SAMSUNG BIOEPIS

Biosimilar Market Report

5th Edition, Q2 2024

FOREWORD

It has been a year since we introduced the first edition of the Samsung Bioepis Biosimilar Market Report.

Over the past year, we have strived to provide the US market with the latest biosimilar insights, and we are grateful for the positive reception from our readers. As we move forward, Samsung Bioepis remains committed to delivering high-quality, safe, and effective biosimilars. Our goal is to be part of the solution in reducing patients' out-of-pocket expenses, while offering savings to the US healthcare system as a whole. Biosimilars continue to be an important option that can improve patient access to vital medications.

To date, 48 biosimilars have been approved in the United States with more on the horizon as exclusivity periods expire. Our report will continue to promptly reflect these developments, ensuring our readers stay abreast of the latest updates on a quarterly basis.

Amid ongoing efforts by the US government to address healthcare costs, this edition delves into some of the implications of the Inflation Reduction Act (IRA) with respect to biosimilars.

We appreciate your continued interest and support, and eagerly anticipate sharing future reports with you.

Thomas Newcomer
Vice President
Head of Market Access, Samsung Bioepis US

SAMSUNG BIOEPIS

Our mission

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

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

“Unlocking the **future of healthcare** by breakthrough **innovation and science**”

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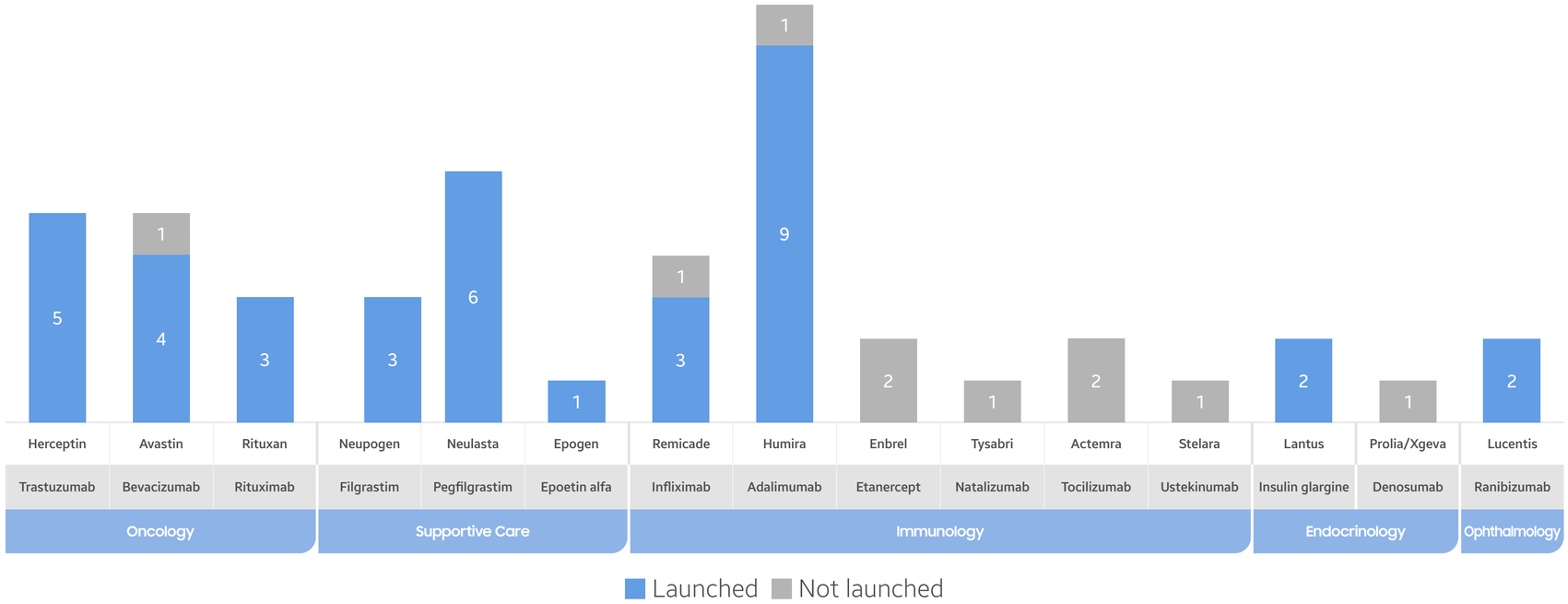
FDA Approval and Launch Status of US Biosimilars

✱ As of April 2024, the FDA has approved a total of 48 biosimilars across 15 unique biological molecules. Of the 48 approvals, 38 biosimilars have launched in the US market.

Cumulative Approvals
48

In last quarter, three new biosimilars were approved in the US. *(See Figure 2 in next slide)*
- Simlandi for Humira (adalimumab) biosimilar
- Jubbonti/Wyost for Prolia/Xgeva (denosumab) biosimilar
- Tyenne for Actemra (tocilizumab) biosimilar

Figure 1. Biosimilars Approval and Launch Status in the US[1*] (As of April 2024)



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

Figure 2. Biosimilars Approval and Launch Status in the US[1*] (As of April 2024, with Suffix)

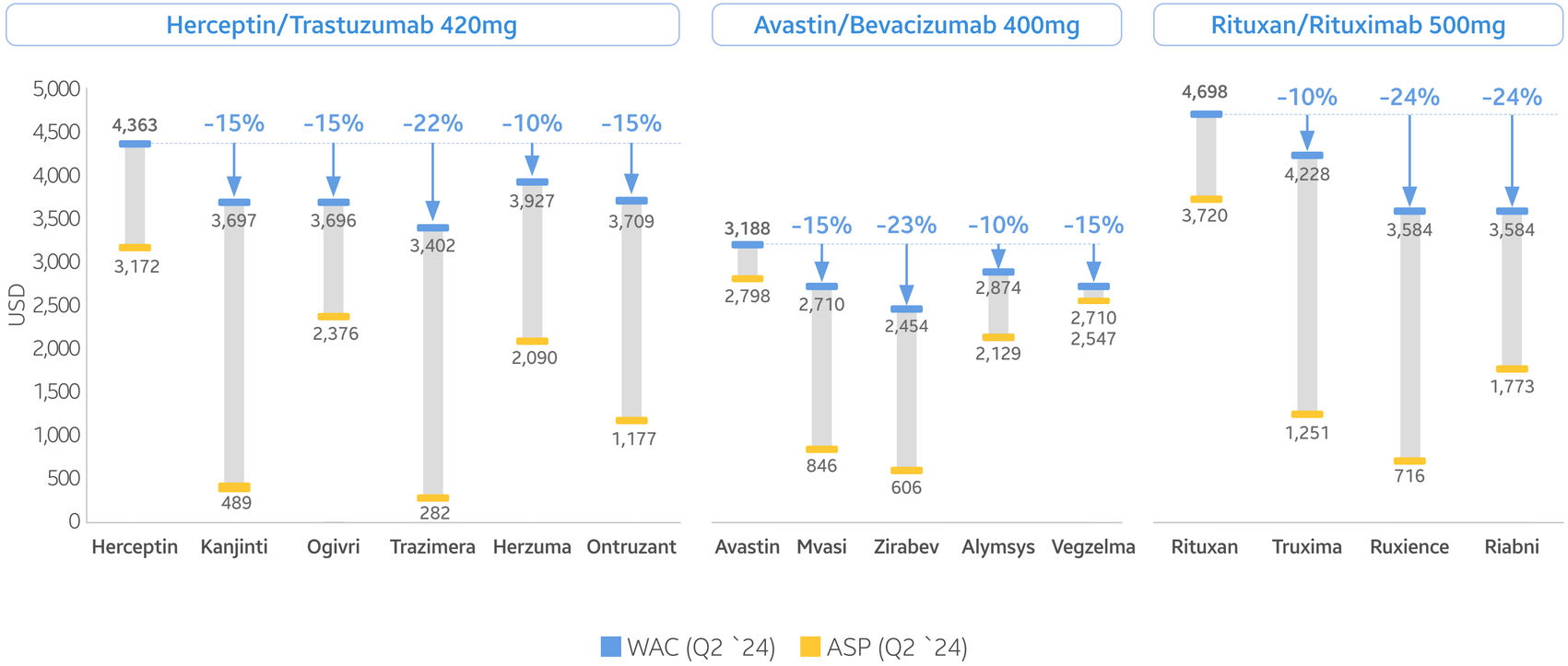
TA	Oncology			Supportive Care			Immunology						Endocrinology		Ophthalmology
Molecule	Trastuzumab	Bevacizumab	Rituximab	Filgrastim	Pegfilgrastim	Epoetin alfa	Infliximab	Adalimumab	Etanercept	Natalizumab	Tocilizumab	Ustekinumab	Denosumab	Insulin glargine	Ranibizumab
Reference Product	Herceptin (trastuzumab) Roche 1998	Avastin (bevacizumab) Roche 2004	Rituxan (rituximab) Genentech&Biogen 1997	Neupogen (filgrastim) Amgen 1991	Neulasta (pegfilgrastim) Amgen 2002	Epogen (epoetin alfa) Amgen 1898	Remicade (infliximab) Janssen 1998	Humira (adalimumab) AbbVie 2002	Enbrel (etanercept) Amgen 2003	Tysabri (natalizumab) Biogen 2004	Actemra (tocilizumab) Genetech 2010	Stelara (ustekinumab) Janssen 2009	Prolia/Xgeva (denosumab) Amgen 2010	Lantus (insulin glargine) Sanofi 2000	Lucentis (ranibizumab) Novartis 2006
Biosimilar	Ogivri (trastuzumab-dkst) Biocon 2017	Mvasi (bevacizumab-awwb) Amgen 2017	Truxima (rituximab-abbs) Celltrion&Teva 2018	Zarxio (filgrastim-sndz) Sandoz 2015	Fulphila (pegfilgrastim-jmdb) Biocon 2018	Retacrit (epoetin alfa-epbx) Hospira&Pfizer 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	Jubbonti/Wyost (denosumab-bbdz) Sandoz 2024	Semglee (insulin glargine-yfgn) Biocon 2021	Byooviz (ranibizumab-nuna) Samsung Bioepis&Biogen 2021
	Herzuma (trastuzumab-pkrb) Celltrion&Teva 2018	Zirabev (bevacizumab-bvzr) Pfizer 2019	Ruxience (rituximab-pvvr) Pfizer 2019	Nivestym (filgrastim-aafi) Hospira&Pfizer 2018	Udenyca (pegfilgrastim-cbqv) Coherus 2018		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			Rezvoglar (insulin glargine-aglr) Eli Lilly 2021	Cimerli (ranibizumab-eqrn) Coherus 2022
	Ontruzant (trastuzumab-dttb) Samsung Bioepis&Organon 2019	Alymsys (bevacizumab-maly) Amneal 2022	Riabni (rituximab-arrx) Amgen 2020	Releuko (filgrstim-ayow) Amneal&Kashiv 2022	Ziextenzo (pegfilgrastim-bmez) Sandoz 2019		Avsola (infliximab-axxq) Amgen 2019	Hyrimoz (adalimumab-adaz) Sandoz 2018							
	Trazimera (trastuzumab-qyyp) Pfizer 2019	Vegzelma (bevacizumab-adcd) Celltrion 2022			Nyvepria (pegfilgrastim-apgf) Hospira&Pfizer 2020		Ixifi (infliximab-qbtx) Pfizer 2017	Hadlima (adalimumab-bwwd) Samsung Bioepis&Organon 2019							
	Kanjinti (trastuzumab-anns) Amgen 2019	Avzivi (bevacizumab-tnjn) Sandoz&Bio-Thera 2023			Stimufend (pegfilgrastim-fpgk) Fresenius Kabi 2022			Abrilada (adalimumab-afzb) Pfizer 2019							
					Fylnetra (pegfilgrastim-pbbk) Amneal&Kashiv 2022			Hulio (adalimumab-fkjp) Biocon 2020							
								Yusimry (adalimumab-aqvh) Coherus 2021							
								Idacio (adalimumab-aacf) Fresenius Kabi 2022							
								Yuflyma (adalimumab-aaty) Celltrion 2023							
								Simlandi (adalimumab-ryvk) Alvotech&Teva 2024							

