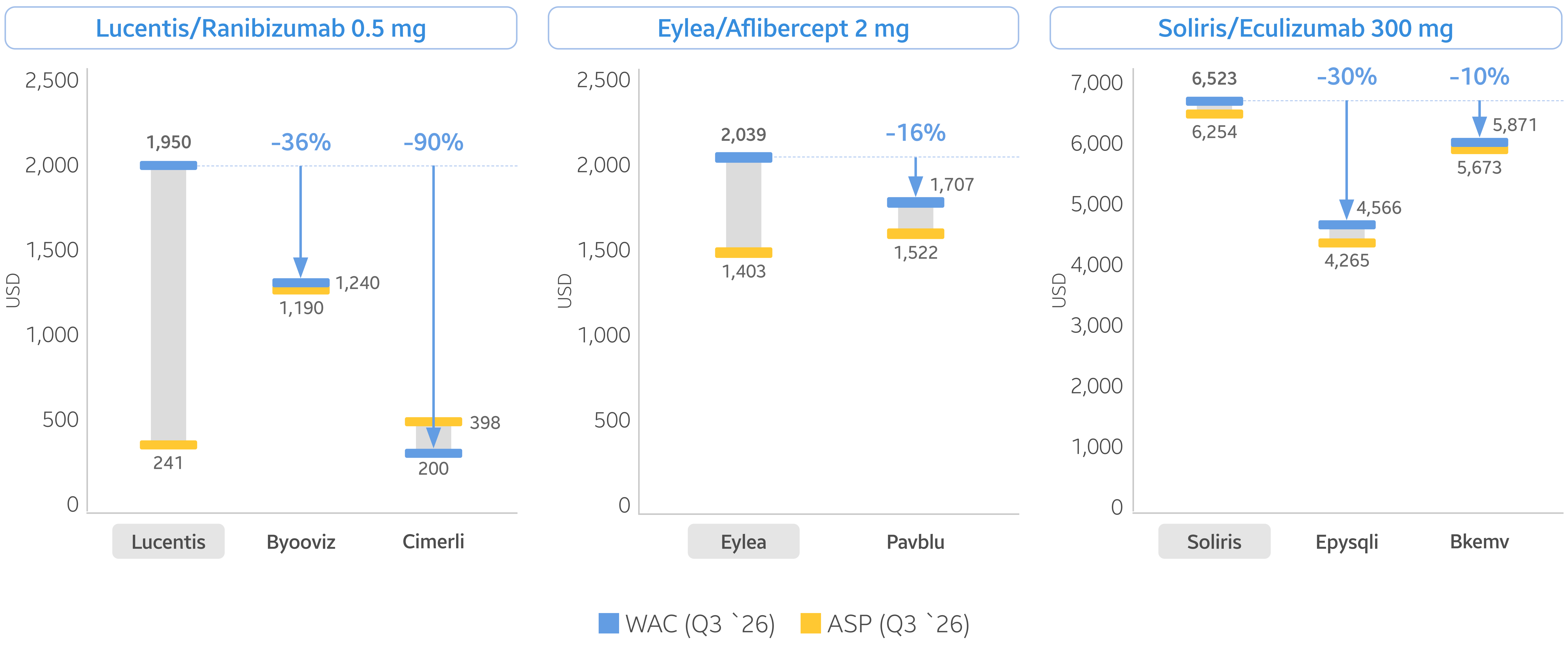


Products are listed in order of launch
WAC: Wholesale Acquisition Cost
*Toujeo is high dose version of Lantus †Basaglar is not a biosimilar, approved under the FDA's New Drug Application pathway

Ophthalmology & Hematology WAC and ASP – Q3 2026

- Ranibizumab WACs represent -36% to -90% 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. Q3 2026 WAC and ASP[2,3]



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

Endocrinology WAC and ASP - Q3 2026

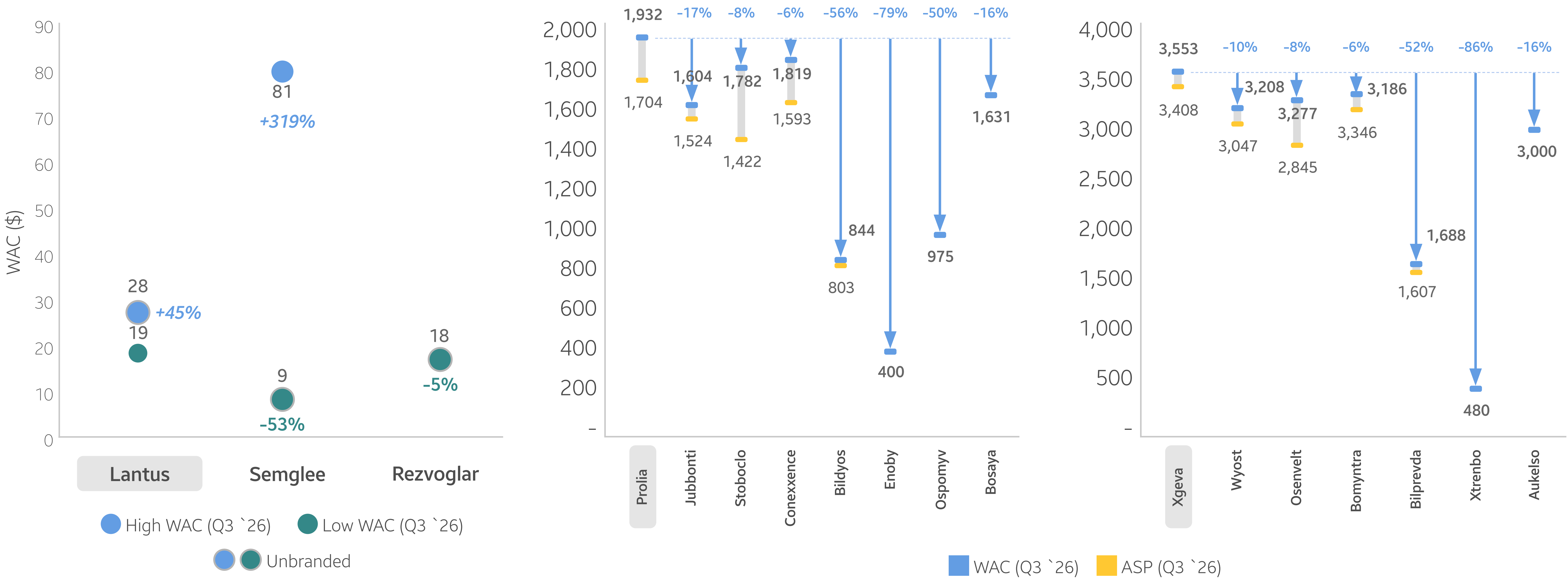
- Insulin glargine products reflect complex pricing practices such as multiple WAC options and unbranded biologics.
- Across denosumab biosimilars, WAC prices are discounted between 6-86% compared to reference products.

Figure 9. Q3 2026 WAC and ASP[2,3]

Lantus/Insulin Glargine 300IU Pre-filled Pen

Prolia/Denosumab 60mg

Xgeva/Denosumab 120mg



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

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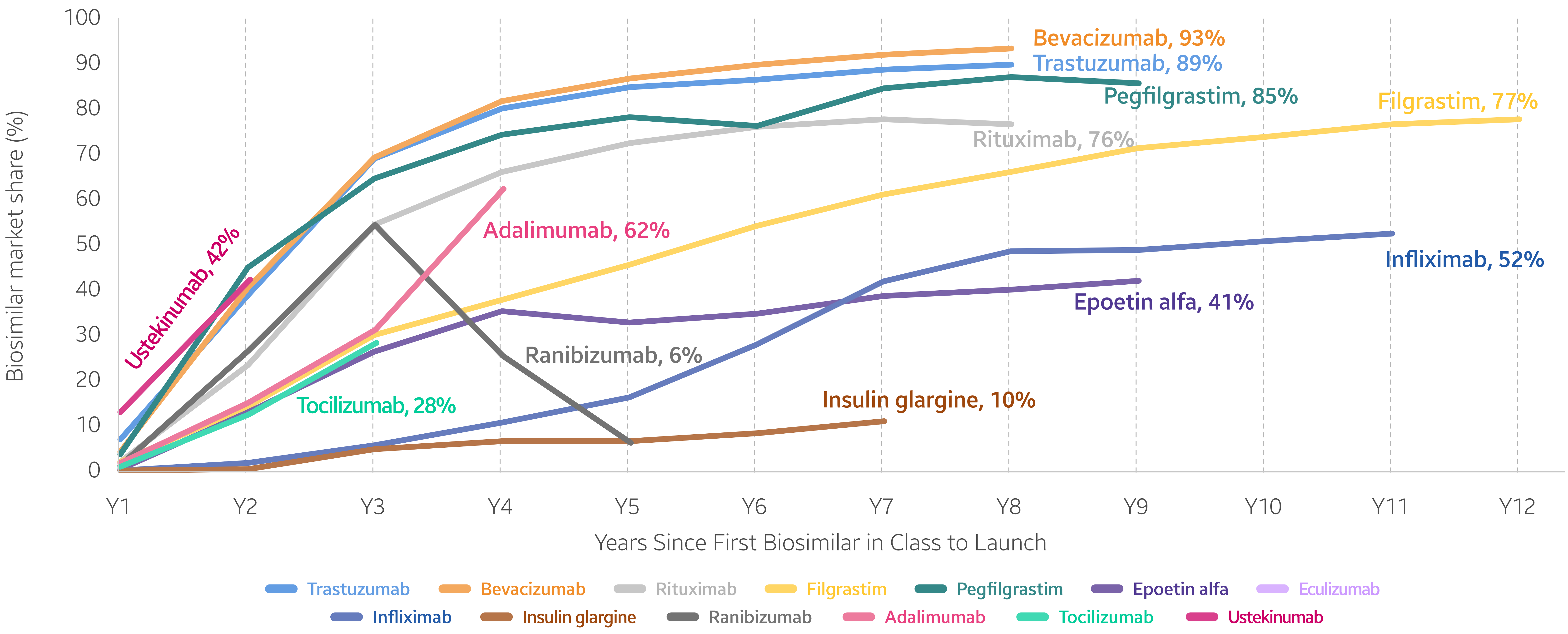
Biosimilar Volume Uptake Varies by Molecule

- On average, biosimilars have gained 47% market share within five years post initial launch.[†] Each molecule has demonstrated unique biosimilar uptake.
- Recently launched immunology biosimilars[*] (within five years of launch) have demonstrated strong growth in biosimilar market share penetration compared with the previous year, with an average increase of 25% year over year.

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

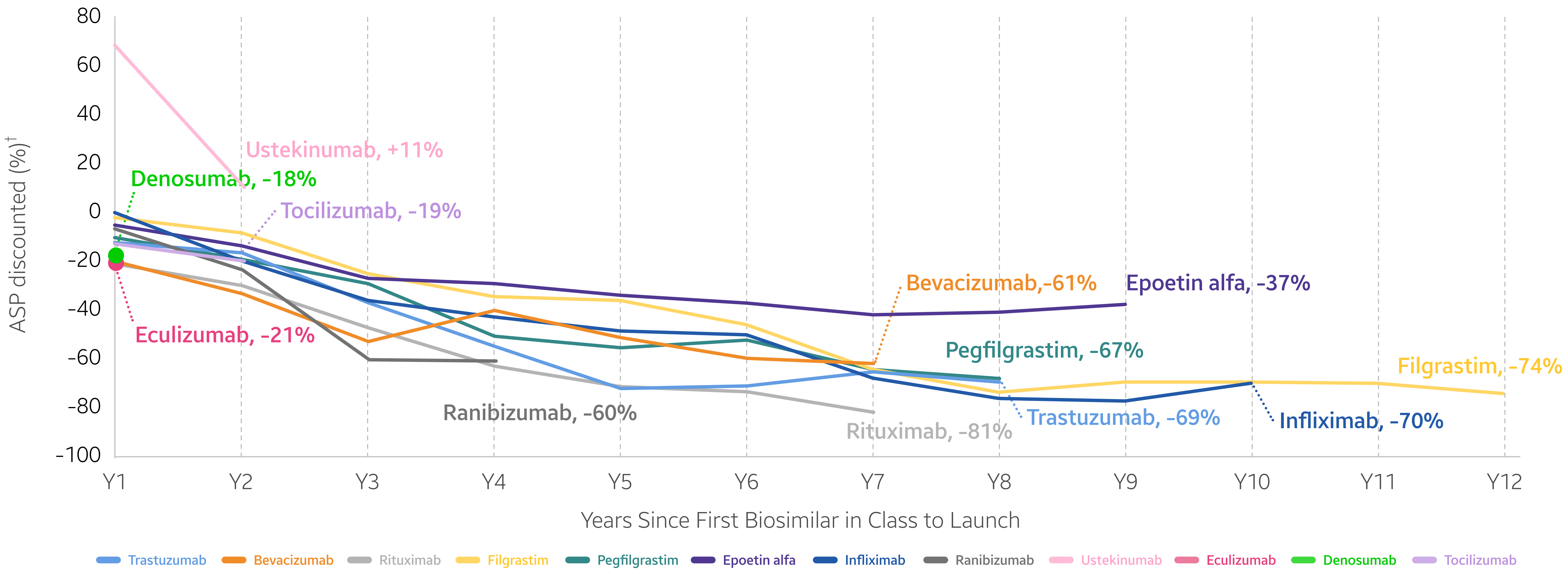


[†]Averages include products that are 5 years or older [*]Adalimumab, Tocilizumab, Ustekinumab [§] Calculated based on calendar year

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 81%).
- 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

Market Share and ASP Trends
- Herceptin (Trastuzumab)

- As of Q1 2026, the biosimilar share of the trastuzumab market was 89% (unchanged vs. last quarter).
- As of Q3 2026, average ASP of all biosimilar products is $1,284, representing a -5% from last quarter.
- 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]

