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

Methodology

The five biologics were selected for the savings analysis based on the following criteria:

- Medicare Part B biologic spending data are available for at least ten years between 2001 and 2017.
- The biologic appears in the data no earlier than 2001 and there is spending data for 2017.
- The biologic makes up a significant portion of Medicare Part B drug spending.

Medicare Part B drug data were used for this analysis because Part B drugs are the only type of drugs for which market-wide spending and volume data are available between 2000 to 2017. All savings are computed for the ten years following the ten-year exclusivity period for each drug.

Assumptions:

- Volume and spending in years beyond 2017 are projected based on each drug's observed compound annual growth rate between 2013 and 2017. To compute a more conservative estimate and take into account expected changes to Orencia's market share, Orencia's growth rate was changed from the computed 25% to 0% for projections between 2021 to 2025.
- Under the modeled policy, drug companies are guaranteed ten years of exclusivity after the launch of each drug. In the eleventh year and beyond they are subject to a discount.
    - A discount of 27% – the average percent a biosimilar price is lower than a branded biologic price – is applied to the average biologic price during the last year of exclusivity and the computed lower price serves as the maximum price for the years that follow. The drug-specific price ceilings are then multiplied by projected volume following the end of the exclusivity period. This approach represents the minimum savings for these drugs, assuming limited or no biosimilar competition. No additional discounts are incorporated for biologics with current or future biosimilar competition; there is too much uncertainty around market share or launch dates of biosimilars.
- Ten years of guaranteed exclusivity will be sufficient incentive for companies to continue to develop innovative therapies that force them to take on greater financial risk.
- All else stays equal, including the current patent system, market demand, and trend.

Citations

1 Congressional Research Service, "Biologics and Biosimilars: Background and Key Issues," Updated June 6, 2019. **https://fas.org/sgp/crs/misc/R44620.pdf**

2 IQVIA, "Medicine Use and Spending in the U.S.: A Review of 2017 and Outlook to 2022," April 2018. **https://www.iqvia.com/-/media/iqvia/pdfs/institute-reports/medicine-use-and-spending-in-the-us-a-review-of-2017-and-outlook-to-2022.pdf?_=1576021466660**

3 IQVIA, 2018.

4 Congressional Research Service, 2019.

5 Andrew W. Mulcahy, Jakub P. Hlávka, and Spencer R. Case, "Biosimilar Cost Savings in the United States," The RAND Corporation, 2017. **https://www.rand.org/content/dam/rand/pubs/perspectives/PE200/PE264/RAND_PE264.pdf**

The brief is available at: **www.uhg.com/biologic-exclusivity-research**.