Launched Not launched Updated brand vs. last quarter

Oncology WAC and ASP – Q2 2024

- Across oncology biosimilars, WAC prices represent a modest discount (between 10-25%) compared to reference products.
- Savings are seen in ASP where oncology biosimilars can save the health care system up to 90% compared to their reference products.

Figure 3. Q2 2024 WAC and ASP[2,3]

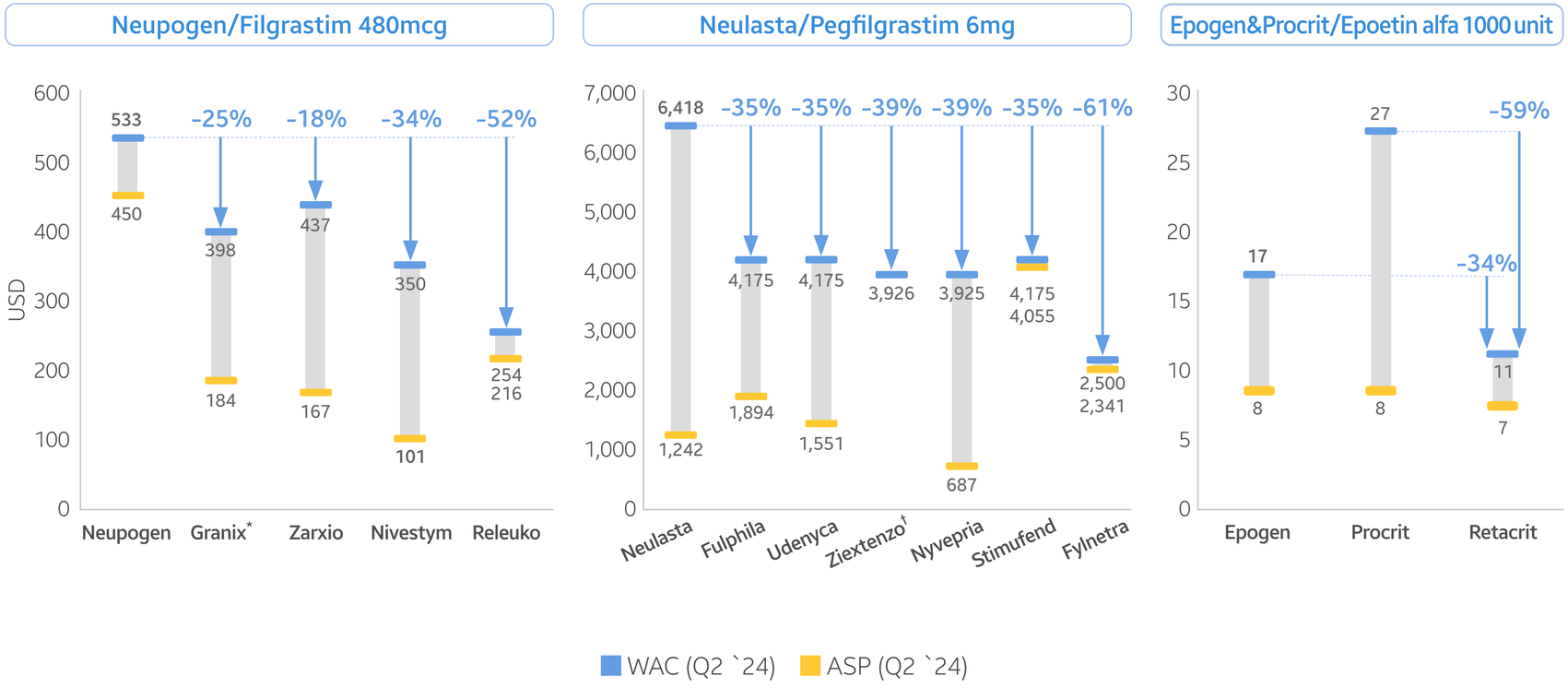


Products are listed in order of launch
ASP: Average sales price; **WAC**: Wholesale acquisition cost

Supportive Care WAC and ASP - Q2 2024

* In pegfilgrastim and epoetin alfa, the reference product ASP matches the biosimilars in an effort to retain market share.
* However, Neupogen maintains higher ASP relative to biosimilars.

Figure 4. Q2 2024 WAC and ASP[2,3]

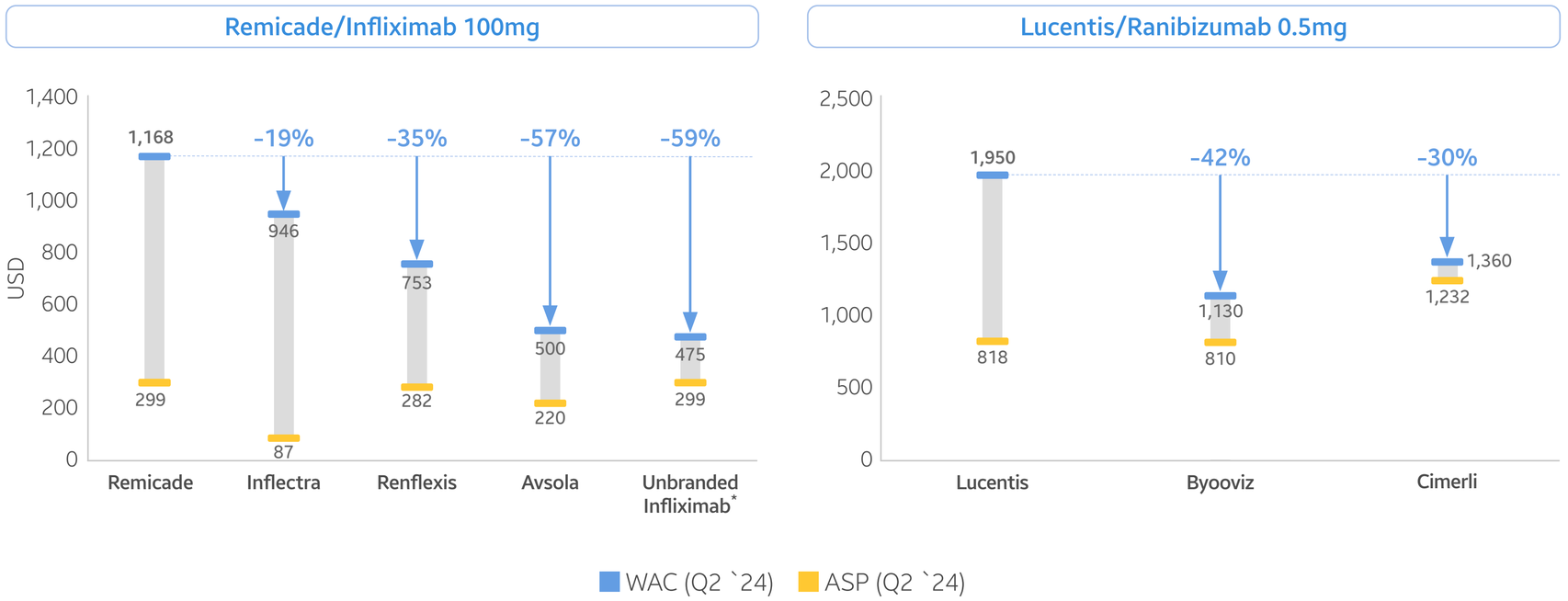


Products are listed in order of launch
ASP: Average sales price; **WAC**: Wholesale acquisition cost
*Granix is not a biosimilar; approved under the FDA's New Drug Application pathway †Ziextenzo ASP is unpublished as of Q2 2024

Immunology & Ophthalmology WAC and ASP - Q2 2024

- Infliximab biosimilars launched with progressively lower WACs, ranging from -19% to -59% in discounts. Biosimilar competition has led to ASP prices 75-90% lower than the reference product WAC.
- Recent ranibizumab biosimilar launches have already led to lower reference product ASP costs.