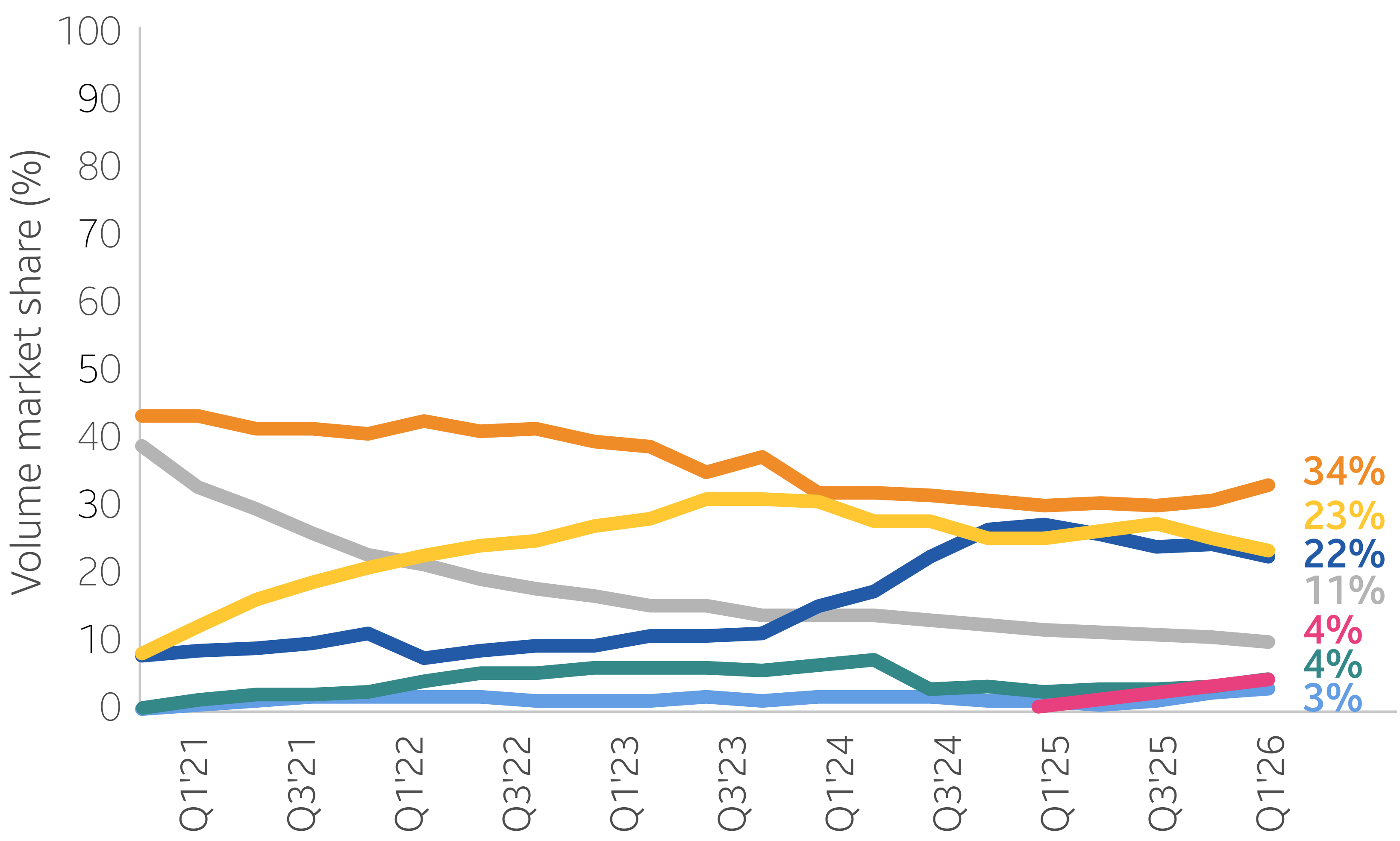
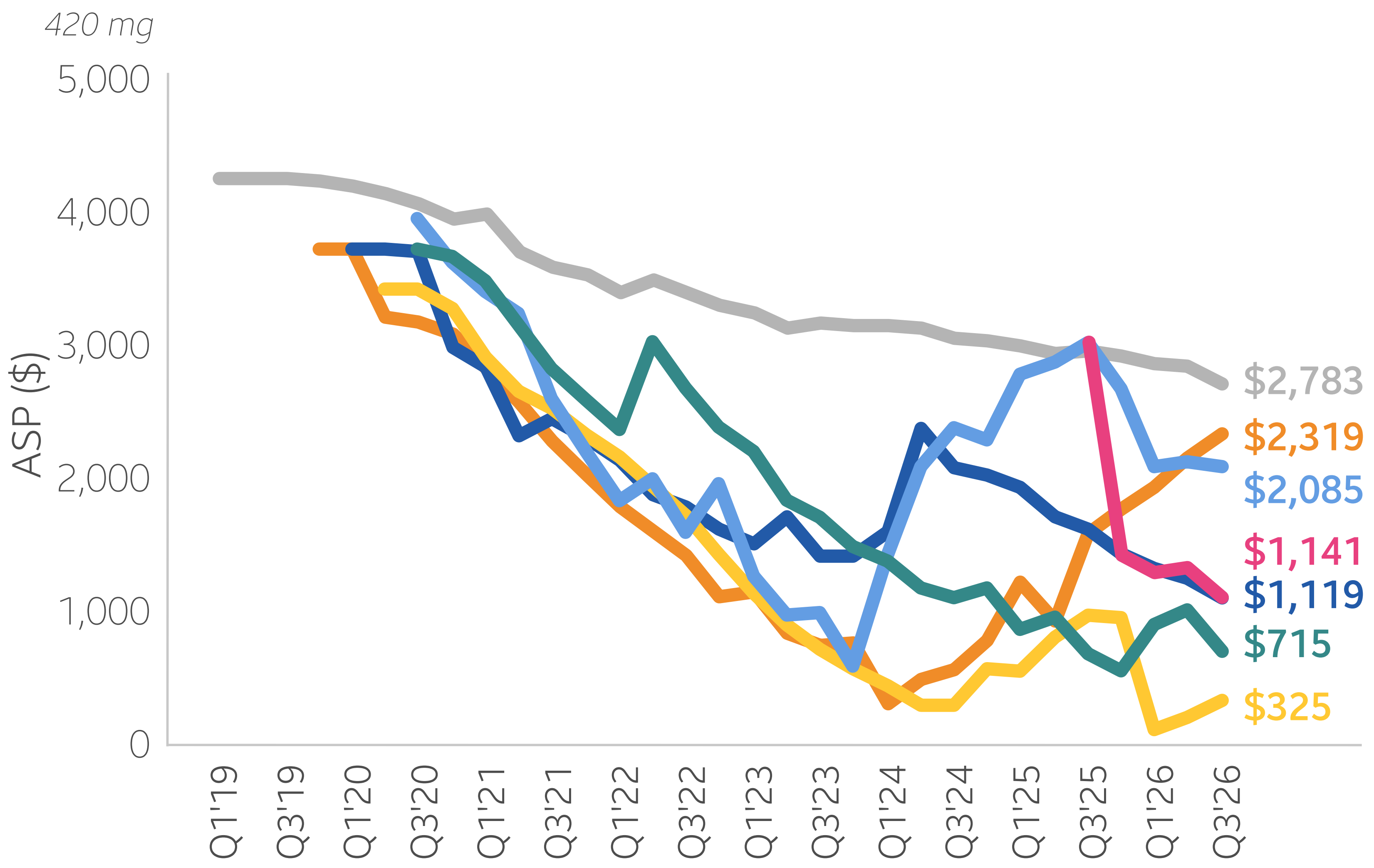


Figure 13. Trastuzumab ASP Trend[3]



Herceptin Kanjinti Ogivri Trazimera Herzuma Ontruzant Hercessi

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

Market Share and ASP Trends
- Avastin (Bevacizumab)

- As of Q1 2026, the biosimilar share of the bevacizumab market was 93% (+1% vs. last quarter).
- As of Q3 2026, average ASP of all biosimilar products is $1,328 (+17% vs. last quarter), mainly driven by ASP increase of Alymsys.
- Alymsys demonstrated a sharp ASP increase while maintaining its market share in the bevacizumab market.

Figure 14. Bevacizumab Volume Market Share[4]

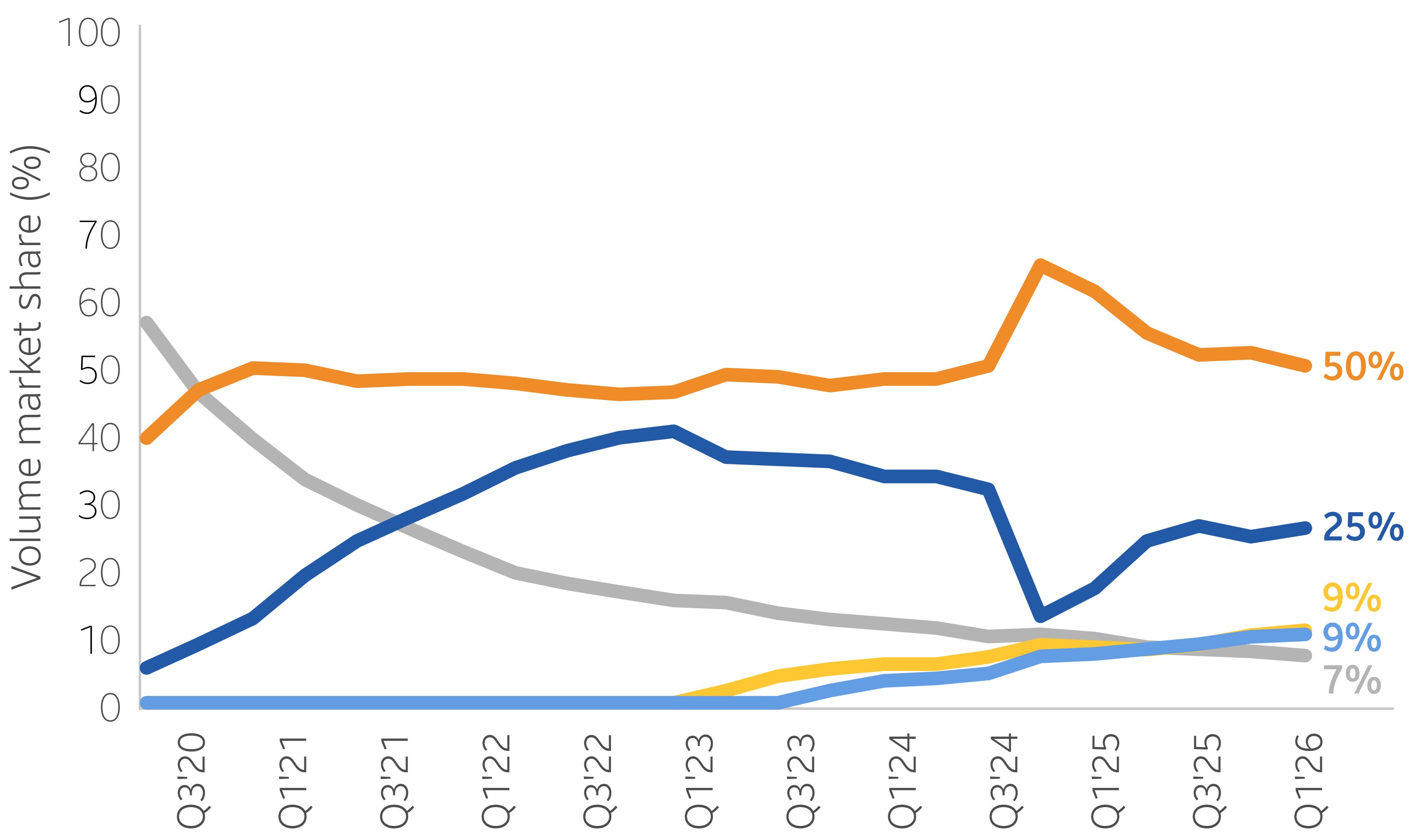
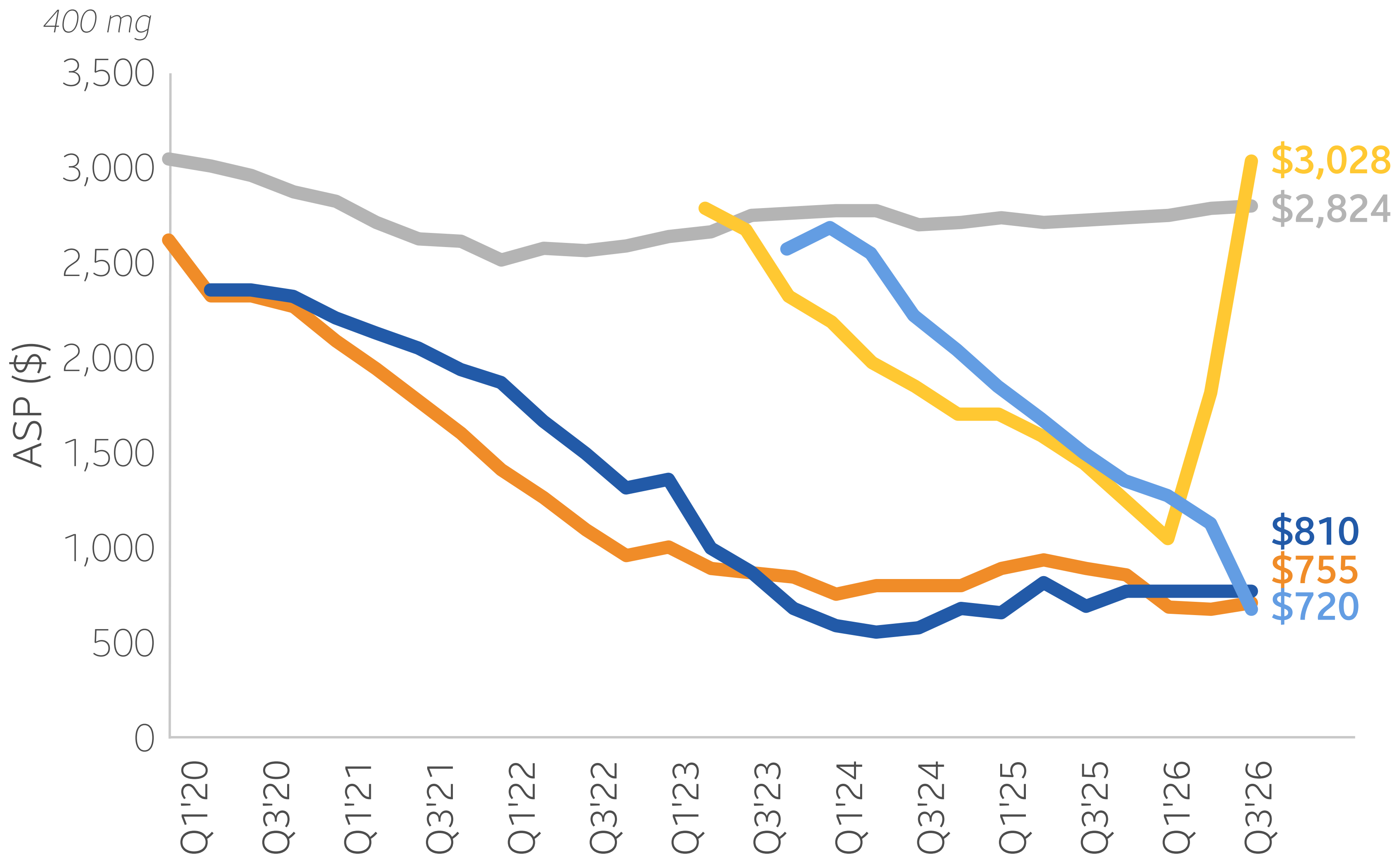


Figure 15. Bevacizumab ASP Trend[3]



Avastin Mvasi Zirabev Alymsys Vegzelma

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

Market Share and ASP Trends
- Rituxan (Rituximab)

- As of Q1 2026, the biosimilar share of the rituximab market was 76% (-1% vs. last quarter).
- As of Q3 2026, the average ASP of all biosimilar products is $878.
- The rituximab market appears bifurcated: The low cost biosimilars make up 76% of the market while the reference product maintains a stable market share despite its high ASP.

