

# **A Unique Pattern of Average Sales Price Erosion of Pegfilgrastim Following Biosimilar Entry Into The US Market**

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## **Background**

- Pegfilgrastim is a granulocyte colony-stimulating factor (G-CSF) supportive biologic agent in oncology.
- Pegfilgrastim is used to manage neutropenia: >90% of patients use it, increasing total healthcare expenditures and limiting patient access.
- Biosimilars are clinically equivalent, lower-cost alternatives that drive market competition.

## **Objectives**

- To quantify the longitudinal impact of biosimilar entry on the Average Sales Price (ASP) of reference pegfilgrastim and its US-approved biosimilars.
- To visualize changes in ASP trends.
- To assess if differences in ASP trends are statistically significant.

## Methods

### Study Design and Data Source

- Retrospective analysis of the real-world acquisition costs through the ASP data over 55 quarters (2010Q4-2024Q2)
- Published ASP Pricing Files at the Centers for Medicare and Medicaid Services (CMS) website

### Biologic and Biosimilars

- Reference agent: pegfilgrastim
- Biosimilars: pegfilgrastim-jmdb, pegfilgrastim-cbqv, pegfilgrastim-bmez, pegfilgrastim-apgf, pegfilgrastim-pbbk, pegfilgrastim-fpgk

### ASP Calculations

- For reference pegfilgrastim:  $ASP = \text{payment limit} / (1 + \text{Add-on } \%)$
- For biosimilars:  $ASP = \text{payment limit} - \text{reference ASP} * \text{Add-on } \%$
- Using CMS payment limits, incorporating temporal add-on percentage changes (4.3%, 6.0%, and 8.0%)

### ASP Erosion Metrics

- ASP difference at biosimilar entry
- Biosimilar ASP % change over time
- Average quarterly percent increase in reference pegfilgrastim ASP pre-biosimilar entry
- Average quarterly percent decrease in reference pegfilgrastim ASP post-biosimilar entry
- Cumulative percent increase in reference pegfilgrastim ASP pre-biosimilar entry
- Projected to actual reference pegfilgrastim ASP in 2024Q2

### Statistical Analysis

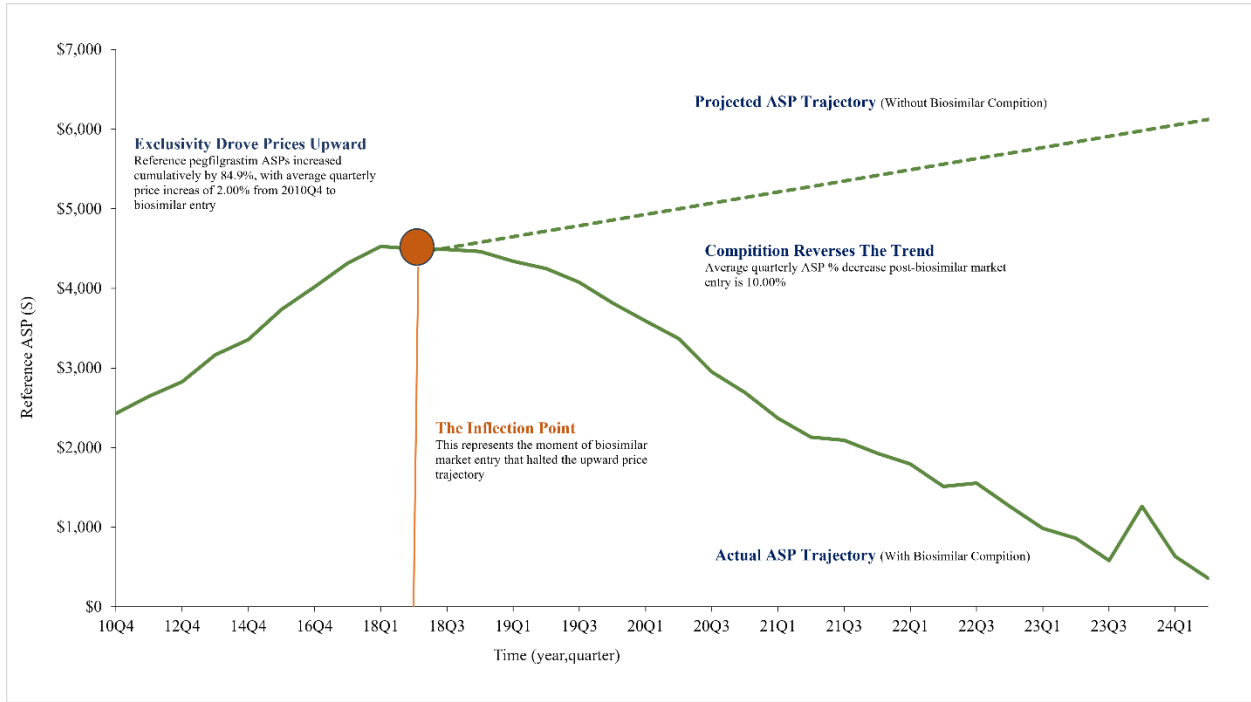
- t-test: Comparing the slope coefficients for reference pegfilgrastim pre- vs. post-biosimilar market entry
- Analysis of Covariance (ANCOVA): Comparing the slope coefficients of biosimilars

## Results and Key Findings

### ASP change of reference pegfilgrastim and its biosimilars in the US market

Biologic	Biosimilar (pegfilgrastim-)	Entry ASP	Reference ASP	Difference	Last ASP	Percent decline
Pegfilgrastim	jmdb	\$4,066	\$4,494	<b>-\$429</b>	\$1,605	-60.5%
	cbqv	\$3,943	\$4,464	<b>-\$520</b>	\$1,699	-56.9%
	bmez	\$3,592	\$3,592	\$0.10	\$282	-92.2%
	apgf	\$3,881	\$2,692	\$1,189	\$1,137	-70.7%
	pbbk	\$2,454	\$862	\$1,592	\$2,213	-9.8%
	fpgk	\$4,138	\$862	\$3,276	\$3,646	-11.9%

## Longitudinal ASP trends of reference pegfilgrastim (2010Q4-2024Q2)



**⚠ Projected reference ASP is 17.08 times the actual reference ASP in 2024Q2**

## Comparative statistical summary of pegfilgrastim vs. biosimilar slope coefficients

Pegfilgrastim pre vs. post-biosimilar entry <b><math>p = 0.007</math></b>
Biosimilar differences <b><math>p &lt; 0.0001</math></b>

## Discussion

- Biosimilar entry forces immediate reference pegfilgrastim ASP reduction, and this reduction continued over time.
- Most pegfilgrastim biosimilars entered markets and continued to have higher ASPs than the reference pegfilgrastim.
- This paradox in pegfilgrastim pricing strategies reflects its high utilization as a supportive care therapy, various administration forms, and specific contracting strategies between payers and providers
- Biosimilar entry drives market competition, enhances the affordability of biologics, and lowers treatment costs.

## **Limitations**

- The analysis covers physician-administered biologics, which may not reflect the dynamics of biologics available through pharmacies.
- The analysis excludes other pricing drivers, including market adoption rates, private-label branding, and payer and provider contracting.

## **Key Takeaway**

Unlike other reference biologics, reference pegfilgrastim ASPs declined unusually after biosimilar entry, reflecting a unique defensive pricing strategy by the manufacturer.

## **References**

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