Figure 5. Q2 2024 WAC and ASP[2,3]

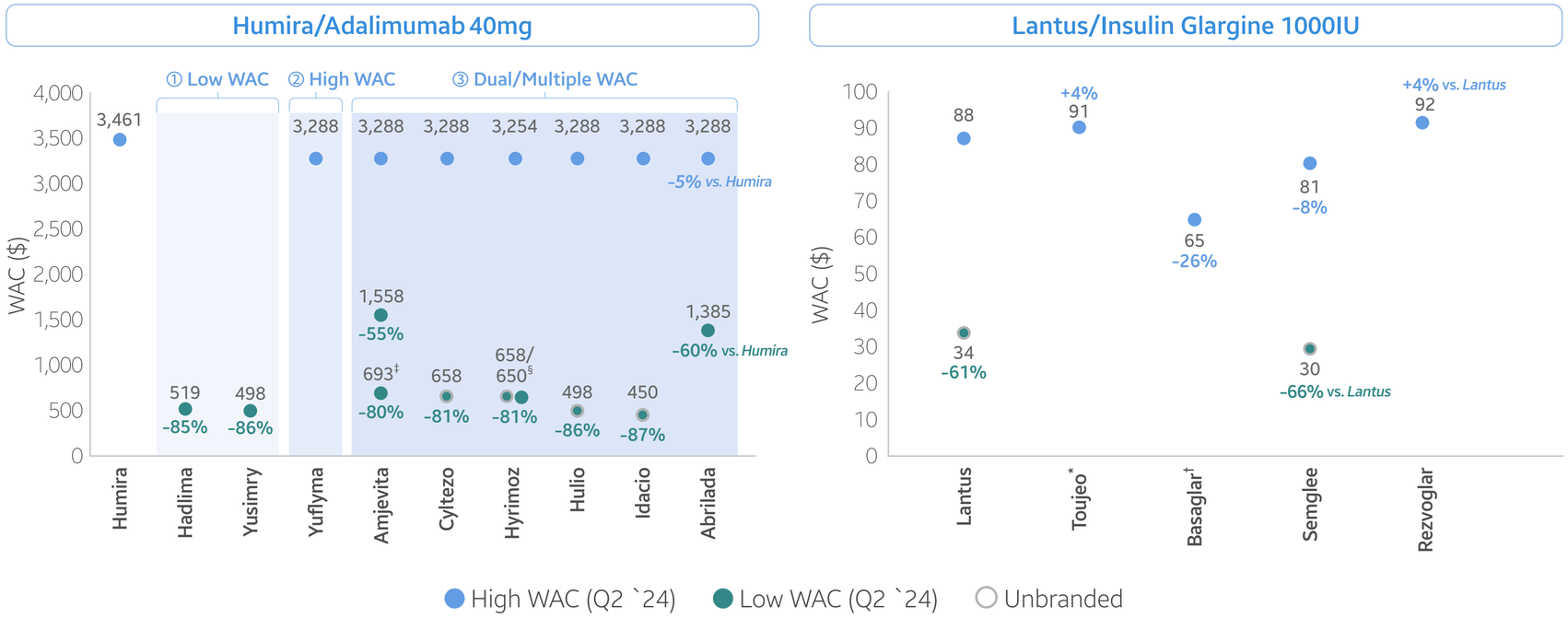


Products are listed in order of launch
ASP: Average sales price; **WAC**: Wholesale acquisition cost
*Janssen's Remicade without the brand name

Immunology & Endocrinology WAC and NADAC - Q2 2024

- Insulin glargine & adalimumab categories reflect recent pricing practices such as "unbranded biologics" and high/low WAC options.
- With no published ASP for products under the pharmacy benefit it is difficult to ascertain true net prices.

Figure 6. Q2 2024 WAC[2]



Products are listed in order of launch
WAC: Wholesale acquisition cost
‡Amjevita only launched in low WAC for high concentration §Cordavis price of Hyrimoz *Toujeo is high dose version of Lantus †Basaglar is not a biosimilar, approved under the FDA's New Drug Application pathway

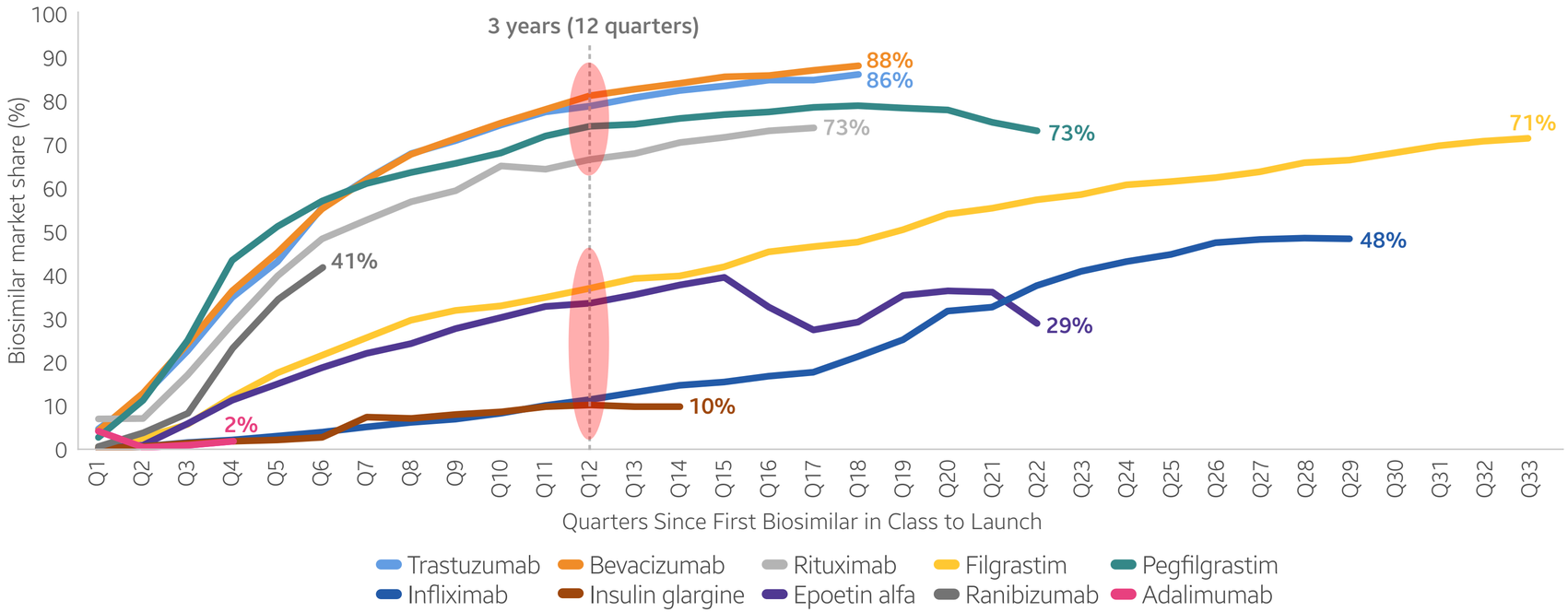
Biosimilar Volume Uptake Varies by Molecule

On average, biosimilars have gained 53% market share within three years (12 quarters) post initial launch. Each molecule has demonstrated unique biosimilar uptake and can be categorized into fast or slow uptake speed.

1) **Fast Uptake Speed**: Oncology*, ophthalmology, and pegfilgrastim biosimilars. Three years post launch, average biosimilar market share reached 75%.†

2) **Slow Uptake Speed:** Immunology‡, filgrastim, epoetin alfa, and insulin glargine biosimilars. On average, only a 23% biosimilar market share was achieved by Year 3.†

Figure 7. Biosimilar Market Share Post-Launch[5]

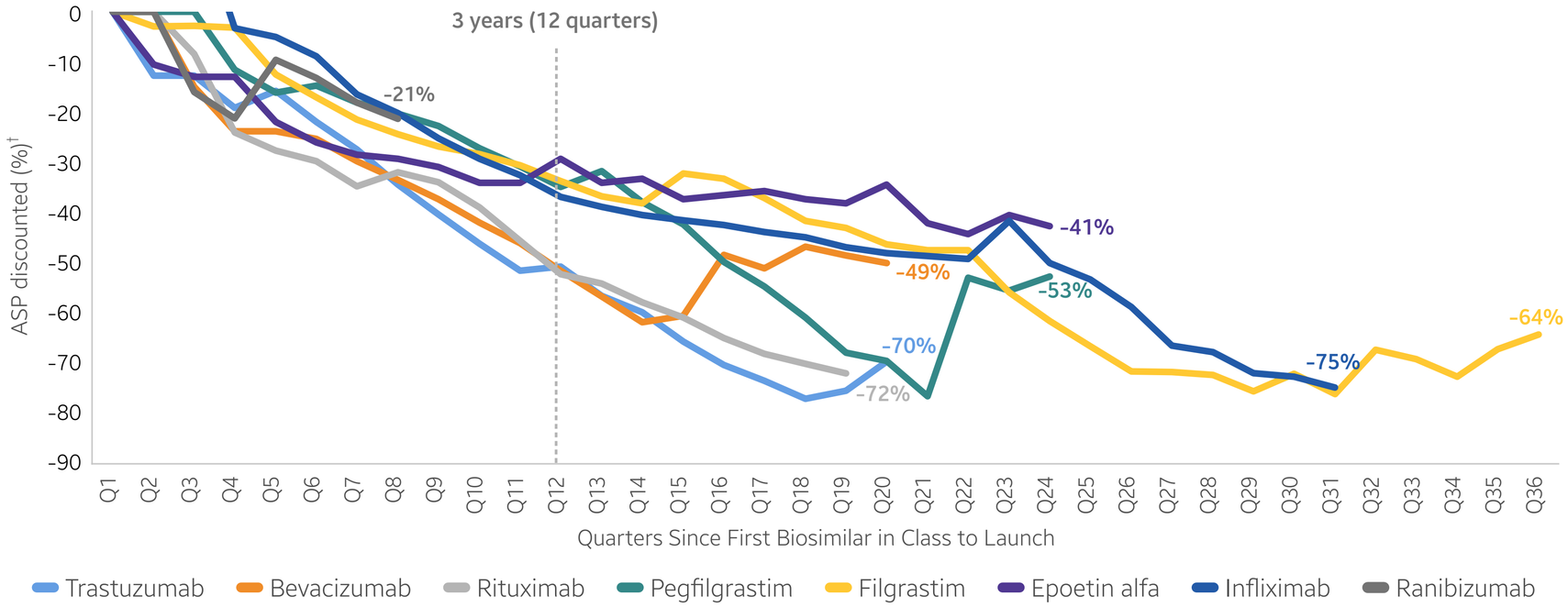


*Trastuzumab, bevacizumab, and rituximab
†Averages include products that are 3 years or older ‡Infliximab and adalimumab

Biosimilars are Reducing Drug Costs across Multiple TAs by Lowering Prices

- Biosimilar launches have led to significant price decreases over time. On average, ASP declined by 41% three years (12 quarters) post first biosimilar launch with more mature markets demonstrating increasing price concessions.
- Recent observed increases in ASP for some markets (e.g. bevacizumab, pegfilgrastim) are an artifact of newly-launched, low-market share biosimilars with ASPs that reflect WAC pricing.