Figure 16. Rituximab Volume Market Share[4]

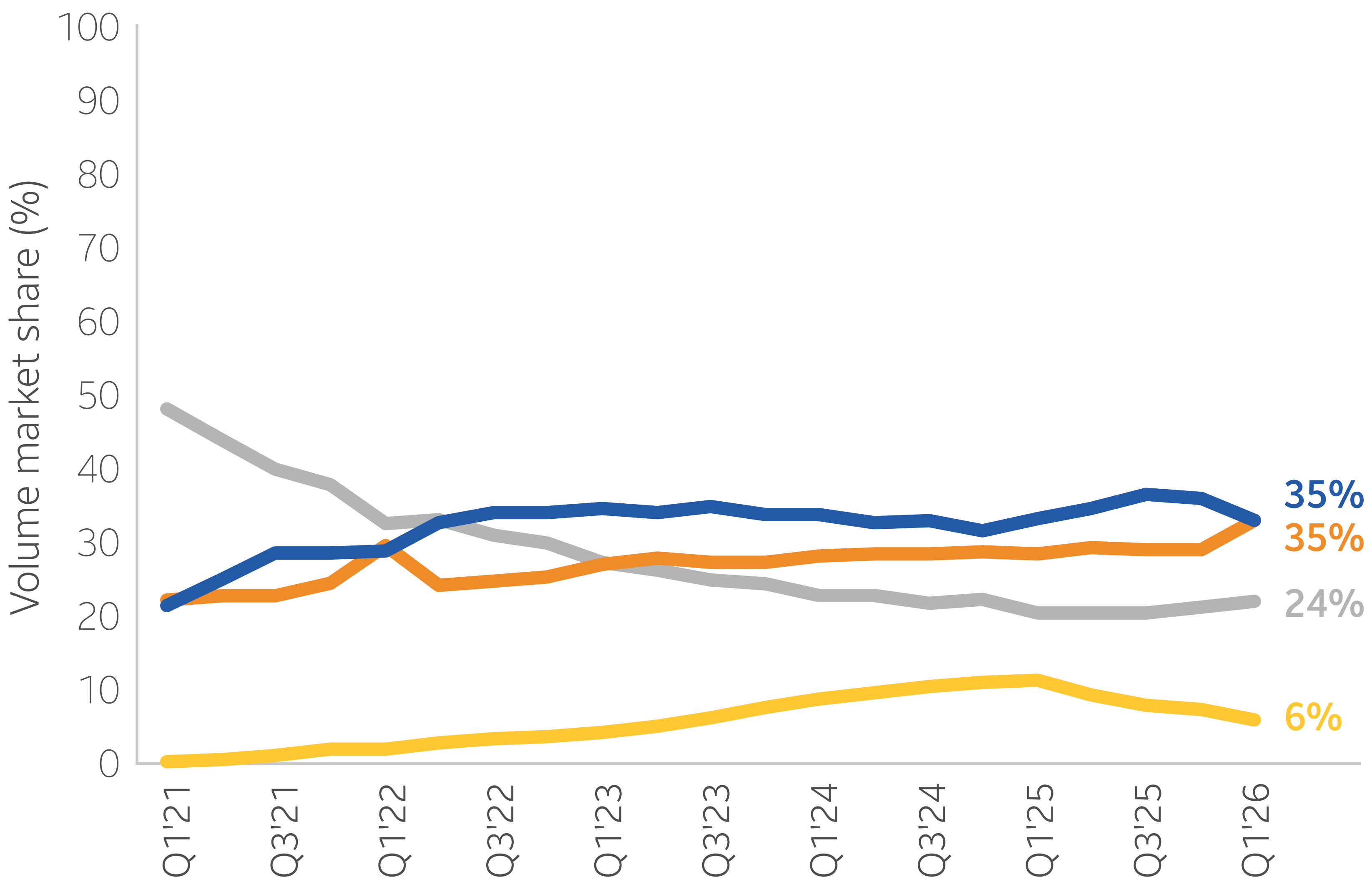
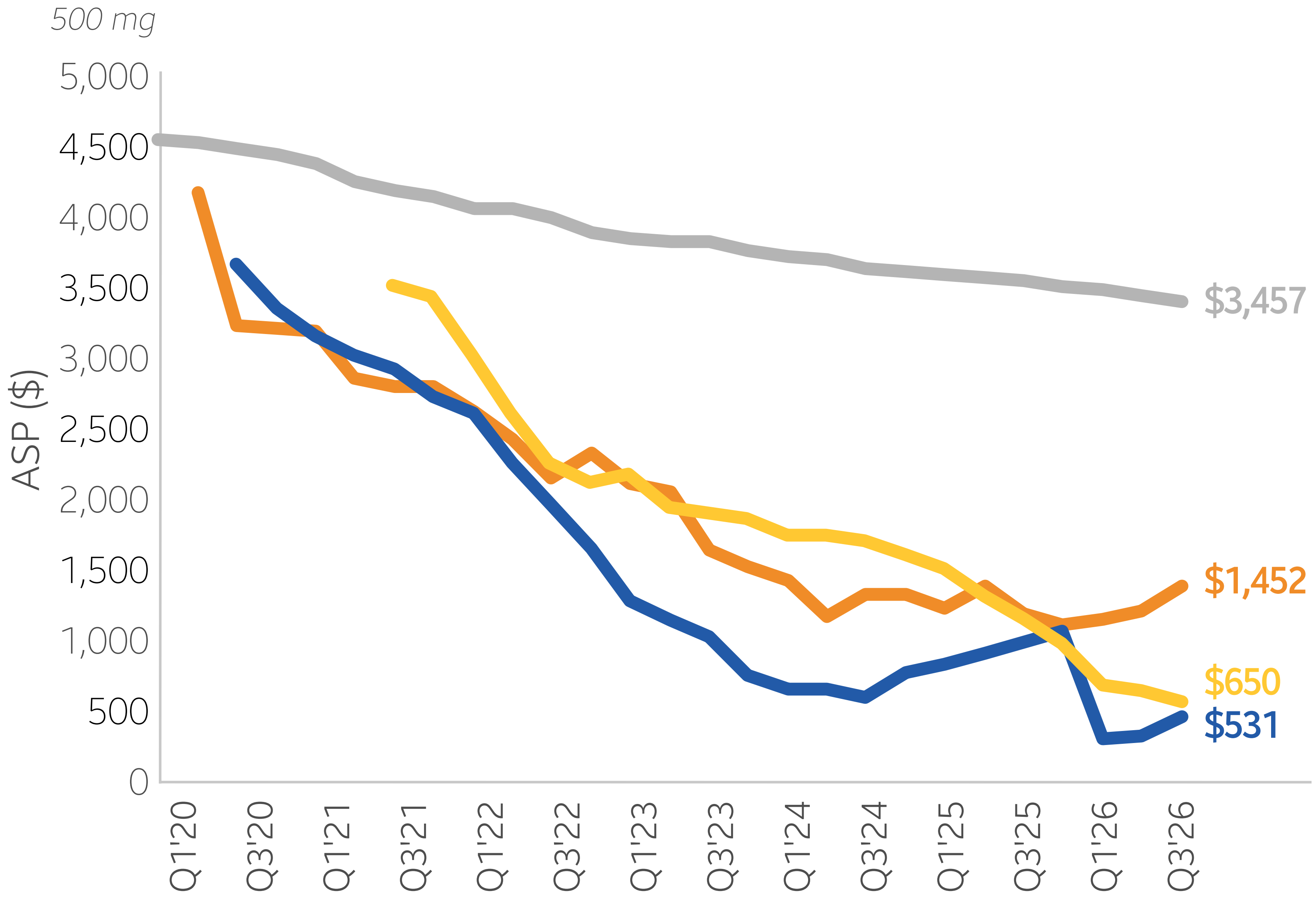


Figure 17. Rituximab ASP Trend[3]



Rituxan Truxima Ruxience Riabni

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

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Market Share and ASP Trends
- Neupogen (Filgrastim)

- As of Q1 2026, the biosimilar share of the filgrastim market has reached 77% (Unchanged vs. last quarter).
- As of Q3 2026, the average ASP of filgrastim biosimilars is $208, influenced by the high ASP of Nypozi, the most recent market entrant.
- Excluding Nypozi, the most recent entrant, filgrastim biosimilars exhibited minimal ASP variability this quarter.

Figure 18. Filgrastim Volume Market Share[4]

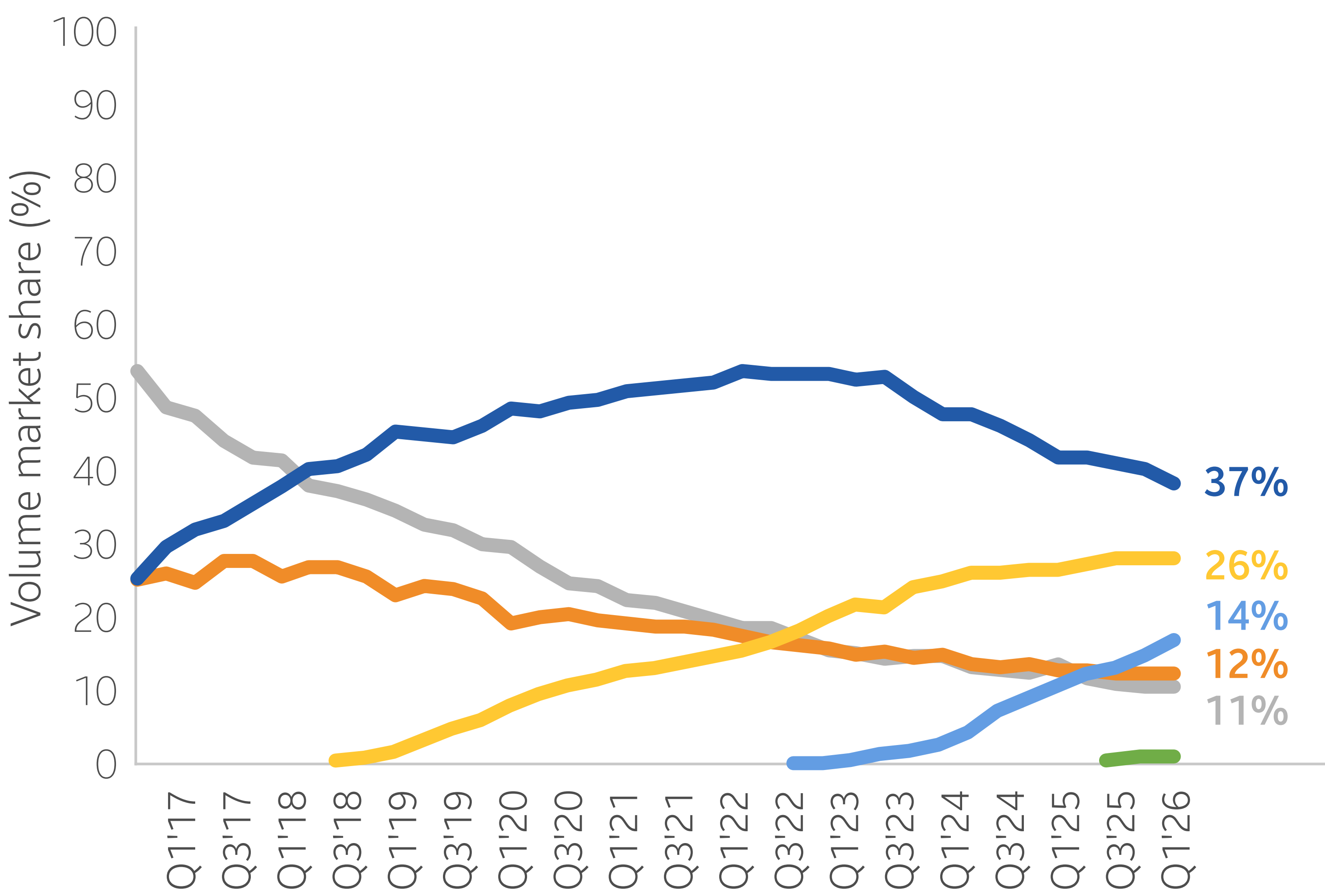
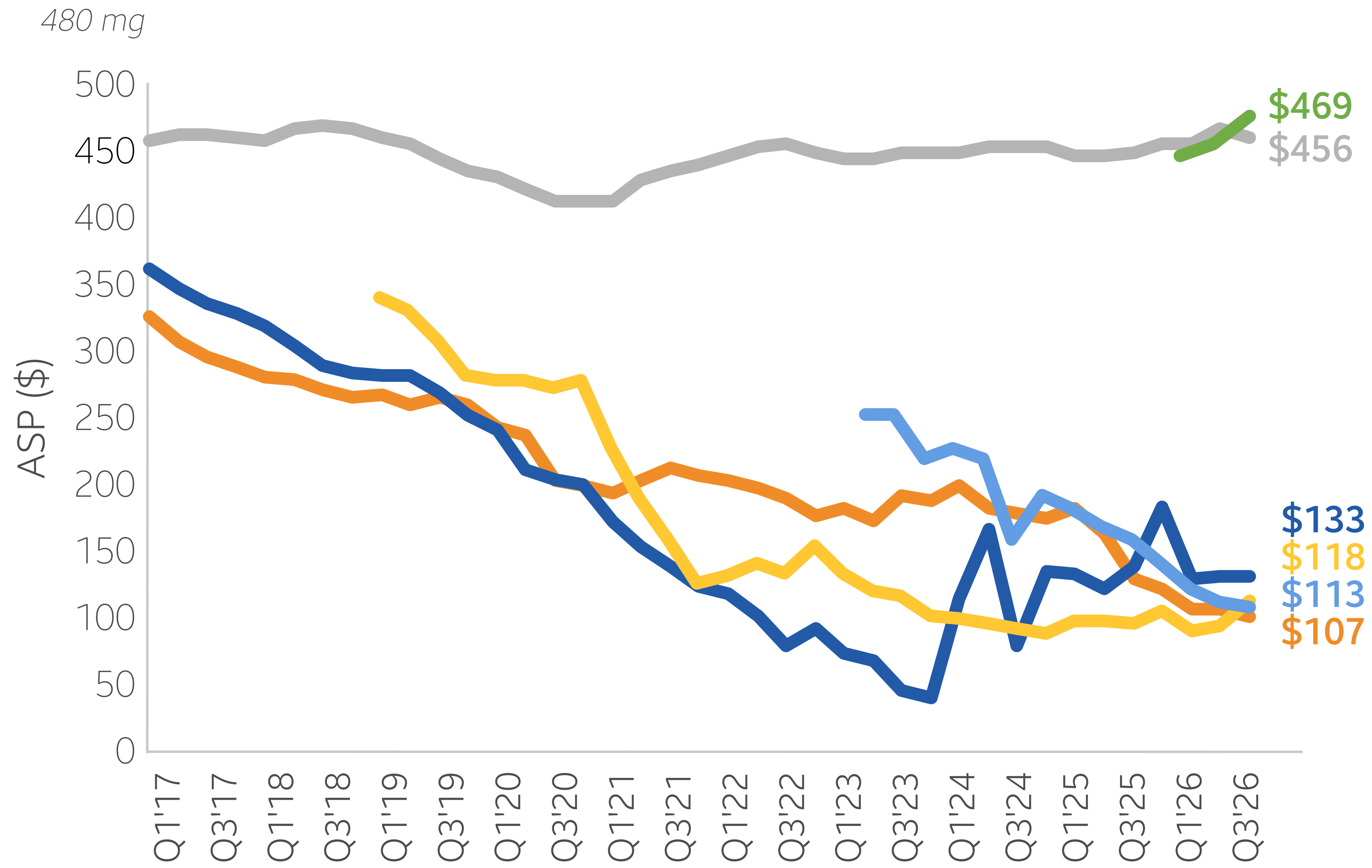


Figure 19. Filgrastim ASP Trend[3]



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

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Market Share and ASP Trends
- Neulasta (Pegfilgrastim)

- As of Q1 2026, the biosimilar share of the pegfilgrastim market was 85% (-2% vs. last quarter).
- As of Q3 2026, the average ASP of all biosimilar products is $1,349 (-2% 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]

