Capping Exclusivity for Biologics Could Save $20 Billion on Drug Spending

Biologics, large molecule drugs produced in living systems, have significantly improved treatment for many individuals with autoimmune diseases, macular degeneration, anemia, and cancer. However, biologics are driving a significant portion of drug spending in the United States; fewer than 2% of Americans use biologics, but biologics represent 40% of total drug spending.[1] Between 2013 and 2017, spending on biologics increased 56% ($76.9 billion to $120.1 billion).[2] Even though an approval pathway was established for biosimilars – lower-priced biologic alternatives to already approved "original" biologics – uptake has been limited. In 2017, biosimilars reflected less than 1% of the total biologic market.[3]

Drug exclusivity, which encompasses patent protections and regulatory exclusivity, shields original biologics from biosimilar competition and price decreases. Large volumes of patents that make it more tedious, costly, and risky for competitors to enter the market often allow many original biologics to maintain their monopoly for additional years past the 12 year regulatory exclusivity period.[4] The number of years many biologics control the market can keep prices high and drive increases in health care spending.

A $20 Billion Savings Opportunity

$ Savings could be achieved by:

- Capping **exclusivity for all original biologics at ten years**, regardless of the number and duration of patents.
- Establishing **a price discount for each biologic** after its exclusivity ends.

Giving all original biologics a ten year exclusivity window after the development and approval process would continue to incentivize innovation, while also establishing a guaranteed point in time when original biologic prices will decrease to a benchmark biosimilar rate. Biosimilars, on average, are priced at a discount of 27% of the original biologic.[a,5] Five original biologics that make up approximately 13% of Medicare Part B drug spending – Neulasta, Orencia, Avastin, Lucentis, and Aranesp – were analyzed to *illustrate* a portion of the potential savings from reforming exclusivity.[b] Under current law, each biologic studied is protected for an average of 14 years following its launch, however, most will likely face little, if any, competition for additional years to follow.

With ten years of exclusivity and an automatic 27% price discount on each of the five biologics, **Medicare Part B drug spending would decrease by $20.2 billion for the ten years following the end of each exclusivity period**.[c]

Ten Year Medicare Part B Savings for Five Biologics

Original Biologic	Baseline Spending	Spending After Exclusivity Cap	Savings
Neulasta	$ 15.6 B	$ 7.0 B	$ 8.6 B
Orencia	$ 12.2 B	$ 5.4 B	$ 6.8 B
Avastin	$ 11.0 B	$ 9.0 B	$ 2.0 B
Lucentis	$ 7.3 B	$ 5.4 B	$ 1.9 B
Aranesp	$ 2.5 B	$ 1.6 B	$ 0.9 B
TOTAL	**$ 48.6 Billion**	**$ 28.4 Billion**	**$ 20.2 Billion**

a A RAND review of estimates of biosimilar savings found that assumptions for biosimilar prices average 27% lower than original biologic prices.
b Only five drugs and their Medicare Part B spending were analyzed due to data availability, but more savings could be achieved across additional biologics.
c The modeled 27% price reduction represents immediate potential savings. Additional savings will be possible as competition intensifies.

Methodology and sources for citations are available at: **www.uhg.com/biologic-exclusivity-research**.

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