Figure 8. ASP Trend by Molecule[3]



TA: Therapeutic area; ASP: Average sales price
*Trastuzumab, bevacizumab, and rituximab are included †ASP discounted % vs. reference product ASP when first biosimilar in class launch

Market Share and ASP Trends - Herceptin (Trastuzumab)

* **As of Q4 2023, the biosimilar share of the trastuzumab market has reached 86% (+2% vs. last quarter).**
  - First-to-market biosimilar, Kanjinti, has been the market leader since Q4 2020, although Trazimera share continues to steadily catch up.
* **As of Q2 2024, average ASP of all products is $1,598 (-62%)* and the average for biosimilars alone is $1,283 (-70%)*.**
  - The average ASP has increased in 2024 due to recent increases in Ogivri and Herzuma ASPs.
* **In the trastuzumab market, biosimilar products with the lowest ASPs have the dominant market share.**

Figure 9. Trastuzumab Volume Market Share[5]

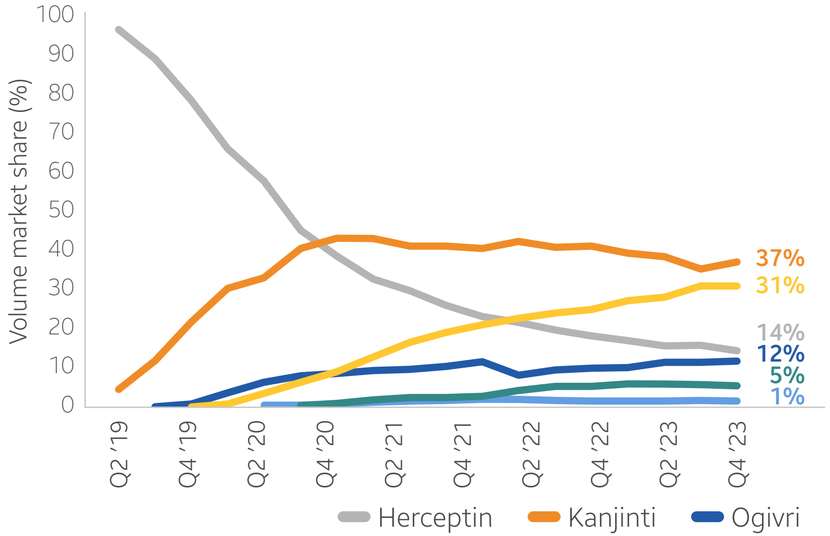
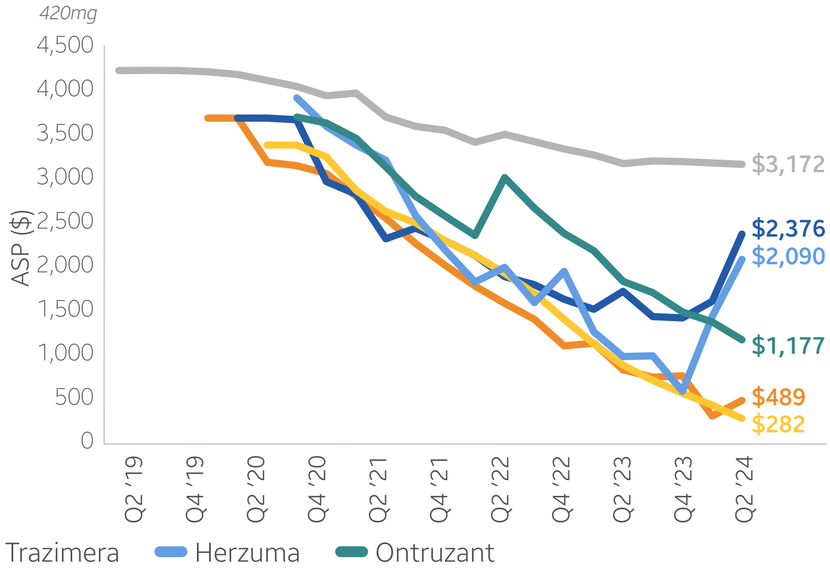


Figure 10. Trastuzumab ASP Trend[3]



Products are listed in legends in order of launch **ASP**: Average sales price
*Percentages reflect the change from the reference product's ASP at the time of the first biosimilar launch.

Market Share and ASP Trends - Avastin (Bevacizumab)

- As of Q4 2023, the biosimilar share of the bevacizumab market was 88% (+1% vs. last quarter).
  - Biosimilars achieved a higher market share than the originator as of Q4 2020.
- As of Q4 2024 average ASP of all products is $1,785 (-42%)* and the average for biosimilars alone is $1,532 (-50%)*.
- In the bevacizumab market, biosimilars with the lowest ASPs have dominant market share.

Figure 11. Bevacizumab Volume Market Share[5]

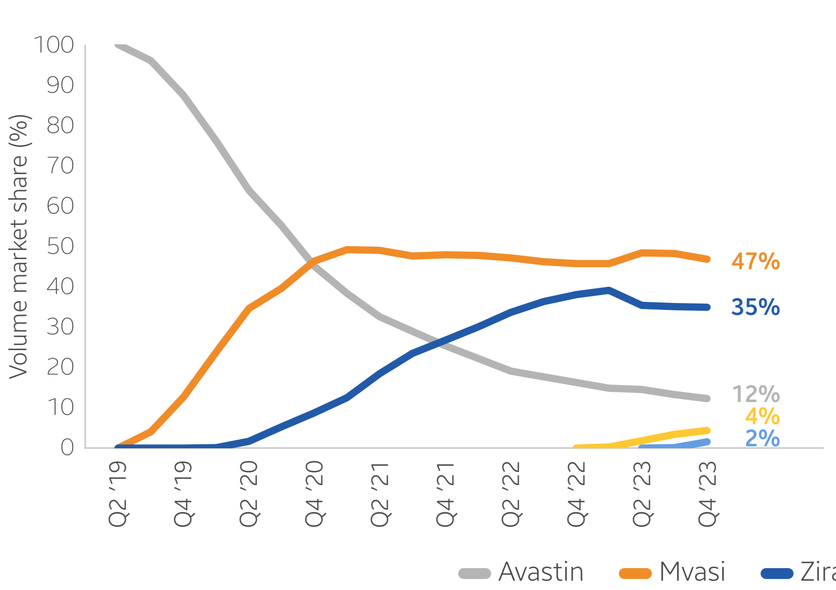
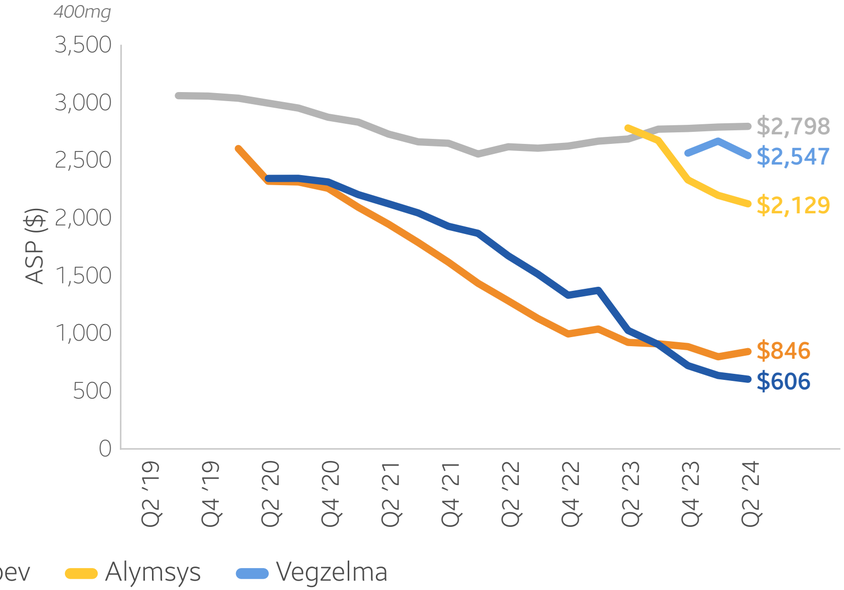


Figure 12. Bevacizumab ASP Trend[3]



Products are listed in legends in order of launch **ASP**: Average sales price
*Percentages reflect the change from the reference product's ASP at the time of the first biosimilar launch.

Market Share and ASP Trends - Rituxan (Rituximab)

- As of Q4 2023, the biosimilar share of the rituximab market was 73% (Unchanged vs. last quarter).
  - A rituximab biosimilar, Ruxience, has become the market leader as of Q3 2022.
- As of Q2 2024, the average ASP of all products is $1,865 (-58%)* and the average for biosimilars alone is $1,247 (-72%)*.
- In the rituximab market, lower priced biosimilars are dominating the market.