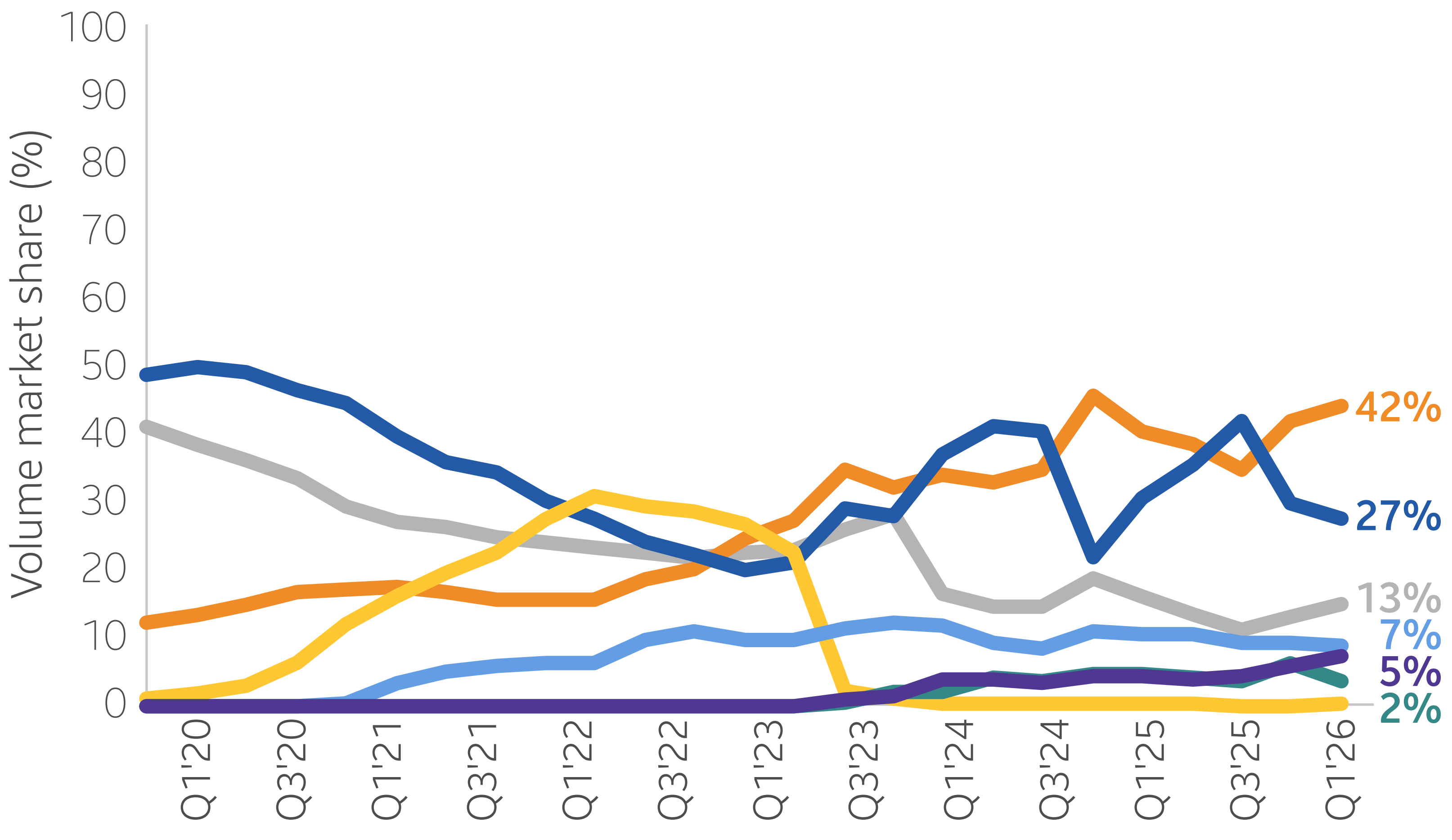
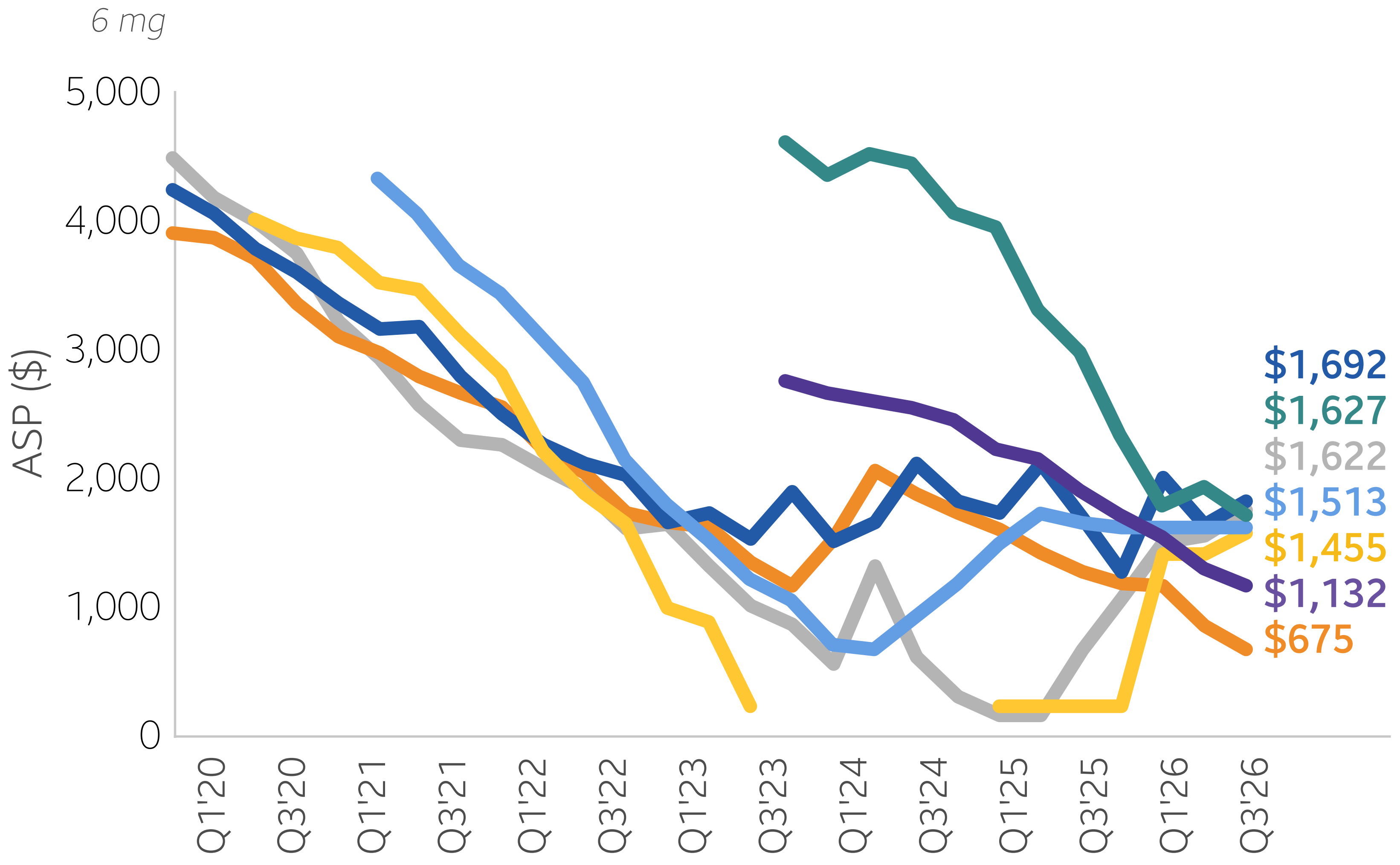


Figure 21. Pegfilgrastim ASP Trend[3]



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

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]

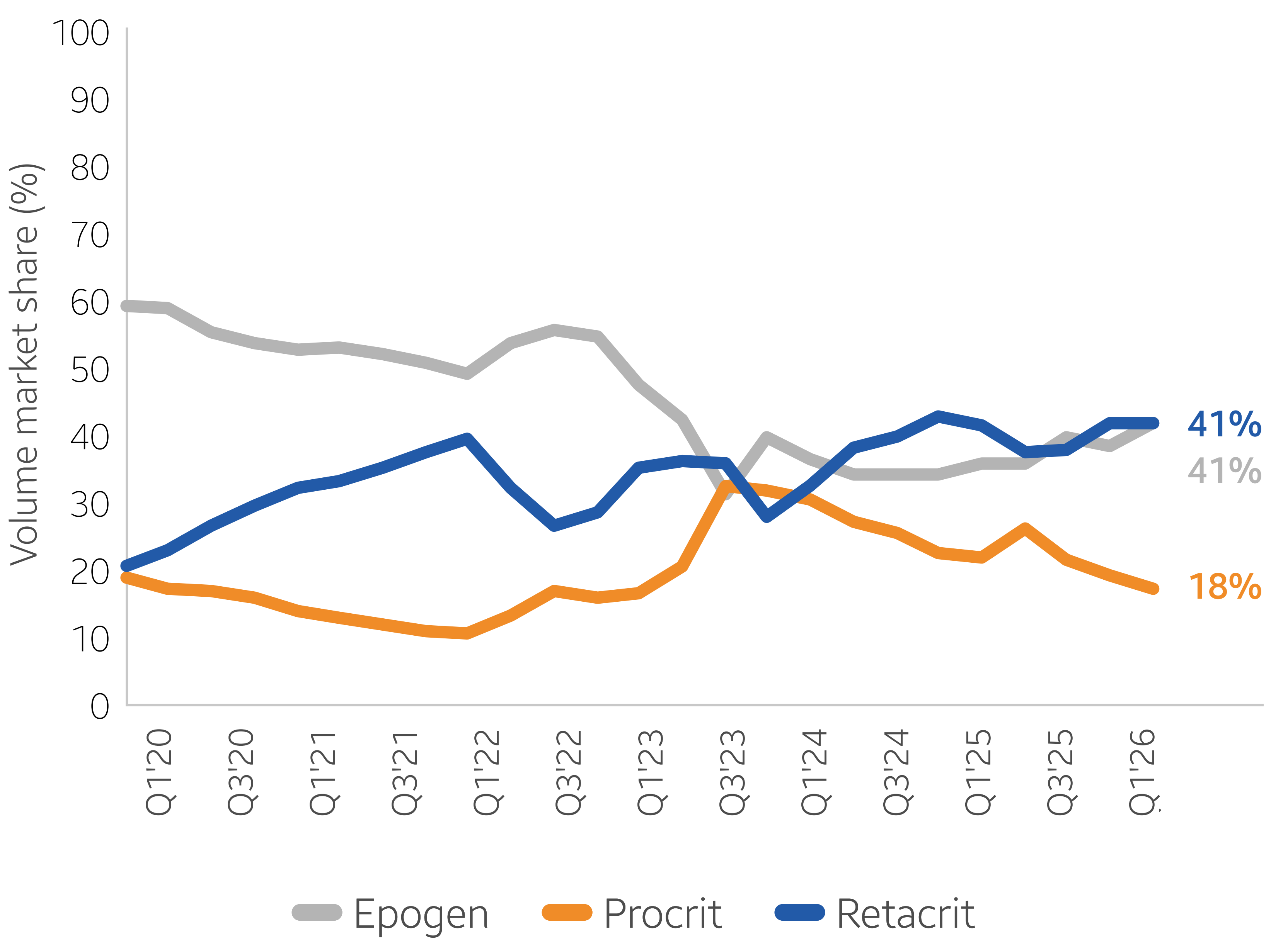
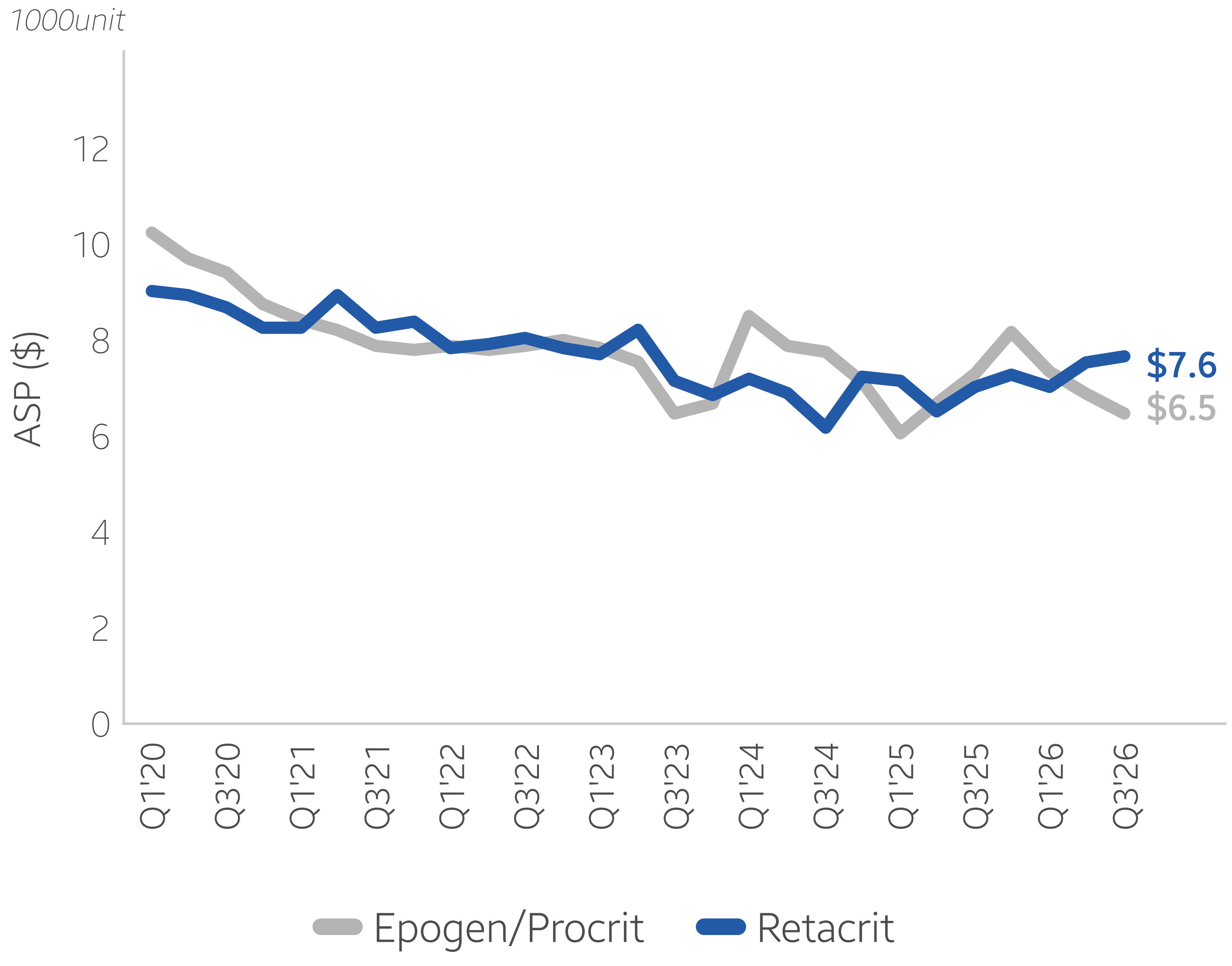


Figure 23. Epoetin Alfa ASP Trend[3]



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 Q1 2026, infliximab biosimilar market share has reached 52% (+1% vs. last quarter).
- As of Q3 2026, the average ASP of all biosimilar products is $260 (+6% vs. last quarter).
- Infliximab products demonstrated relatively limited ASP variability in the current quarter.

