An Updated Evaluation of Various Predictors Suspected of Influencing Biosimilar Market Share in the U.S.

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OBJECTIVES

Biosimilar products, which are derived from an originator biological molecule, have had a significant impact on various therapeutic areas. Examining the impact of new biosimilar entrants on patient access is critical to understanding market share.

Biosimilars are typically priced lower than their originator products and aim to gain preferred placement on health plan formularies to increase market share. In response, originator manufacturers often use contracting strategies, including discounts and rebates, to defend their market position against biosimilar competition. Building on prior assessments of factors influencing biosimilar market share, this study expands the analysis by examining a broader range of biosimilar products.

METHODS

To evaluate the impact of predictor variables on individual biosimilar market share, an updated multivariate regression model developed in 2023 and refined in 2024 was again utilized. The analysis included 38 commercially available biosimilars and their 9 respective originators. Variables included aggregate biosimilar market share relative to each originator, number of biosimilar competitors, duration of biosimilar competition, WAC differentials to the originator, and payer management. An analysis of 15 health plans' formulary documents as of 12/1/24 was conducted to identify step therapy requirements for each product. Market share and model inputs were captured from FDA, NORD, IQVIA Biosimilar Report, Drugs.com, and other publicly available sources. The significance level was α=0.05.

RESULTS

The 5-variable model including all 38 products was statistically significant with an R^2 of 0.653 ($p<0.0001$). After adjusting for all variables in the model, all were statistically significant predictors of market share ($p<0.05$ for each) except for WAC differential to originator. The most determinative factor associated with aggregate biosimilar market share is payer management. A reduction of 5 plans with a step across the 15 plans measured would result in an increase in biosimilar market share of ~1%. The adjusted-R^2 for this model indicates that about 61.1% of the variability in biosimilar market share was accounted for by the combination of other predictor variables included.

Aggregate Biosimilar Market Share - ISPOR 2025 Model			
Model Type	**Variable**	**Parameter Value**	**P-Value**
Model Including All Biosimilars	WAC Price Differential Between Originator & Biosimilar(s)	0.287	0.784
	Duration of Biosimilar Competition (months)	0.002	0.020
	Number of Biosimilar(s)	-0.023	0.001
	Payer Management (step therapy in 15 plans)	-0.216	0.001

Table 1. Statistical output of a multivariate regression model from 2025

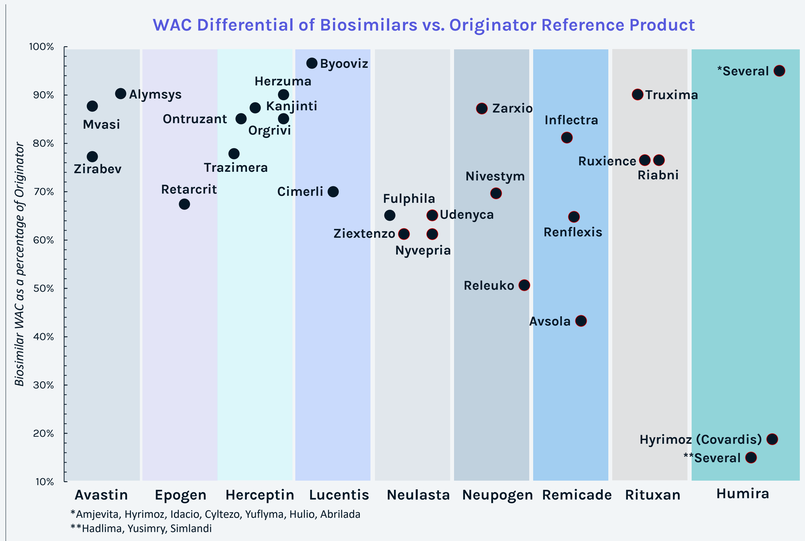

Figure 1. WAC differential of biosimilar vs. originator for individual biosimilar products

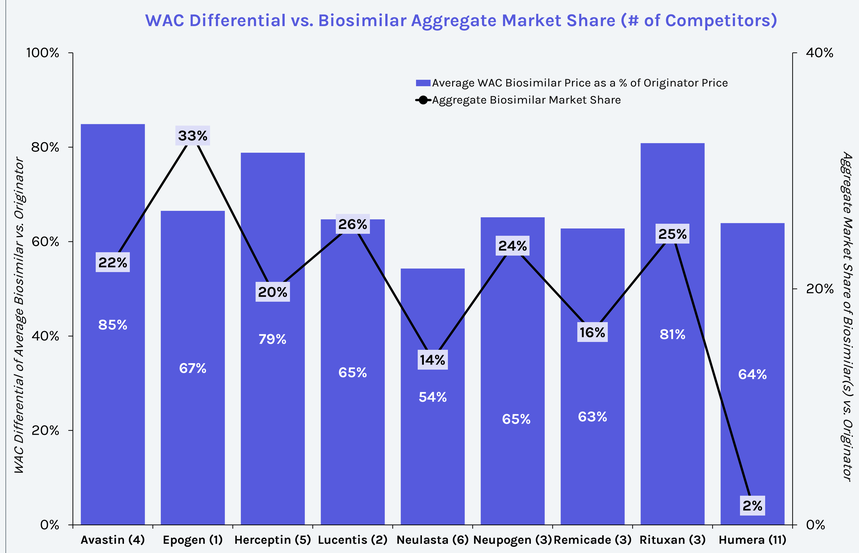

Figure 2. WAC differential by originator and the biosimilar aggregate market share

To further explore the responses, we eliminated the other predictor variables to isolate how payer management and number of biosimilars influenced the overall significance of the model. When WAC differential and number of biosimilar competitors are eliminated, the model achieved nominally increased significance ($p<0.0001$), but the R^2 and adjusted-R^2 marginally decreased (0.588 and 0.565, respectively). After confirming no significant correlation between all four independent variables, these findings underscore the accuracy of the full regression.

Output of ISPOR 2025 Model			
Model Type	**Variable**	**Parameter Estimates**	**P-Value**
Model Including All Biosimilars	Payer Management (out of 15 plans)	-0.005	<0.001
	Number of biosimilar competitors	-0.034	<0.001

Table 2. Statistical output of a multivariate regression model from 2025

CONCLUSIONS

Model findings were consistent with the previous year but showed improved fit, likely due to a larger sample size. The 2024 model found two isolated independent variables had higher individual R^2 values in comparison to the full regression. In 2025, the full 5 variable model has a higher R^2 than all isolated regressions and thus better explains biosimilar market share.

Consistent across all model years, WAC price is not statistically significant predictor of market share. This suggests that net prices likely differ considerably from list prices. Step therapy remains the crucial determinant of market share in the model. Net price is likely correlated with payer management except in circumstances where payers are willing to pay a premium for the originator to avoid switching costs.

Also consistent to previous models, longer cumulative duration of biosimilar competition and number of biosimilars did not materially affect market share, despite statistical significance. Potentially affecting the predictive power of the number of competitors, Humira retained the highest [originator] market share despite the most biosimilar competitors and largest WAC price differential.

FUTURE IMPLICATIONS

As more biosimilar products are commercialized, understanding the factors that influence aggregate market share is crucial for creating strategies to optimize commercial opportunities for a product expected to lose exclusivity. Given the typically lower cost of biosimilars, payers may seek to further limit originator use in favor of biosimilar alternatives. It will be important to monitor how biosimilar aggregate market share changes due to suspected price erosion following the originator's loss of exclusivity.

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