Figure 13. Rituximab Volume Market Share[5]

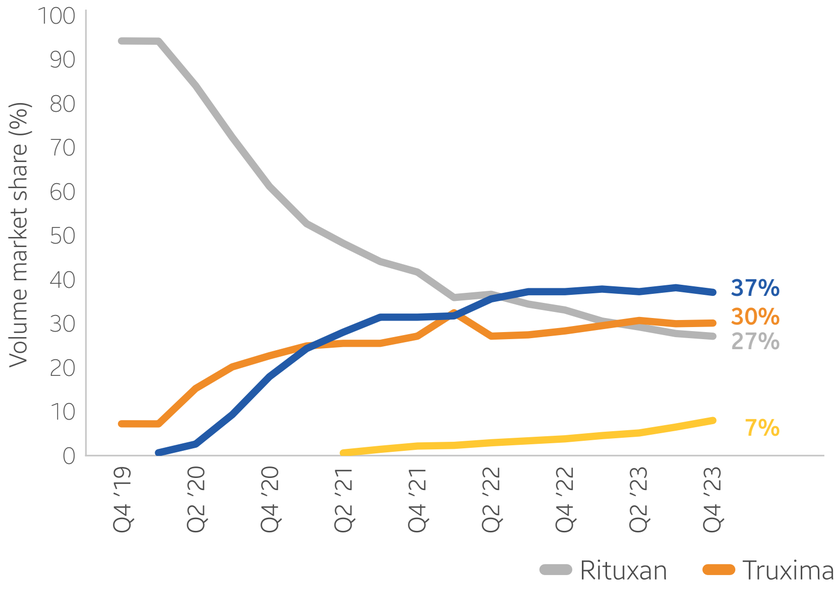
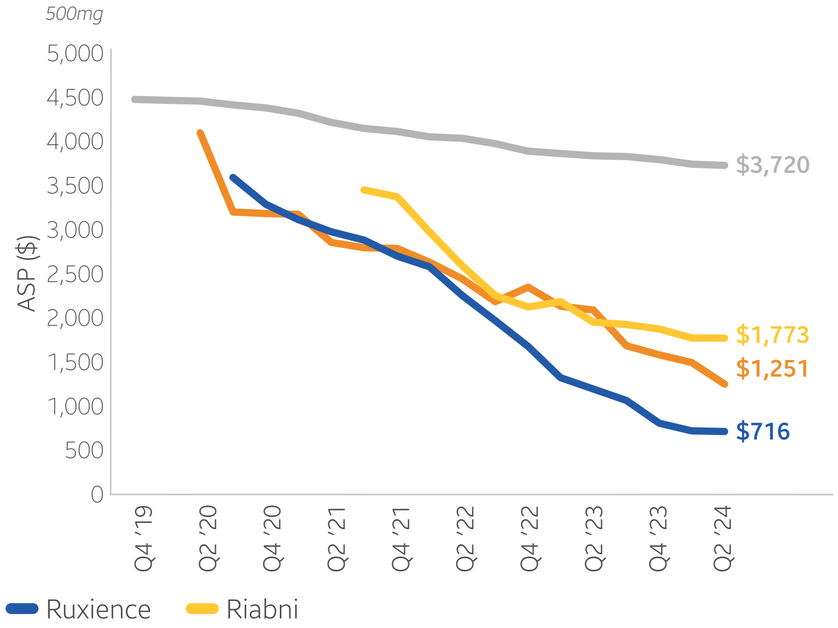


Figure 14. Rituximab ASP Trend[3]



Products are listed in legends in order of launch ASP: Average sales price
*Percentages reflect the change from the reference product's ASP at the time of the first biosimilar launch

Market Share and ASP Trends - Neupogen (Filgrastim)

- As of Q4 2023, the biosimilar share of the filgrastim market has reached 86% (Unchanged vs. last quarter).
  - The first filgrastim biosimilar to launch has been the US market leader since Q3 2018.
- As of Q2 2024, the average ASP of all products is $224 (-50%)* and the average for biosimilars alone is $161 (-64%)*.
- In the filgrastim market, lower priced biosimilars were dominating the market however, Zarxio, the market leader, has shown an ASP price correction in 2024.

Figure 15. Filgrastim Volume Market Share[5]

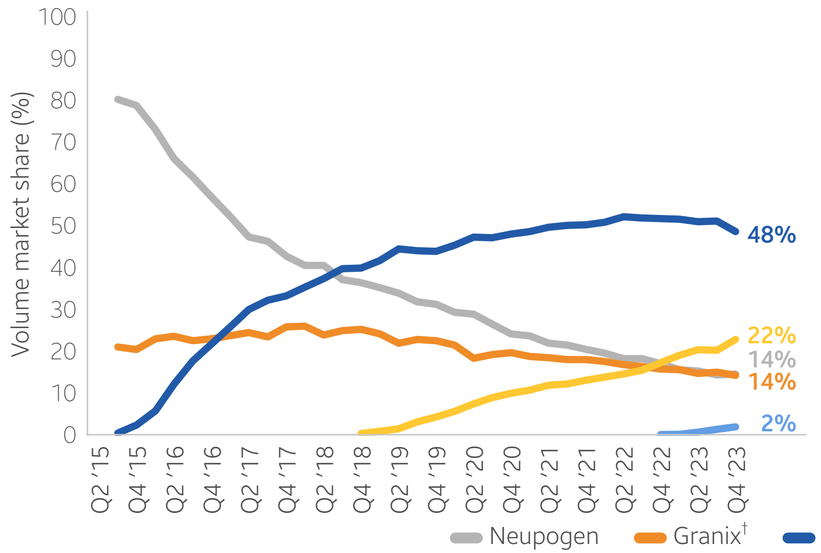
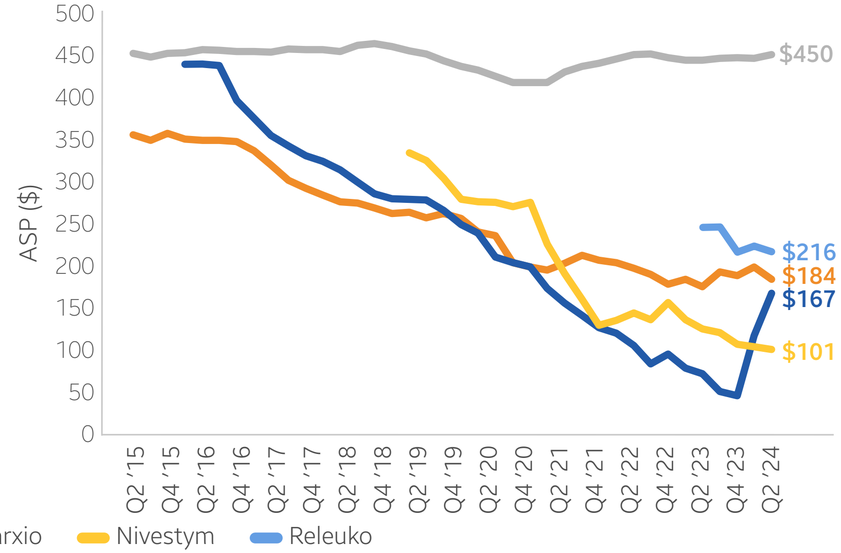


Figure 16. Filgrastim ASP Trend[3]



Legends are listed in order of launch **ASP**: Average sales price
*Percentages reflect the change from the reference product's ASP at the time of the first biosimilar launch
†Granix is not abiosimilar; It's approved under FDA, a new drug application pathway

Market Share and ASP Trends - Neulasta (Pegfilgrastim)

- **As of Q4 2023, the biosimilar share of the pegfilgrastim market was 73% (-2% vs. last quarter).**
  - The biosimilar share has slightly decreased after Ziextenzo fell out of the market in Q3.
- **As of Q2 2024, the average ASP of all products is $1,962 (-56%)* and the average for biosimilars alone is $2,106 (-53%)*.**
  - The 2024 average ASP has increased slightly due to Ziextenzo market removal and ASP correction strategies from Neulasta and Fulphila.
- **Reference product ASP pricing is very competitive with biosimilars allowing the reference product to maintain a steady market share.**

Figure 17. Pegfilgrastim Volume Market Share[5]

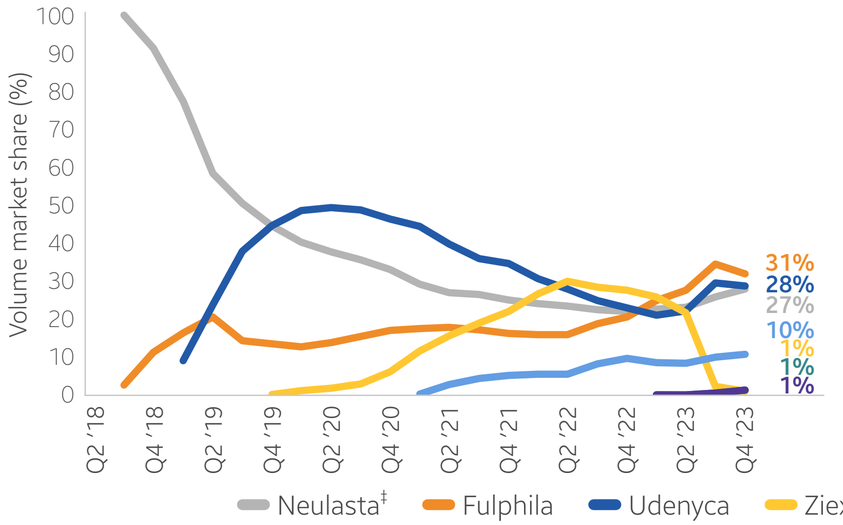
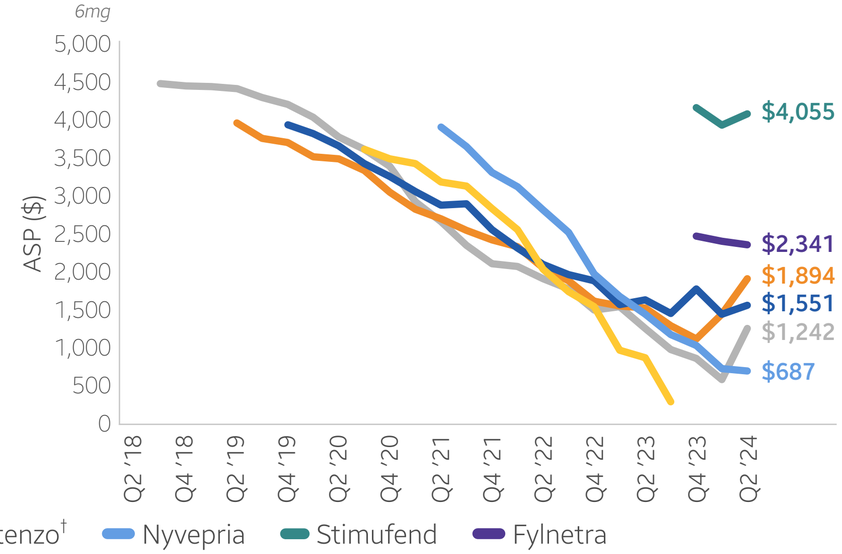


Figure 18. Pegfilgrastim ASP Trend[3]



Legends are listed in order of launch **ASP**: Average sales price
*Percentages reflect the change from the reference product's ASP at the time of the first biosimilar launch †Ziextenzo ASP is not published in 4Q 2023 ‡Onpro is not included

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

* Retracrit, the only biosimilar of epoetin alfa, maintains about a third of the epoetin alfa market share.
* By matching ASP, the two reference products have maintained a combined share of approximately 70%.