Figure 24. Infliximab Volume Market Share[4]

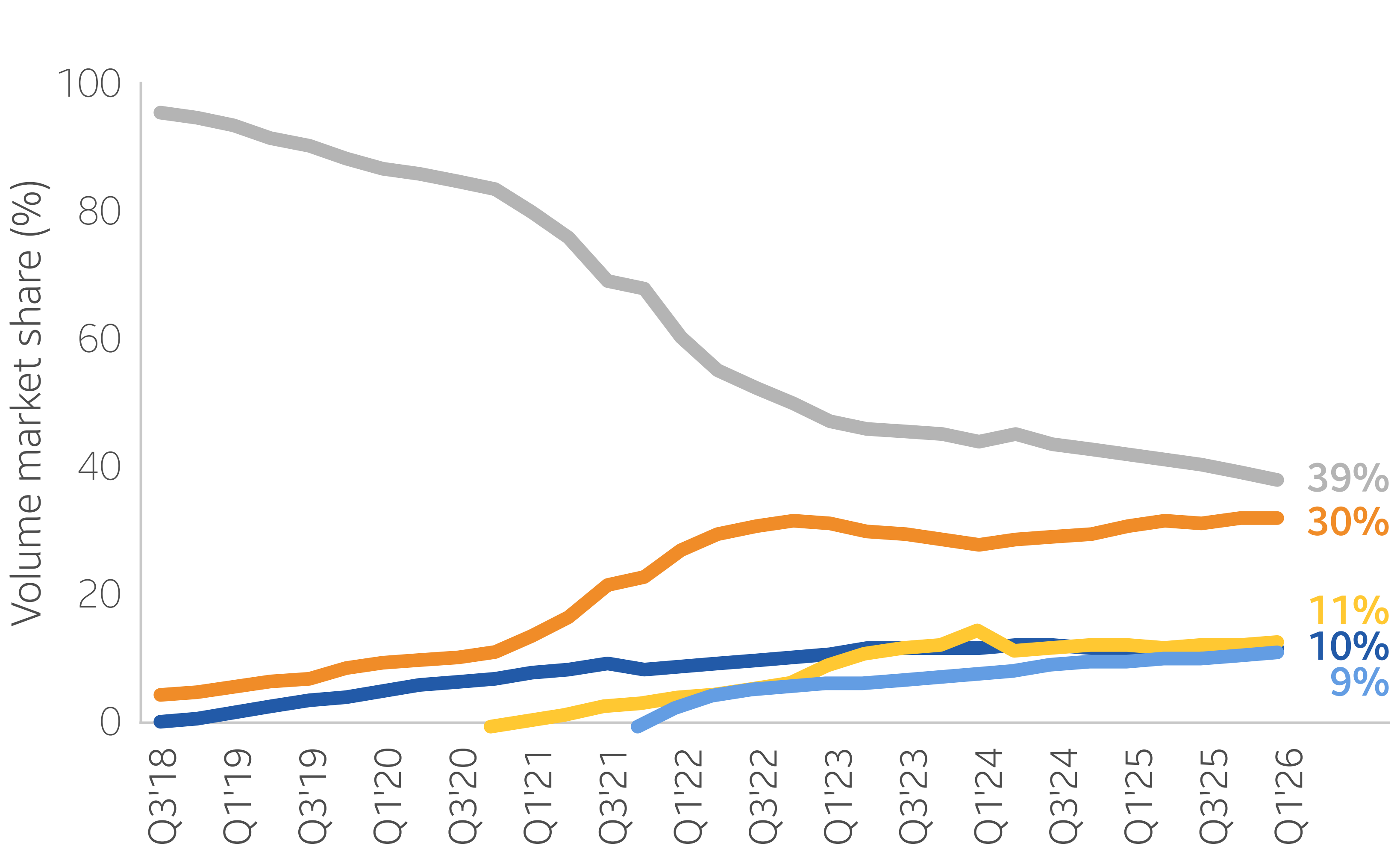
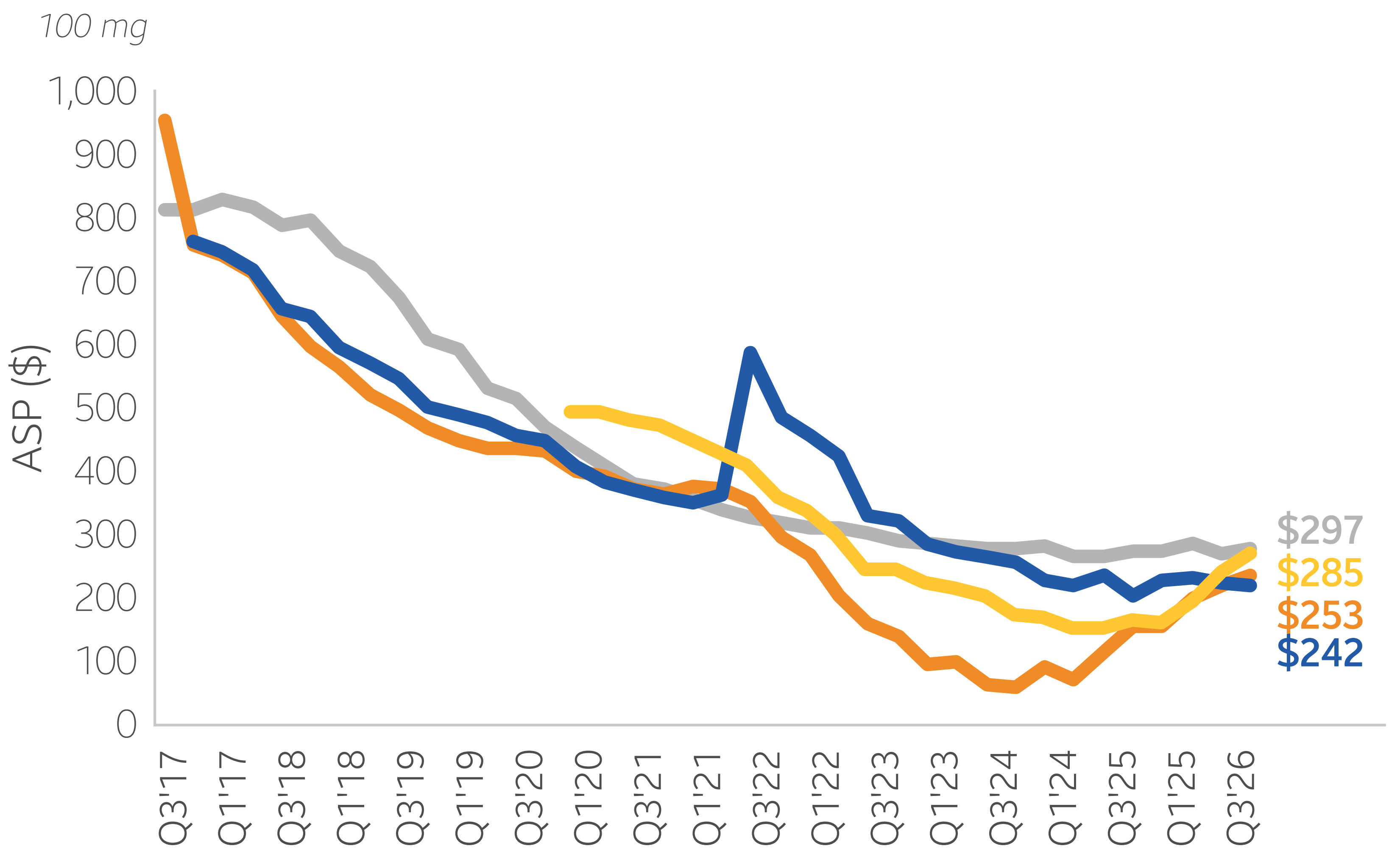


Figure 25. Infliximab ASP Trend[3]



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

Market Share and WAC Trends
- Humira (Adalimumab)

- **As of May 2026, biosimilar penetration increased to 65%, 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]

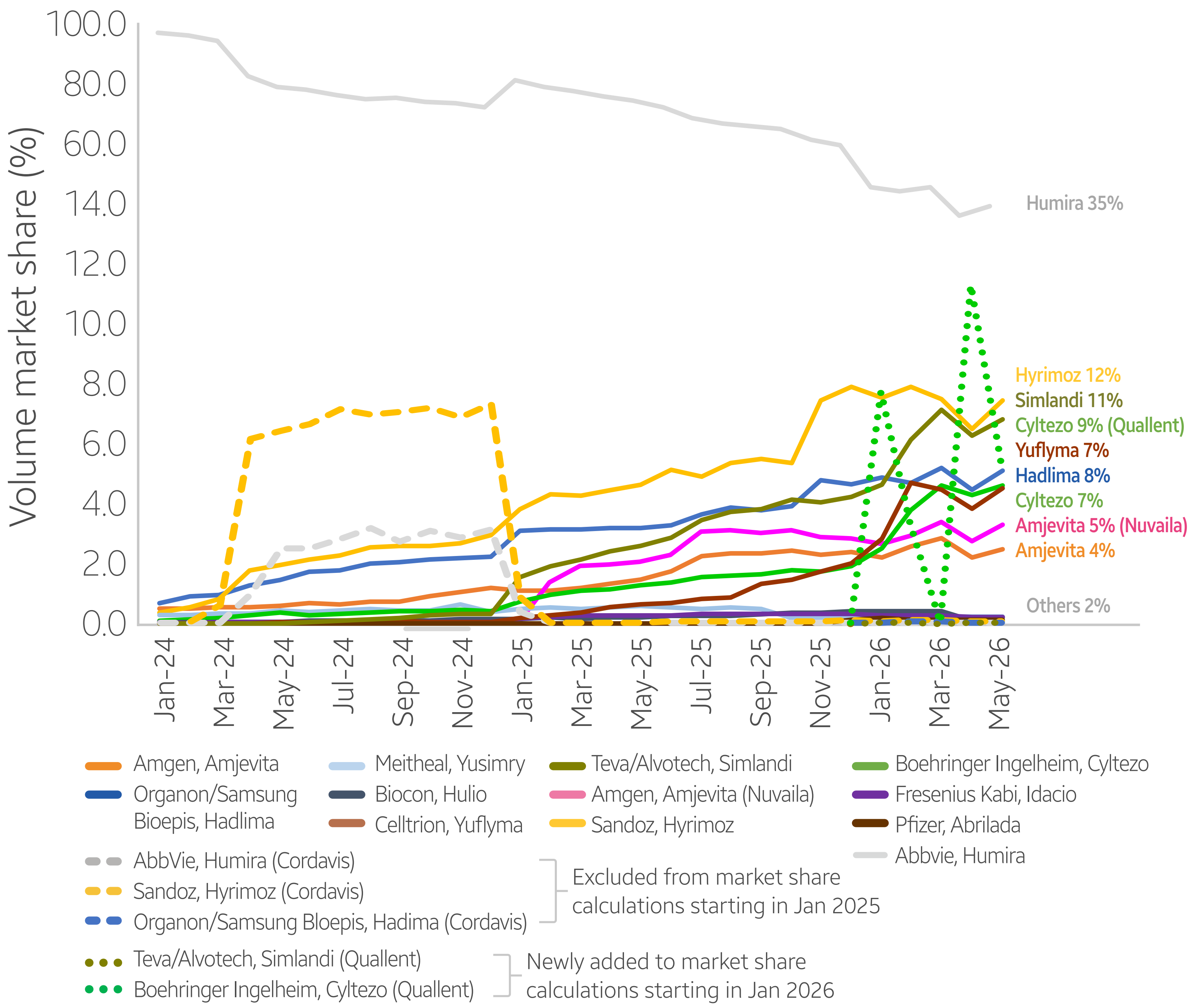
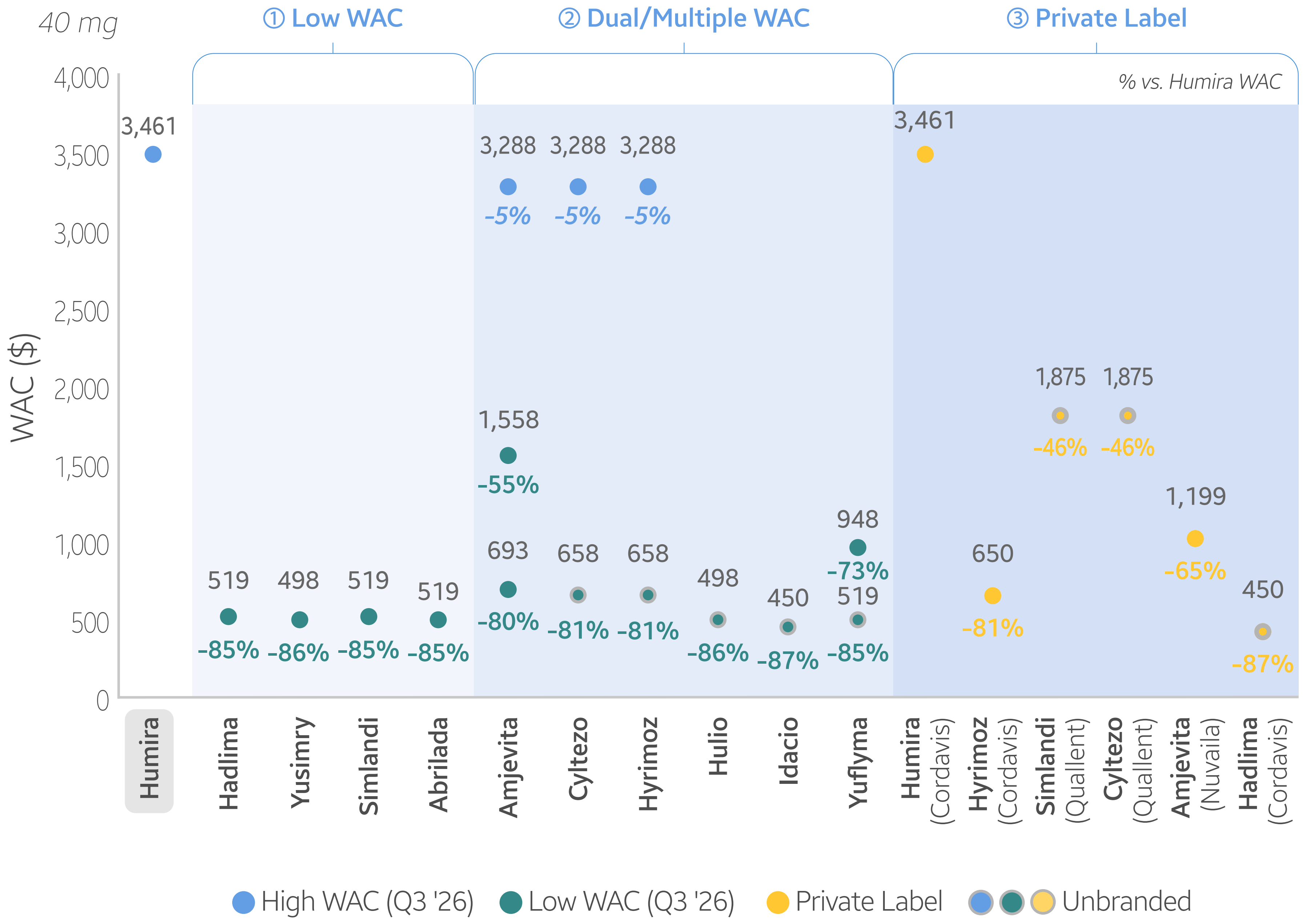


Figure 27. Adalimumab WAC Trend[z]



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

Market Share and ASP Trends
- Actemra (Tocilizumab)

- As of Q1 2026, tocilizumab biosimilar penetration has reached 28% (+10% vs. last quarter).
- As of Q3 2026, the average ASP of all biosimilar products is $1,672 (-4% vs. last quarter).
- Tyenne, the tocilizumab biosimilar with the relatively higher ASP discount (29% lower than the reference product), has been consistently gaining market share.

Figure 28. Tocilizumab Volume Market Share[4]

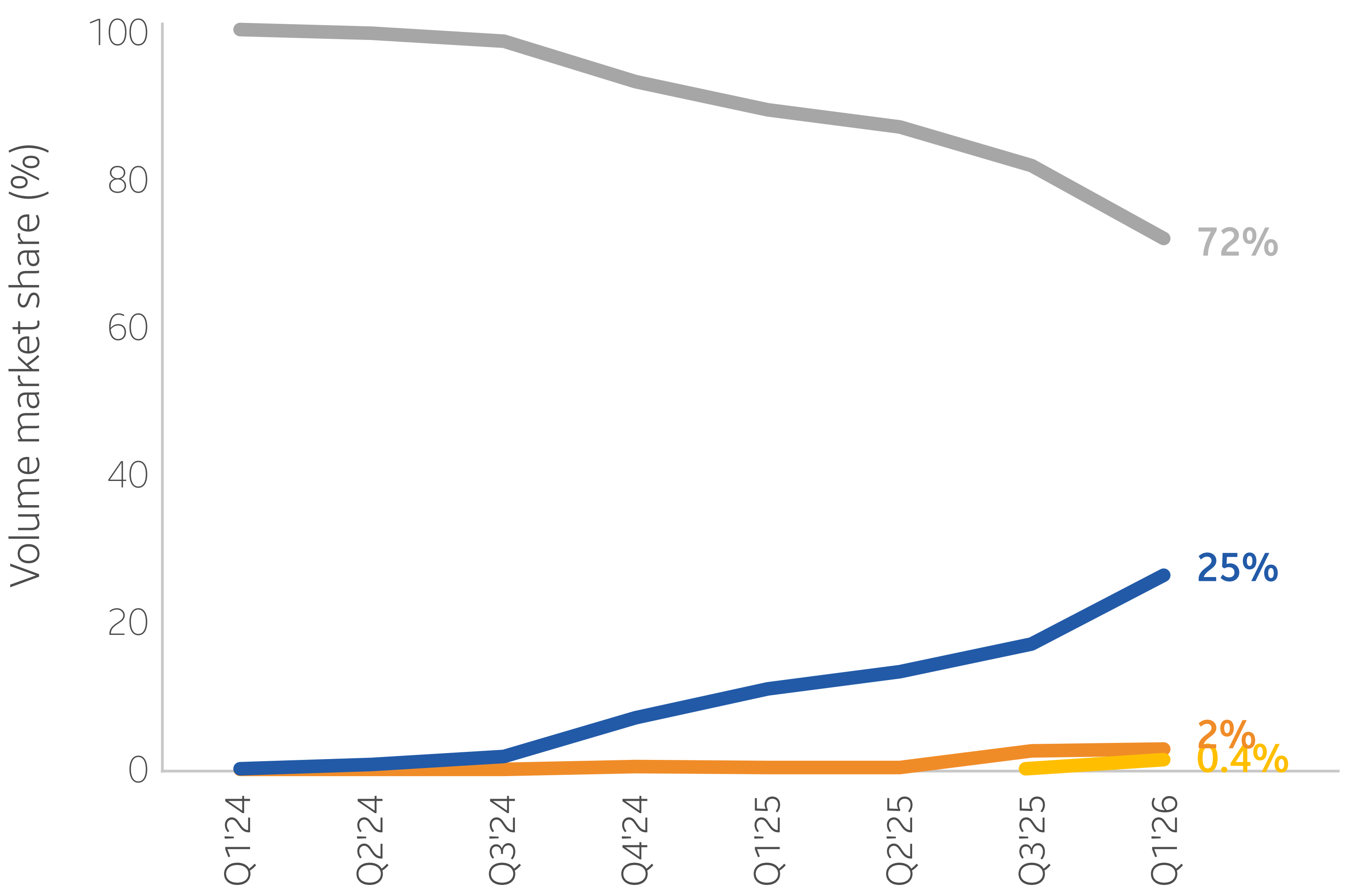
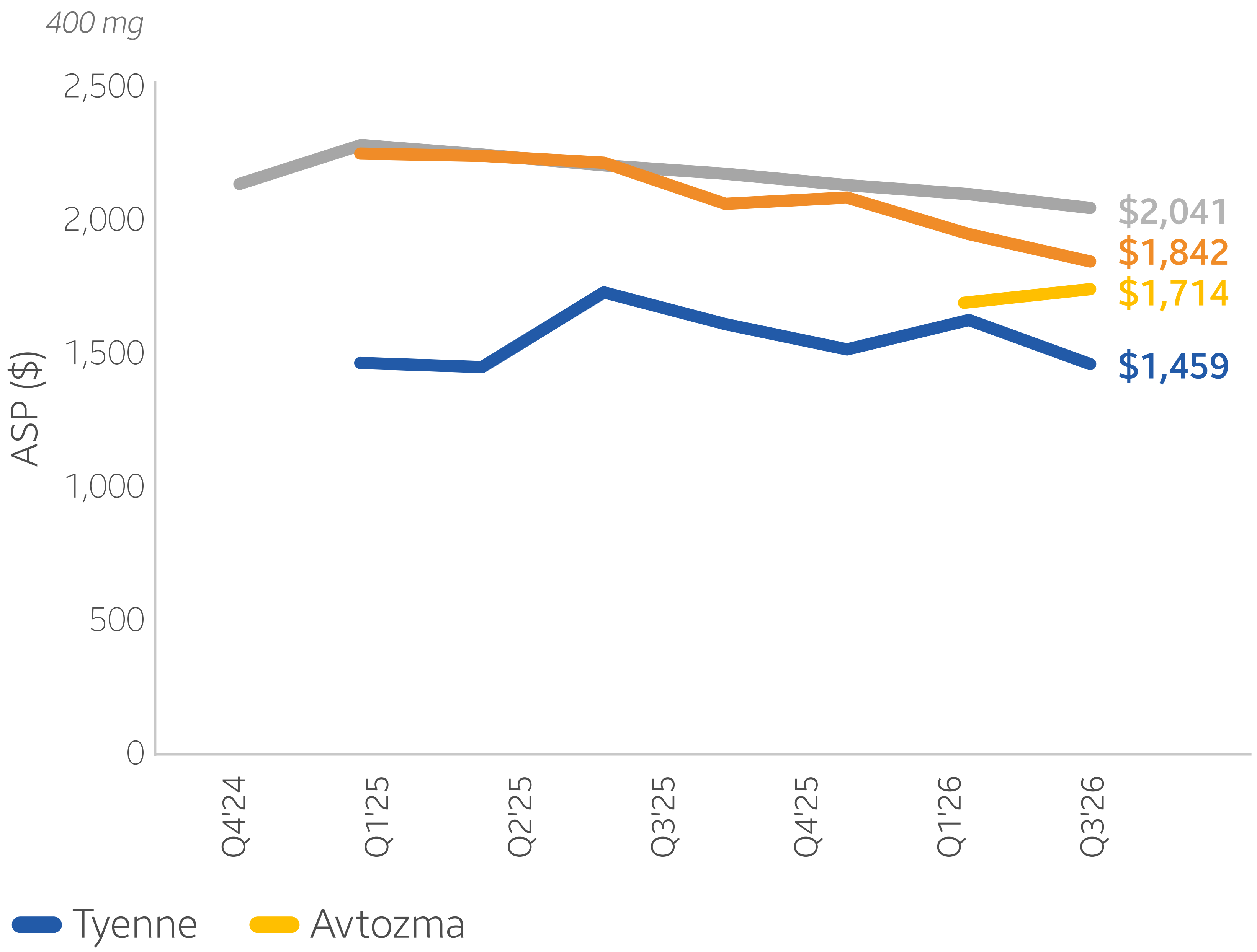


Figure 29. Tocilizimab ASP Trend[3]



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

Market Share and WAC Trends
- Stelara (Ustekinumab)

- As of Q1 2026, ustekinumab biosimilar market share has reached 42% (+15% vs. last quarter).
- As of Q3 2026, the average ASP of all ustekinumab biosimilar products is $872 (+16% vs. last quarter).
- In the ustekinumab market, Stelara biosimilar penetration is increasing at a significantly faster pace compared to adalimumab biosimilars, despite both being immunology products mainly covered under the pharmacy benefit.

Figure 30. Ustekinumab Volume Market Share[4]

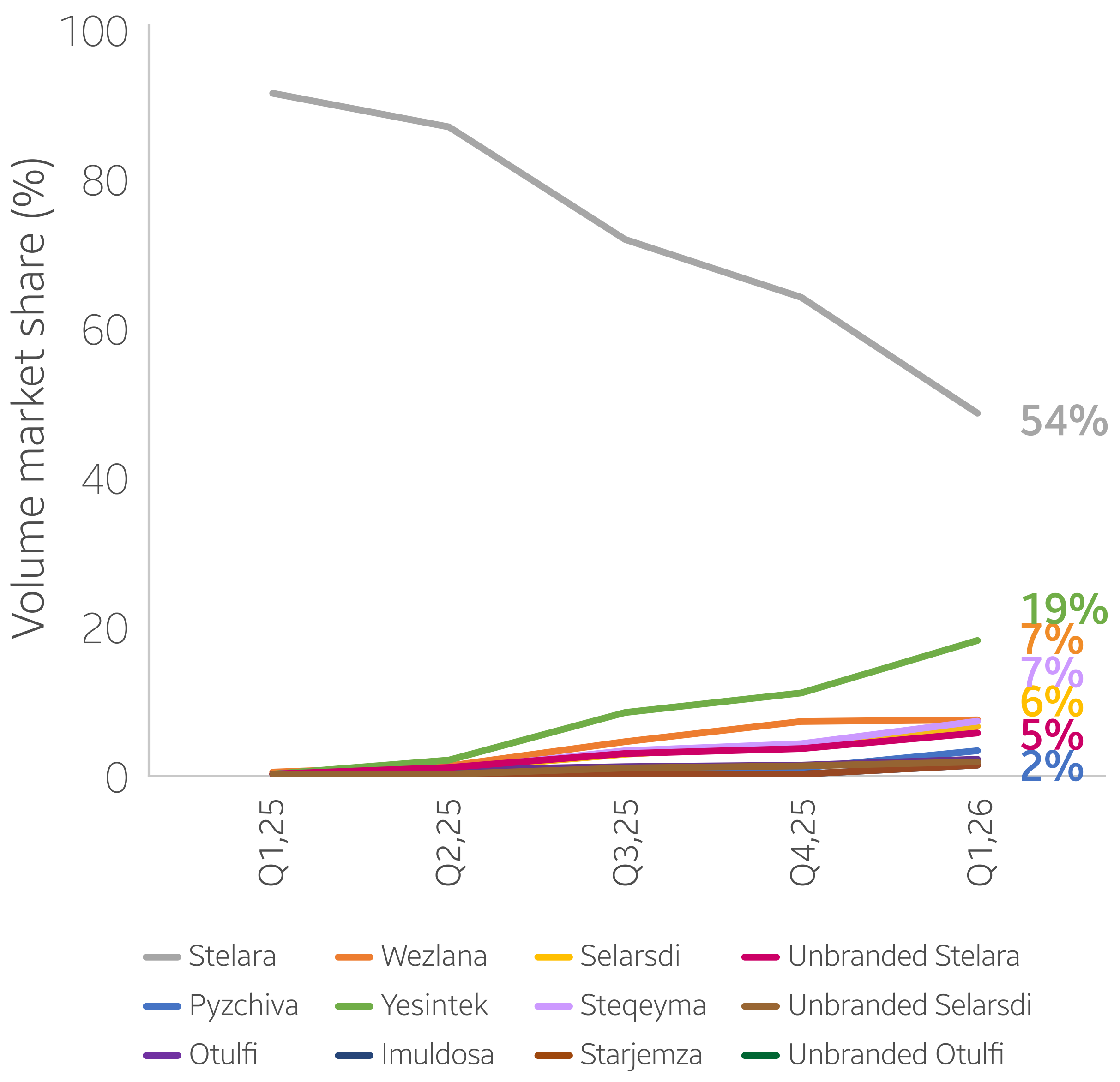
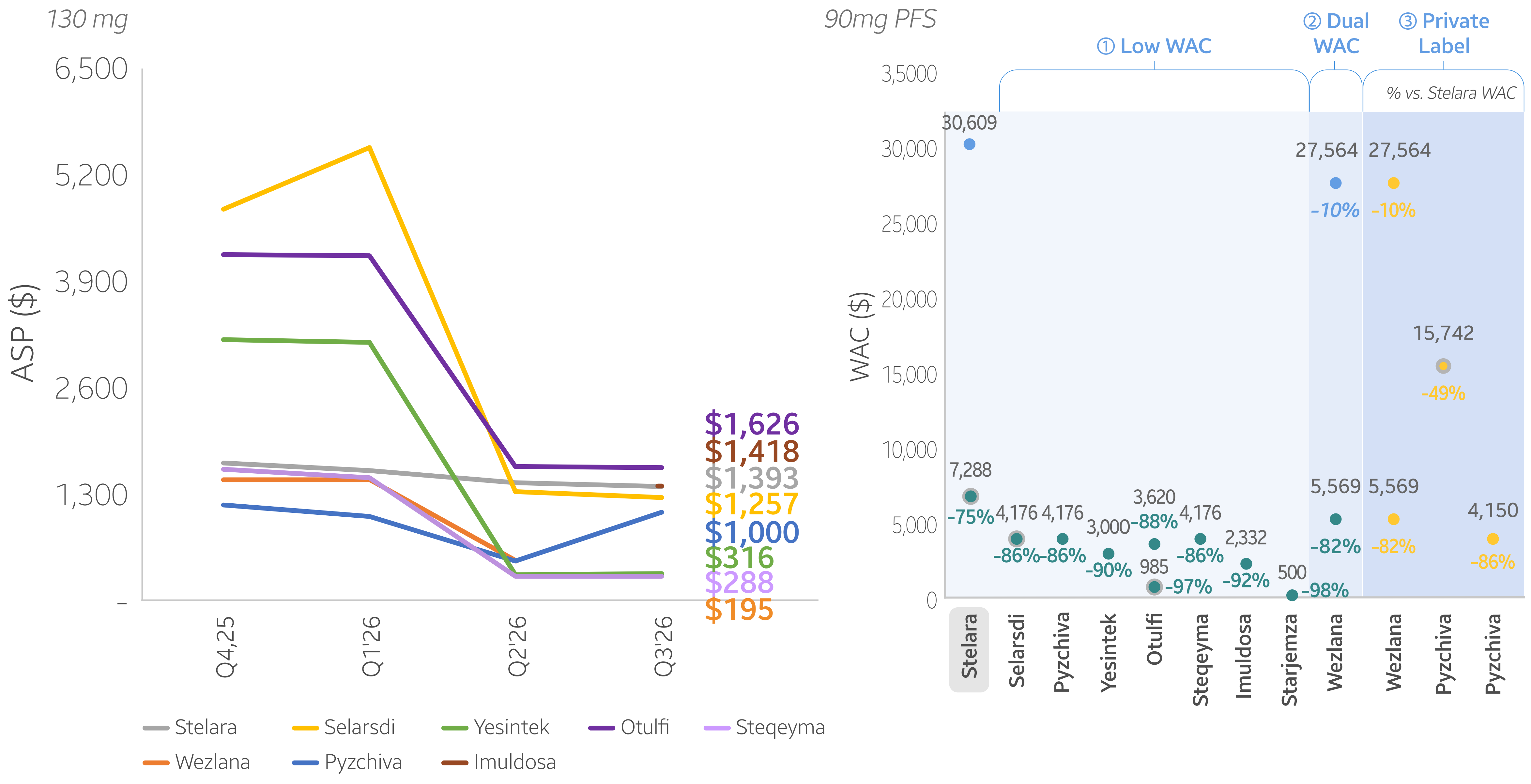


Figure 31. Ustekinumab ASP Trend & WAC



WAC: Wholesale acquisition cost
*Market share calculations do not take sales data for Cordavis and Quallent into account.