Figure19. Epoetin Alfa Volume Market Share[5]

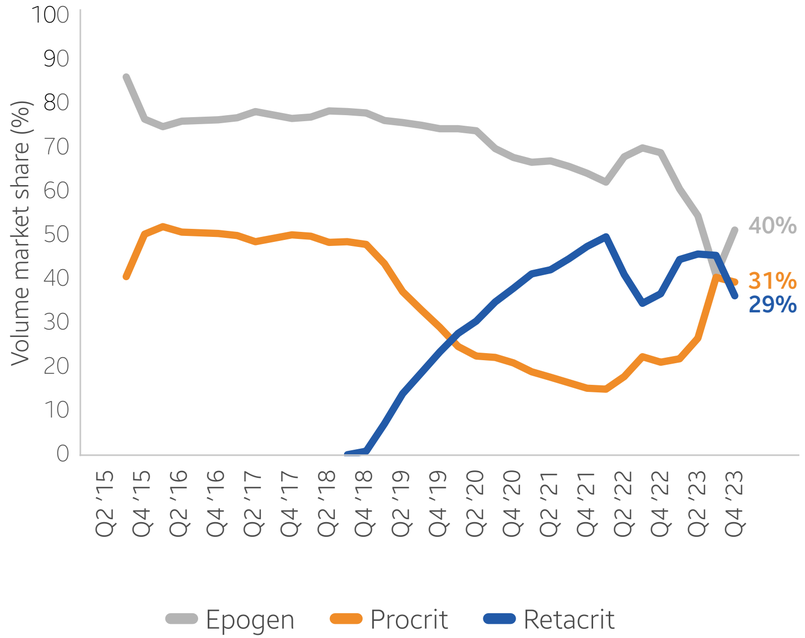
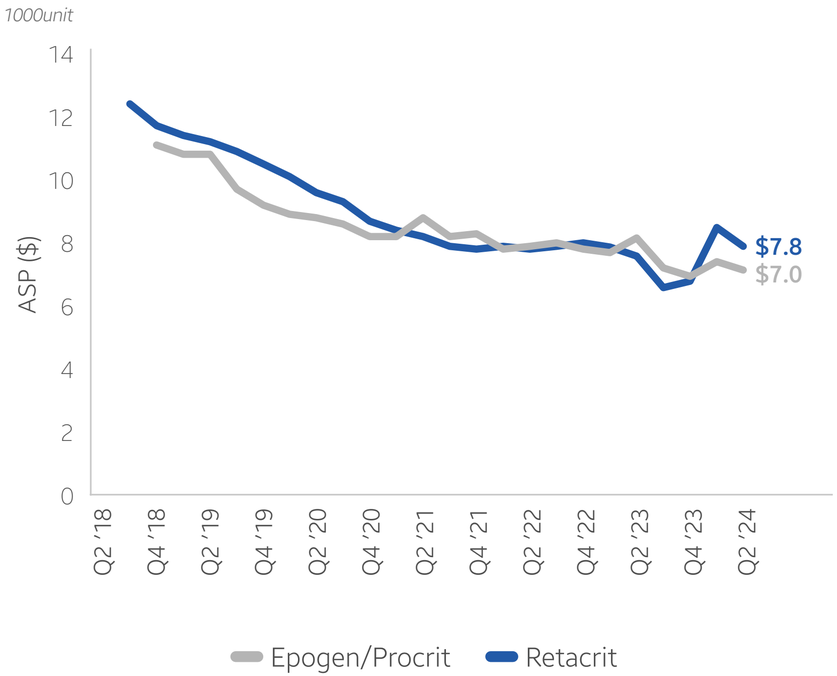


Figure 20. Epoetin alfa ASP Trend[3]



Legends are listed in order of launch
ASP: Average sales price

Market Share and ASP Trends - Remicade (Infliximab)

- **After a slow start, the Infliximab biosimilar market began to accelerate in year three.**
  - As of Q4 2023, Infliximab biosimilar market share has reached 48% (Unchanged vs. last quarter).
- **As of Q2 2024, the average ASP of all products is $222 (-72%)* and the average for biosimilars alone is $196 (-75%)*.**
- **Janssen's competitive ASP pricing and launch of an unbranded infliximab of Remicade in Q4 2022 has allowed the reference product to hold onto the market leading position.**

Figure 21. Infliximab Volume Market Share[5]

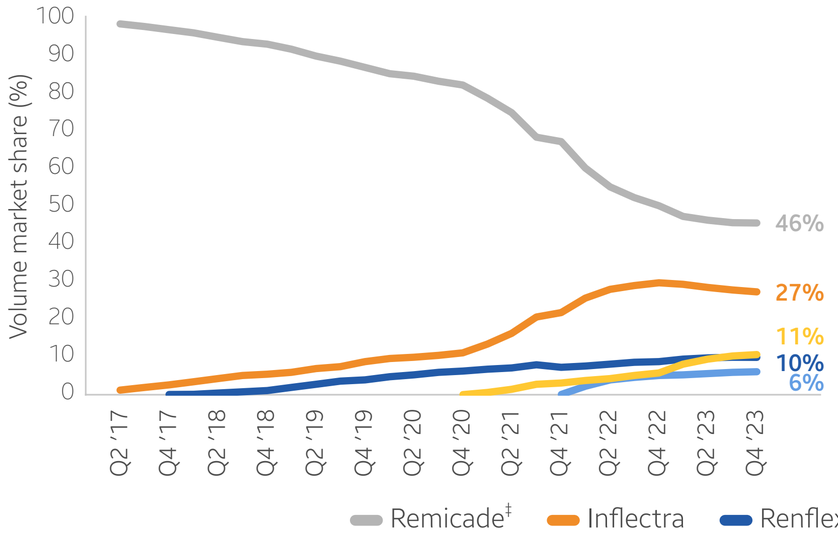
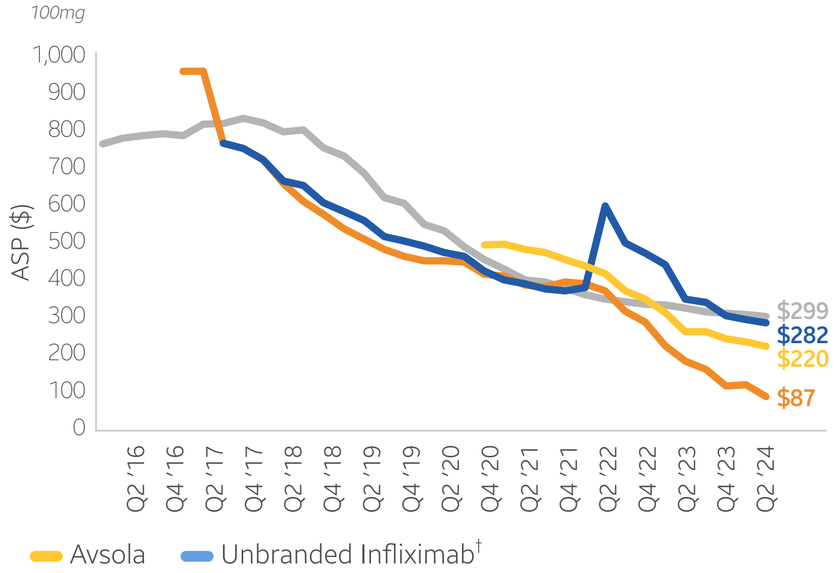


Figure 22. Infliximab ASP Trend[3]



Legends are listed in order of launch
ASP: Average sales price
*Percentages reflect the change from the reference product's ASP at the time of the first biosimilar launch †Janssen's Remicade without the brand name ‡Remicade and Unbranded Infliximab share a J code

Market Share and WAC Trends - Humira (Adalimumab)

- **As of February 2024, adalimumab biosimilar market share is 4% (+2% vs. last quarter).**
- **Brands are providing customers with a wide range of pricing options,**
  1) Hadlima, Yusimry are offering a low WAC: ~85-86% less than Humira
  2) Yuflyma are offering a high WAC just 5% below Humira
  3) Cyltezo, Amjevita, Hyrimoz, Hulio, Idacio, and Abrilada are offering dual/multiple pricing options including both a low and high WAC

Figure 23. Adalimumab Volume Market Share[6]