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]

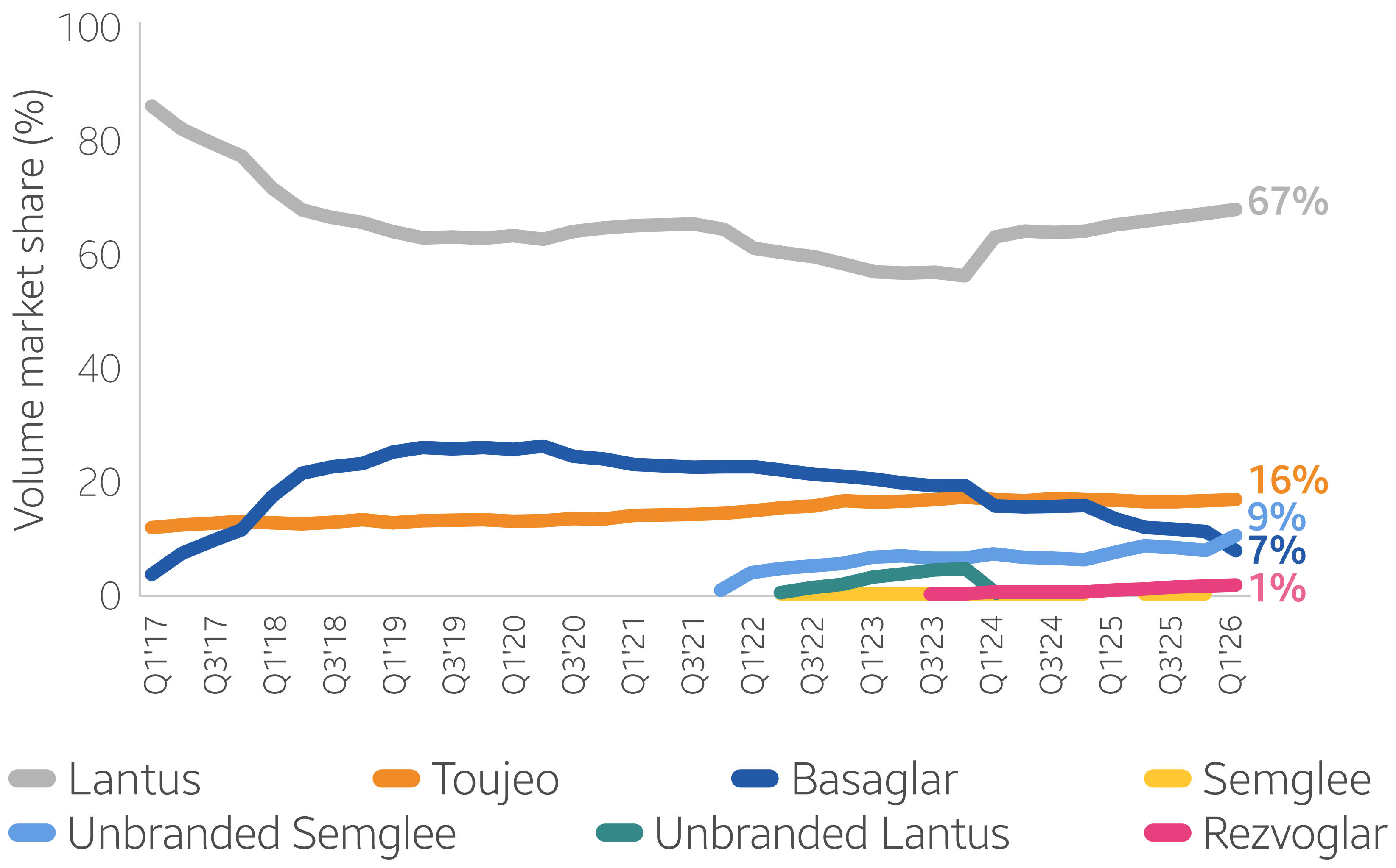
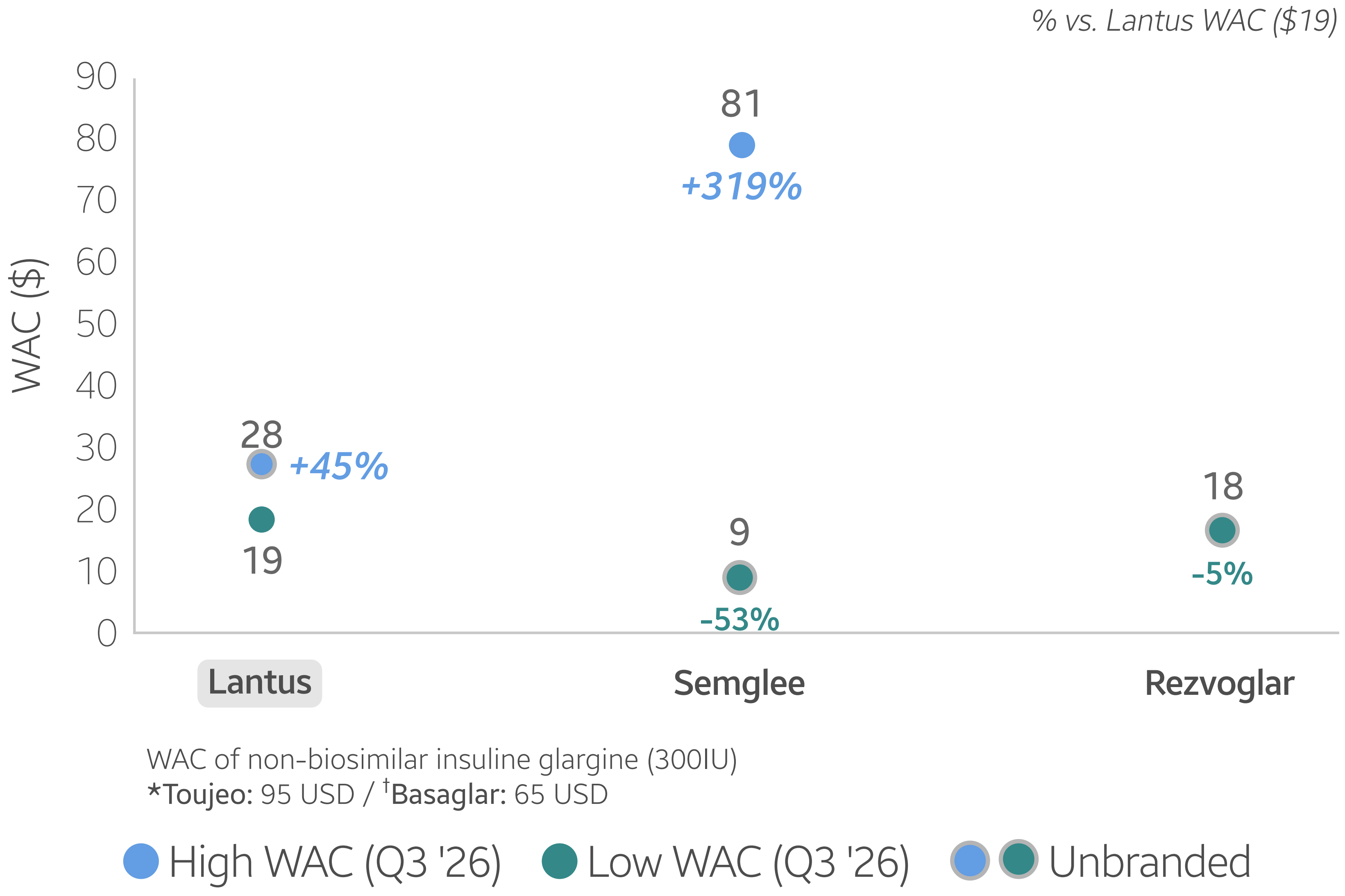


Figure 33. Insulin Glargine WAC Trend[2]



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

Market Share and ASP Trends
- Lucentis (Ranibizumab)

- As of Q1 2026, ranibizumab biosimilar market share has reached 6% (+4% vs. last quarter).
- As of Q3 2026, the average ASP of all biosimilar products is $794 (+117% vs. last quarter), which is mainly driven by the ASP increase of Byooviz.
- Byooviz experienced a substantial increase in ASP following its commercialization partner transition.

Figure 34. Ranibizumab Volume Market Share[4]

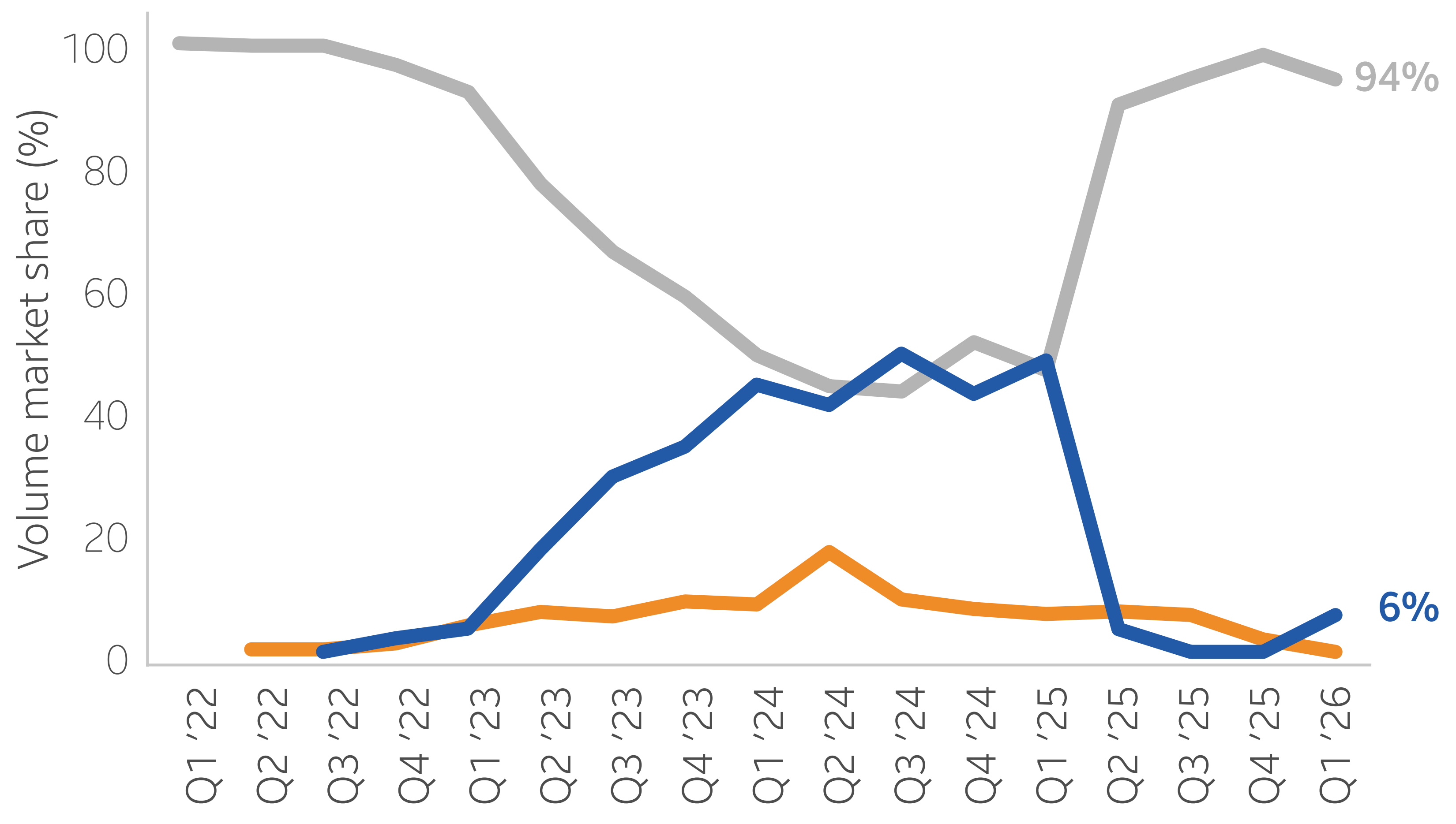
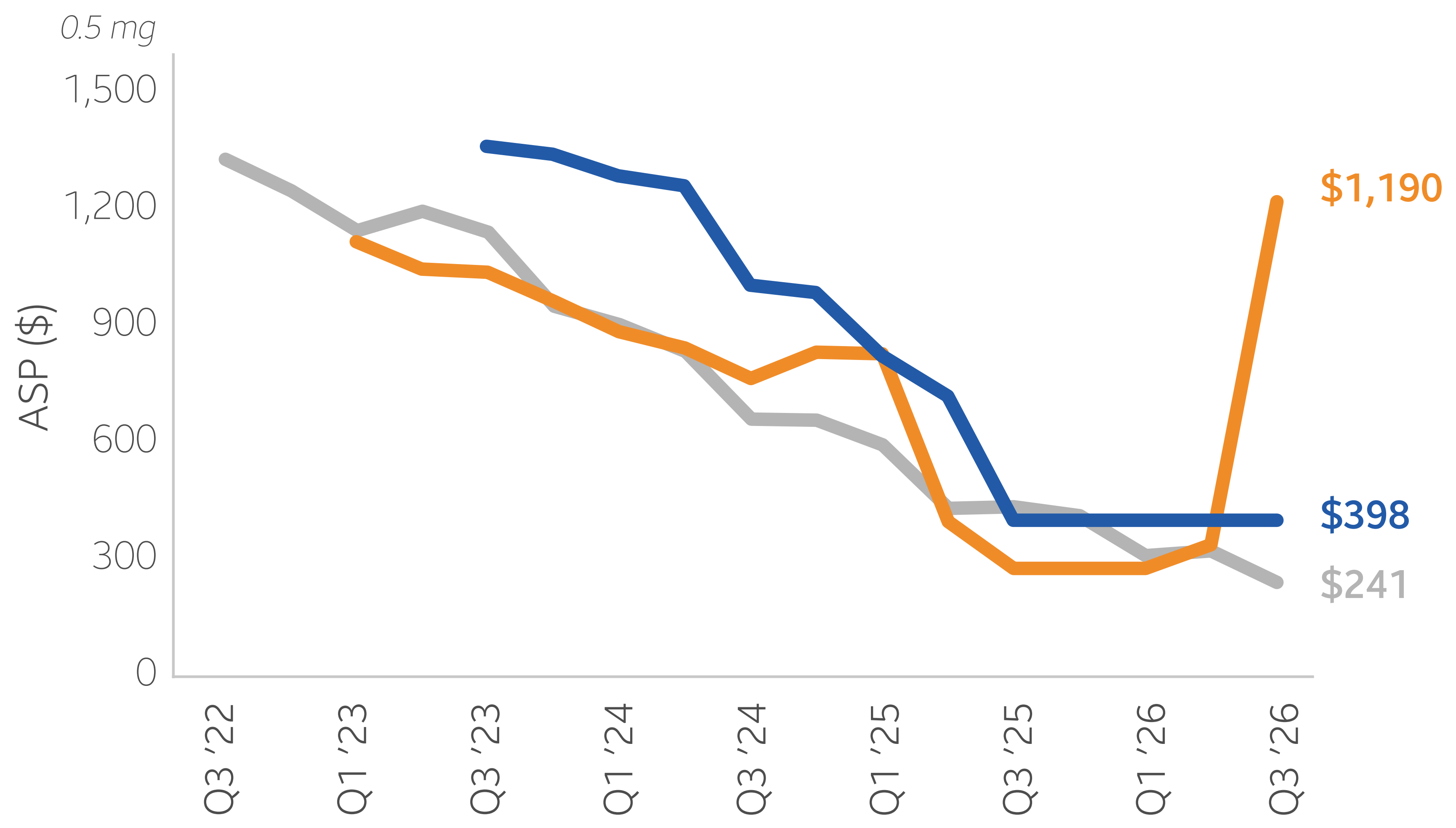


Figure 35. Ranibizumab ASP Trend[3]



Lucentis Byooviz Cimerli

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

Market Share and ASP Trends
- Soliris (Eculizumab)

- As of Q1 2026, eculizumab biosimilar market share has reached 35% (+13% vs. last quarter).
- As of Q3 2026, the average ASP of all biosimilar products is $4,969 (-1% 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]

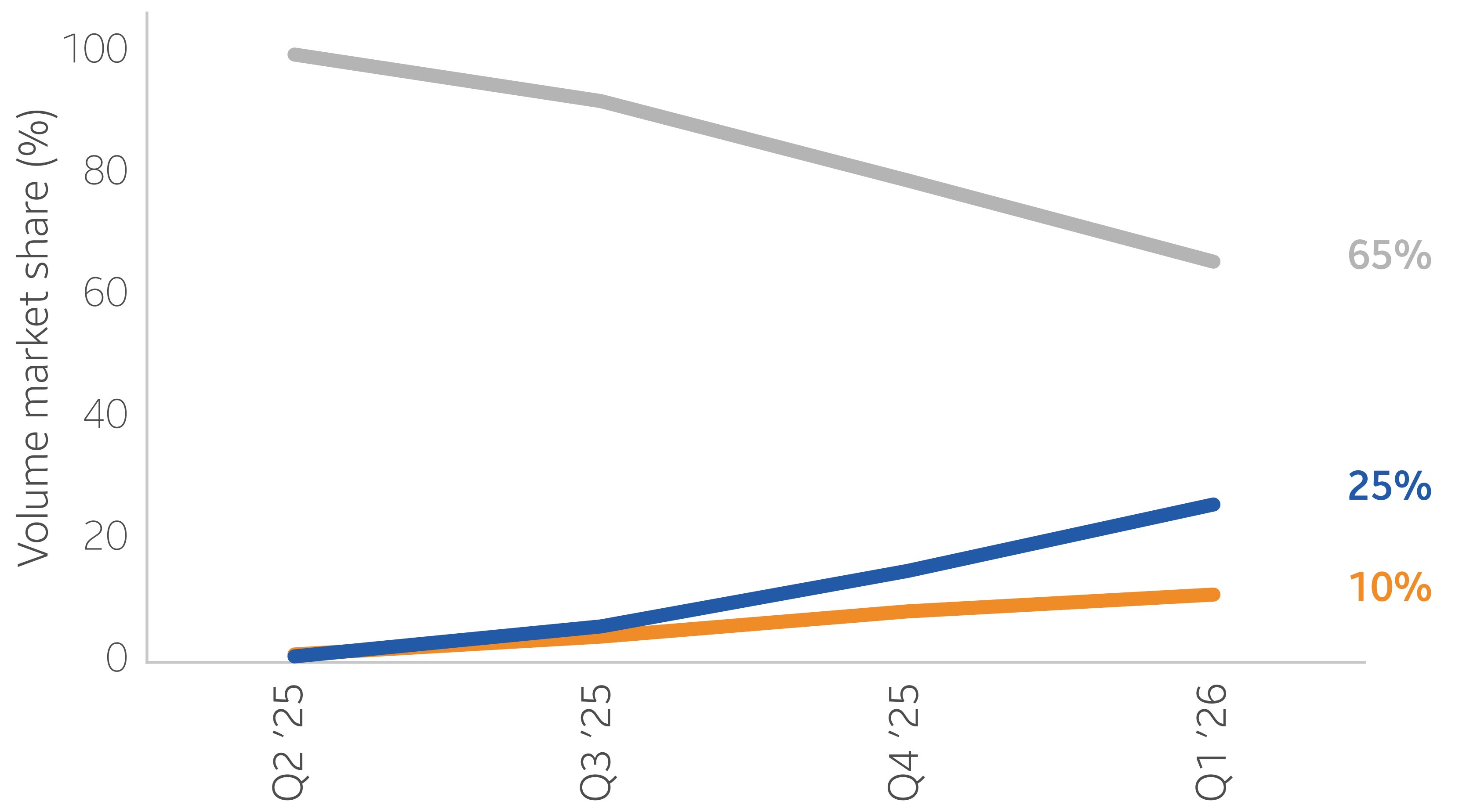
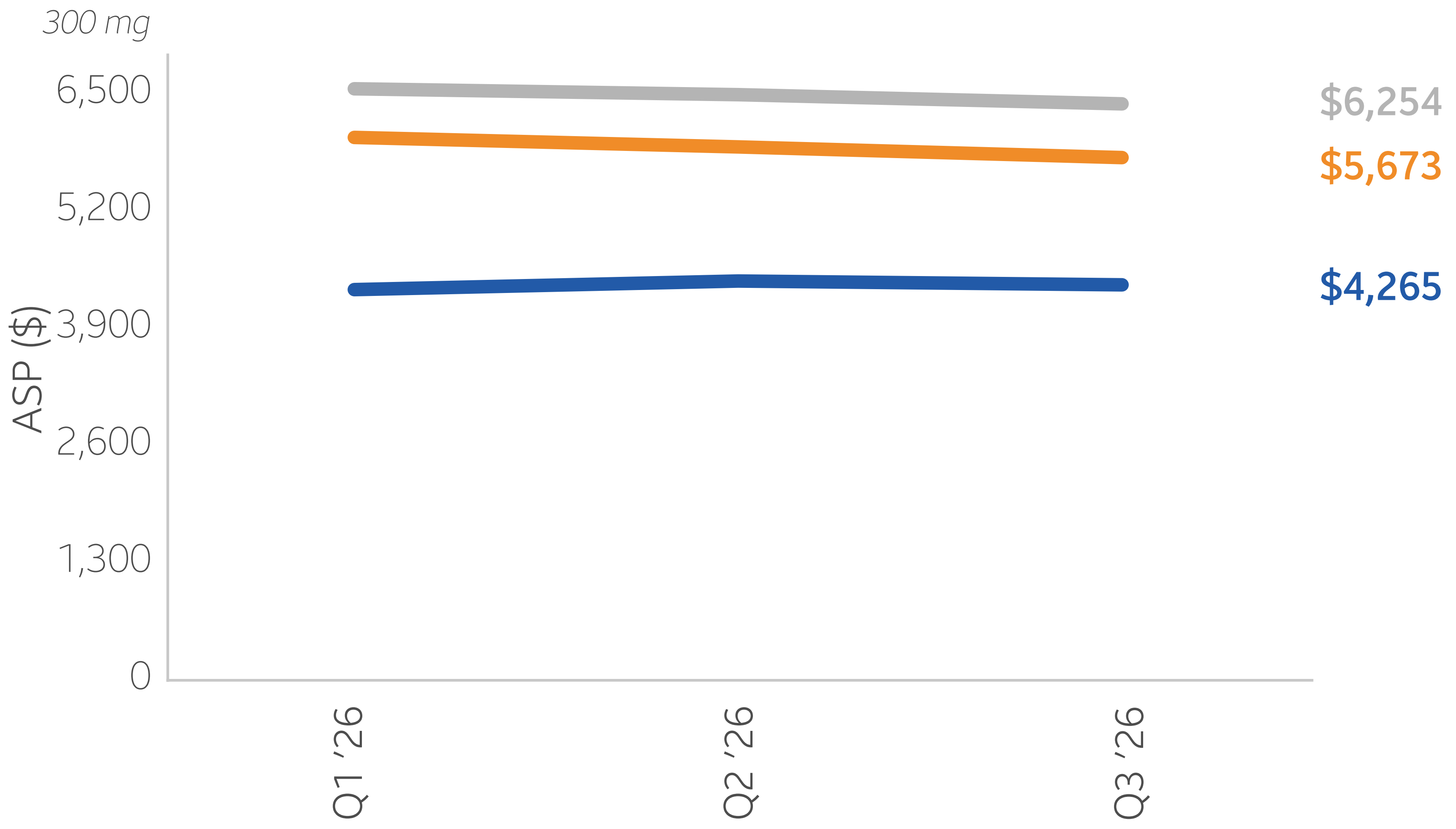


Figure 37. Eculizumab ASP Trend[3]



Soliris Bkemv Epysqli

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

IV. Biosimilar Deep Dive

340B Reform

340B Program Overview & Reform Background

What the 340B program is

- A federal program administered by the Health Resources and Services Administration (HRSA) that requires manufacturers in the Medicaid Drug Rebate Program to sell outpatient drugs at steeply reduced prices to qualifying "covered entities"
- Established under the Veterans Health Care Act of 1992 to help hospitals and clinics serving high shares of low-income and uninsured patients stretch scarce resources and fund services for their communities

Current structure and scale

- More than 60,000 covered entity sites participate, which is roughly a 600% increase since 2000
- Discounts are delivered as an upfront price reduction at the point of purchase
- There have been long-standing questions and concerns about limited HRSA oversight
- Growth of the program has driven larger health systems to acquire 340B-covered entities to take advantage of the additional savings 340B offers

Why reform is being discussed

- There have long been concerns that health systems may purchase products at discounted 340B prices while billing payers at standard reimbursement rates. Additionally, many stakeholders are concerned that duplicate discounts often go undetected
- July 2025: HRSA announced a pilot letting drugmakers issue post-sale rebates instead of upfront discounts; the American Hospital Association and others successfully sued to block it
  - January 2026: First Circuit Court of Appeals upheld a halt on the pilot, and the Department of Justice (DOJ) declined to appeal further, leaving the near-term future of 340B program reform uncertain
- 340B was created for Medicaid; in reality, however, its impact has expanded beyond Medicaid alone. Commercial health plans have millions of dollars clawed back quarterly due to 340B claims

340B Reform and the Problems It Aims to Address

Goal: Transparency in how 340B dollars flow

- Reform seeks clearer visibility into how discounts are used and whether savings reach the patients and communities the program was built to serve
- On April 2025 Senate Health, Education, Labor and Pensions (HELP) Committee report flagged concerns about transparency, oversight, and whether savings are reaching the patients and communities the program was designed to serve
- There are some discrepancies in how 340B claims are dispensed. 340B-covered entities argue that they cannot determine whether a drug qualifies for 340B pricing at the time of dispensing. Instead, they contend that eligibility can only be determined retrospectively, after the drug has been dispensed
  - This lack of transparency has led to questions of accuracy of reporting and supports the argument that reform may not actually impact 340B entities as much as they anticipate

Goal: Oversight of duplicate discounts

- A central driver is preventing duplicate discounts, where a single drug captures both a 340B price and a Medicaid rebate
- Manufacturers argue inadequate oversight lets some entities purchase at 340B prices while billing payers at much higher rates

Goal: Realign program scope and economics

- The program is bigger than originally intended. 60,000+ covered entities and system acquisitions have expanded 340B well beyond its original safety-net intent
- Though designed for Medicaid, in practice, the 340B program impacts commercial lines of business for health plans, as well
- Manufacturers contend that reform would reduce 340B pricing concessions and improve gross-to-net economics

Competing definitions of reform: Both manufacturers and providers seek 340B reform

- Industry-driven efforts (e.g., the HRSA rebate pilot) aim to tighten verification and shift to post-sale rebates
- Provider-aligned legislation (340B Patients Act of 2025) instead aims to protect 340B-covered health systems and ensure manufacturers meet their 340B obligations

What is currently changing?

The proposed HRSA rebate pilot reform would replace 340B's upfront discount with a post-sale rebate:

	Current Model: Upfront Discount	Proposed Model: Post-sale Rebate
Payment timing	Discount applied at the point of purchase; the covered entity pays the reduced 340B price immediately	Entity pays the full, non-340B price upfront and receives a rebate after the sale
Mechanism	Manufacturer sells the outpatient drug to the provider organization at the statutory 340B ceiling price	Manufacturer issues a post-sale rebate to provider organizations equal to the 340B discount they receive
Verification & data	Limited claim-level validation; long-standing concerns about insufficient HRSA oversight	Enables claim-level review before a rebate is paid, helping identify duplicate discounts
Administrative burden	Lower day-to-day burden for covered entities	Higher reporting requirements and new processes to substantiate each rebate claim
Financial impact on 340B-covered entities	Neutral: Entities never pay the full cost up front	Negative: Entities pay full price up front and wait for rebates, delaying ability to revenue

Implications for the Biosimilar Market

340B reform could introduce more favorable dynamics for biosimilars

- Today's 340B economics can favor reference product: High-WAC reference biologics can be more profitable and give health systems richer net-cost recovery, discouraging a switch to biosimilars.
- Reform that reduces or redistributes that revenue could remove part of that disincentive to switch to biosimilars and level the field between reference product and biosimilars.
- Greater transparency and duplicate-discount oversight could weaken margin-driven preferences for higher-cost reference product over time, supporting a provider-led shift away from reference product as well.
- The two therapeutic areas in which health plans most frequently experience 340B claim clawbacks are oncology and autoimmune diseases. At the product level, the drugs most commonly associated with these clawbacks are Humira and Stelara. 340B reform could go hand-in-hand with a biosimilar-first approach to formulary redesign.

Mitigating factor: Impact of 340B reform on biosimilar market is indirect

- Reform does not directly reward biosimilar selection and would not, by itself, make biosimilars the more profitable choice.
- Added reporting burden and delaying revenue capture for health systems could squeeze already-strained health systems and divert attention away from the biosimilar value story.
- Because incentives are dialed back on both reference product and biosimilars rather than redirected, the net effect on adoption could also be somewhat muted.

Net assessment

- **Net impact on biosimilars is currently neutral:** Reform would remove the incentive for health systems to favor reference product on a 340B cost basis; however, it would stop short of actively advantaging biosimilars
- **Near-term likelihood of 340B reform is low:** The January 2026 Appeals Court ruling and the DOJ's decision not to appeal leave the rebate pilot on hold

PBM Reform vs. 340B Reform: Comparing the Biosimilar Impact

Both reforms would reshape biosimilar economics, but through different mechanisms and with different expected impact

Dimension	PBM Reform & Evolution	340B Reform
Impact on Biosimilar Uptake	Positive	Neutral
Core mechanism	Shifts PBM contracting from rebate maximization to transparent and fiduciary (trend/PMPM) models	Shifts manufacturer 340B savings from upfront discount to post-sale rebates and tightens program oversight
Effect on biosimilar incentives	Directly realigns incentives toward lower-net-cost biosimilars and biosimilar-first strategies	Reduces reference product-favoring 340B spreads but does not actively reward biosimilar selection
Formulary & access impact	Transparency exposes biosimilars' lower net price; more exclusion of reference products and lower patient cost-share	Limited direct formulary effect; mainly changes health-system purchasing economics
Primary stakeholders	PBMs, health plans, employers, and pharmacies	Health systems, health plans, and manufacturers
Net takeaway for biosimilars	Potential catalyst for biosimilar adoption	Removes disincentives, but does not incentivize adoption

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