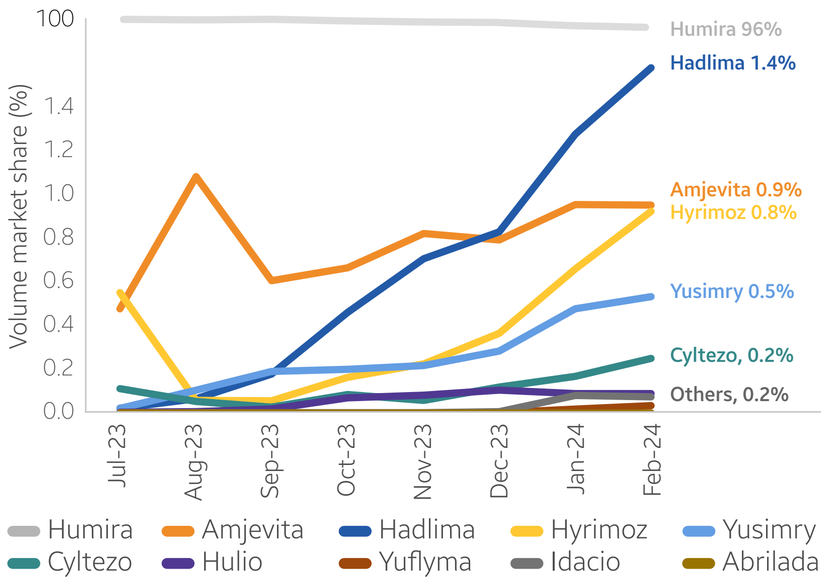
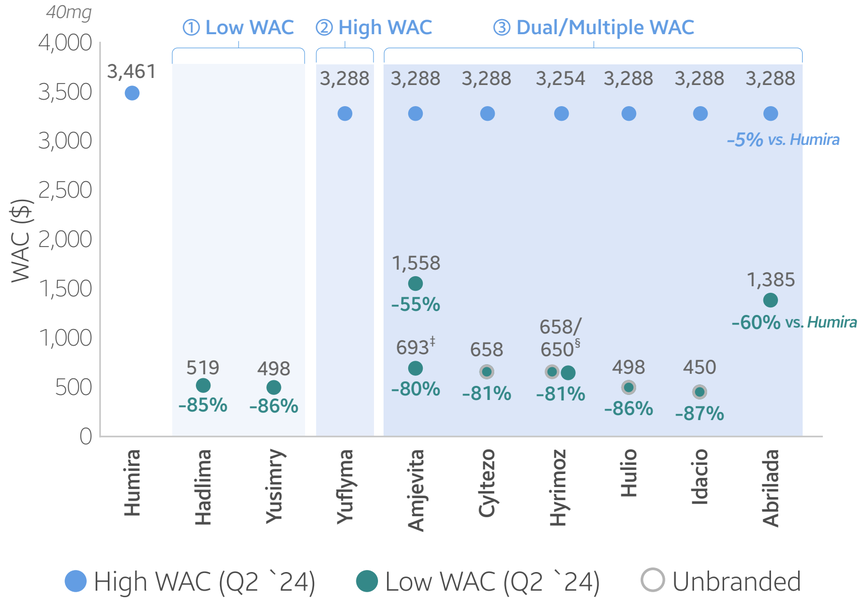


Figure 24. Adalimumab WAC Trend[2]



WAC: Wholesale acquisition cost
‡Amjevita only launched in low WAC for high concentration §Cordavis price of Hyrimoz

Market Share and WAC Trends - Lantus (Insulin glargine)

There are complex product dynamics within the insulin glargine (ISG) market:

- Sanofi markets three versions of insulin glargine (ISG): 1) the reference product, Lantus; 2) Toujeo (a higher dose ISG); and 3) unbranded Lantus.
- Biocon has two Lantus biosimilars, Semglee (insulin glargine-yfgn) and unbranded Semglee (insulin glargine-yfgn).
- Lilly has two insulin glargine products: 1) Basaglar (insulin glargine), approved thru a New Drug Application and 2) Rezvoglar (insulin glargine-aglr), an interchangeable Lantus biosimilar.

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

Figure 25. Insulin Glargine Volume Market Share[5]

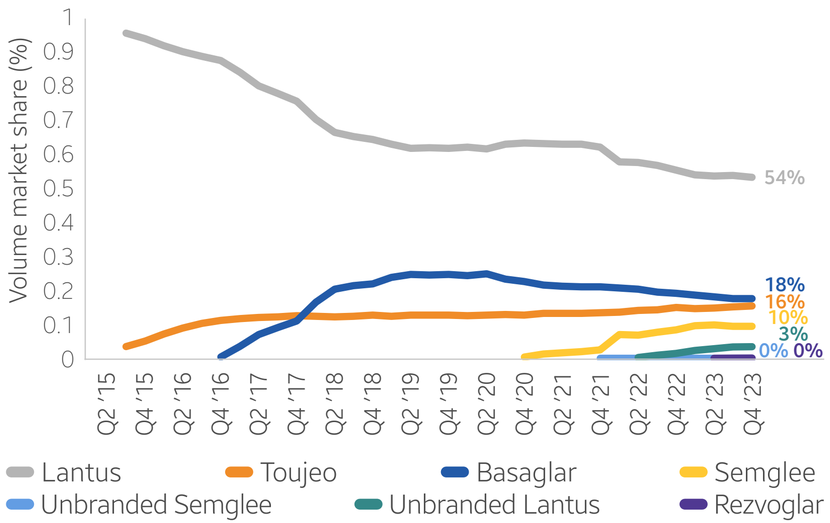
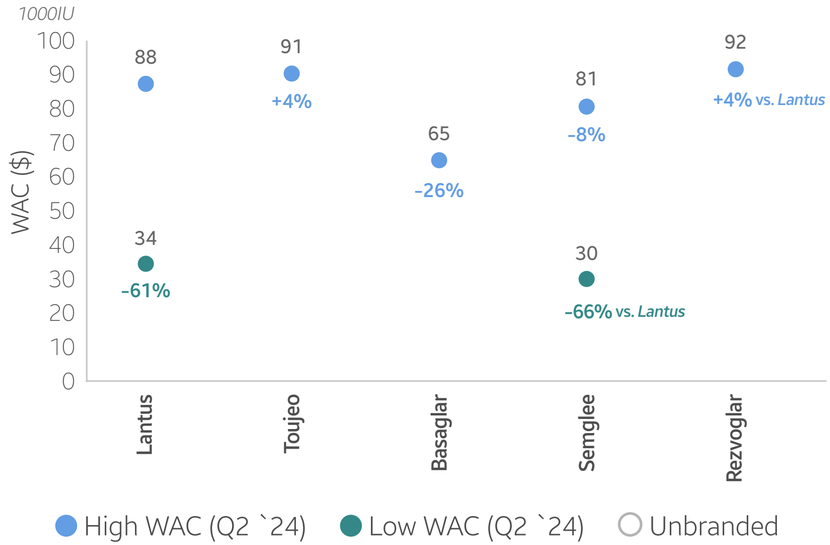


Figure 26. Insulin Glargine WAC Trend[2]



Legends are listed in order of launch
ISG: Insulin Glargine; **WAC**: Wholesale acquisition cost

Market Share and ASP Trends - Lucentis (Ranibizumab)

- As of Q4 2023, two biosimilars have launched accounting for a combined market share of 41% (+7% vs. last quarter).
- As of Q2 2024, the average ASP of all products is $953 (-27%)* and the average for biosimilars alone is $1,021 (-21%)*.
- Counterintuitively, Cimerli continues to grow in market share despite having the highest ASP prices.

Figure 27. Ranibizumab Volume Market Share[5]

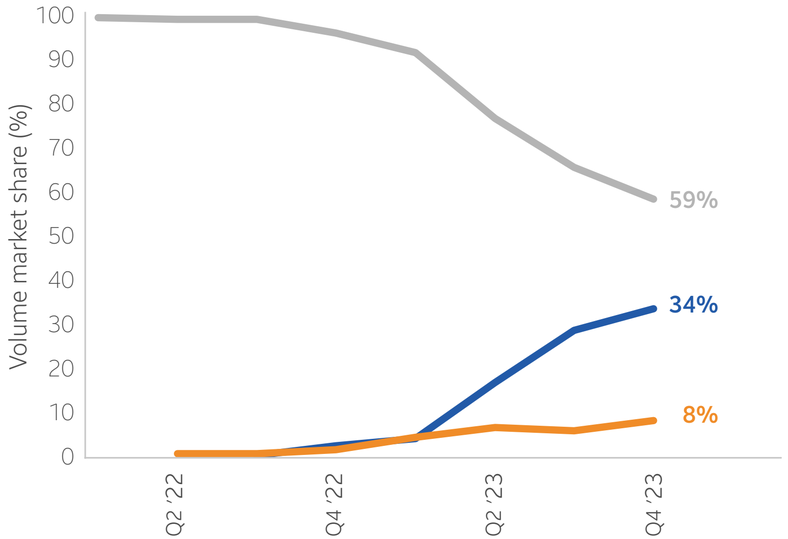
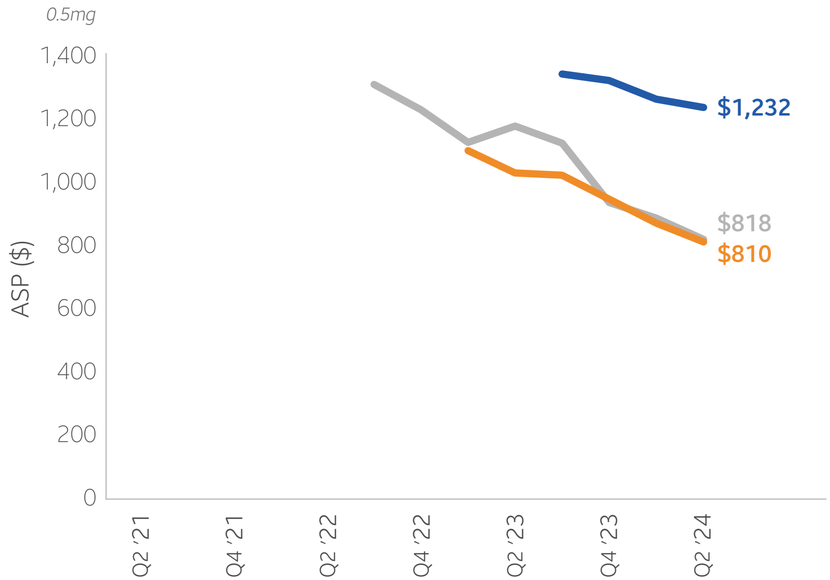


Figure 28. Ranibizumab ASP Trend[3]



Lucentis Byooviz Cimerli

Legends are listed in order of launch
ASP: Average sales price
*Percentages reflect the change from the reference product's ASP at the time of the first biosimilar launch.

Inflation Reduction Act (IRA): Healthcare Provisions

One and a half years have passed since President Biden signed the Inflation Reduction Act (IRA) into law on August 16, 2022. Centers for Medicare & Medicaid Services (CMS) recently revealed details on select provisions impacting healthcare found below.

#	Healthcare Provision	Description	Status	Effective Year
1	Medicare Payment Limit Increase	5-year increase in the Medicare Part B payment for qualifying biosimilars (ASP that is not more than the reference product) from ASP + 6% to + 8% of the reference biological product's ASP.	Active	2022
2	Drug Price Negotiation Detail in slide #24	Require the federal government to negotiate prices for select brand drugs covered under Medicare Part B and Part D with the highest total spending and no biosimilar or generic equivalent.	In progress	2026
3	Inflation Rebates	Require drug companies to pay rebates to Medicare if prices rise faster than inflation for drugs used by Medicare beneficiaries.	Active	2023
4	Part D Benefit Redesign Detail in slide #25	Cap out-of-pocket spending for Medicare Part D enrollees and make other Part D benefit design changes.	In progress	2025
5	Insulin Copay Caps	Limit monthly cost sharing for insulin to $35 for people with Medicare.	Active	2023
6	Improved Adult Vaccine Access	Eliminate cost sharing for adult vaccines covered under Medicare Part D and improve access to adult vaccines in Medicaid and Children's Health Insurance Program (CHIP).	Active	2023
7	Expanded Low-Income Medicare Coverage	Expand eligibility for full benefits under the Medicare Part D Low-Income Subsidy Program.	In progress	2024
8	Delay of Rebate Rule	Further delay in implementation of the Trump Administration's drug rebate rule that intended to eliminate safe harbor protections of rebates within the Anti-Kickback Statute.	In progress	2032

Inflation Reduction Act (IRA): Drug Price Negotiation

Drug Price Negotiation is a provision that requires the Federal Government to negotiate prices for some drugs covered under Medicare.

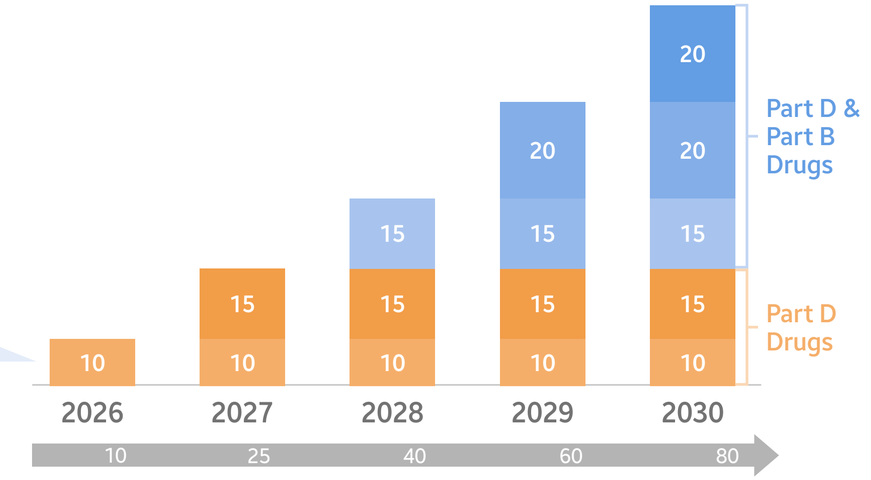
* **Effective Year: 2026**
* **Key Concepts:**
  - In August 2023, CMS announced the first 10 drugs selected for Part D negotiation, whose "Maximum Fair Prices" will become effective in 2026.
  - By 2030, 70 more Part D and Part B drugs will be selected.
  - Drugs selected for negotiation represent drugs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

10 drugs selected for 2026 Part D negotiation

1. Apixaban (Eliquis)
2. Empagliflozin (Jardiance)
3. Rivaroxaban (Xarelto)
4. Sitagliptin (Januvia)
5. Dapagliflozin (Farxiga)
6. Sacubitril/valsartan (Entresto)
7. **Etanercept (Enbrel)**
8. Ibrutinib (Imbruvica)
9. **Ustekinumab (Stelara)**
10. Insulin aspart

Bold: References products with biosimilars approved but not yet launched

Maximum Number of Negotiated Drugs per Year



Inflation Reduction Act (IRA): Part D Benefit Redesign

IRA Part D Benefit Redesign provision results in dramatic changes to stakeholder (Part D Enrollees, Part D Plans, Drug Manufacturer, Medicare) liability.

* Effective Year: 2025

2023 → 2024

Part D enrollees cost sharing is eliminated in the catastrophic phase.

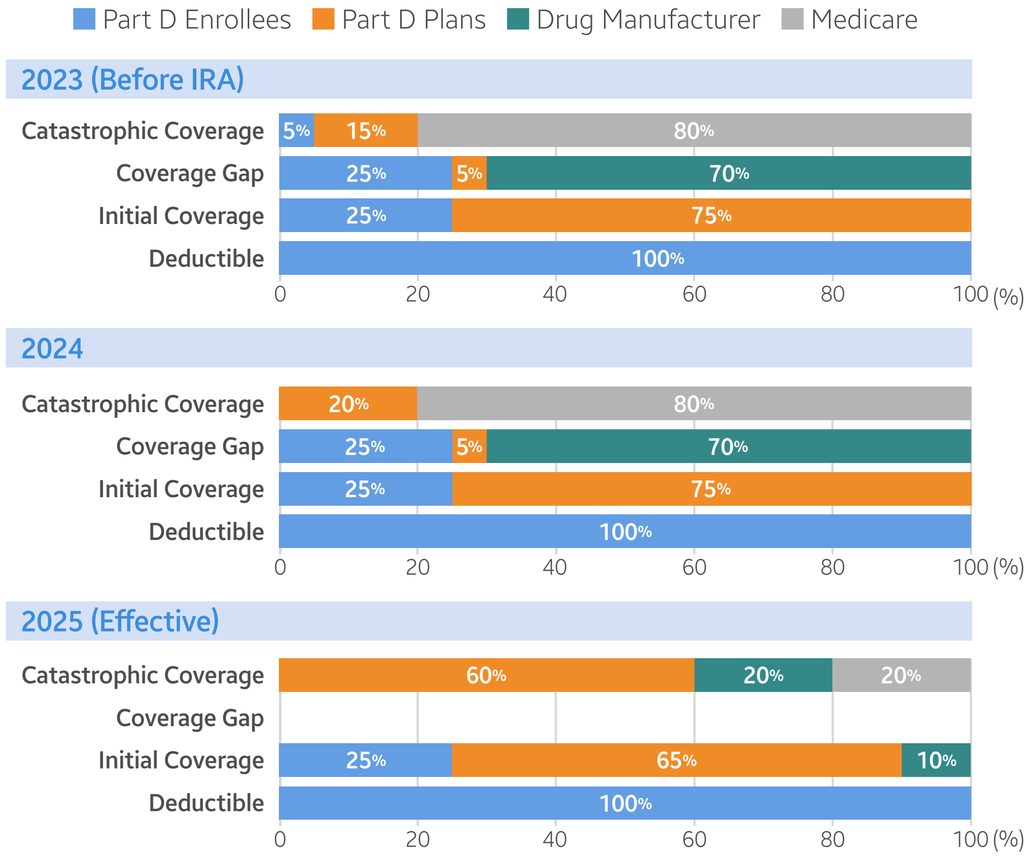
2024 → 2025

1) Government (Medicare) liability is significantly reduced:
   - Share of catastrophic coverage decreases from 80% to 20%.

2) Part D Plans liability is significantly increased:
   - Share of catastrophic coverage increases from 20% to 60%.

3) Part D enrollees liability is further reduced:
   - Total annual cost sharing across all coverage stages drop from $3,333 to $2,000

Medicare Part D Drug Costs Share Change in 2024&2025[7]



Inflation Reduction Act (IRA): Impacts on the Biosimilar Market[8-11]

In an effort to lower prescription drug costs, the IRA will have a dramatic impact on manufacturer and plan sponsor economics. These changes result in opposing forces on the future growth, adoption, and incentivization of biosimilars. Whether these regulations end up causing net harm or net benefit to the biosimilar market remains to be seen.

Pro Biosimilar Forces

I. Loss of manufacturer revenue from Medicare Drug Price Negotiation and Inflation Rebate may lead manufacturers to launch with higher list prices and/or reduce rebate rates in other therapeutic areas or lines of business (e.g. private insurance). Biosimilars may offer greater cost relief in those future markets.

II. Increasing plan liability in Medicare Part D may incentivize payers to more tightly manage the Part B benefit cost. Since biosimilars often offer savings opportunities, plans may be more incentivized to implement and ensure the success of biosimilars in some categories.

III. The increased Medicare payment limit for biosimilars to ASP + 8% helps offset some of the losses that providers may incur when using cheaper ASP biosimilars on the medical benefit.

IV. Orphan drugs are excluded from the drug negotiation program, as a result these markets may still greatly benefit from biosimilar entrants and competition.

Anti Biosimilar Forces

I. Medicare Drug Price Negotiation will impose pricing pressure on the selected drugs and their associated competitors. In those markets (i.e. Enbrel, Stelara), the savings that biosimilars can offer to plans may be reduced, making step therapy through biosimilars a less attractive strategy for plan sponsors to implement.

II. Reductions and caps in the Part D member cost sharing requirements, while a positive improvement for the overall affordability of Medicare beneficiaries, unintentionally reduces the financial incentive for members to switch to a biosimilar from an originator product.

ASP: Average sales price

Reference

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SAMSUNG BIOEPIS

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