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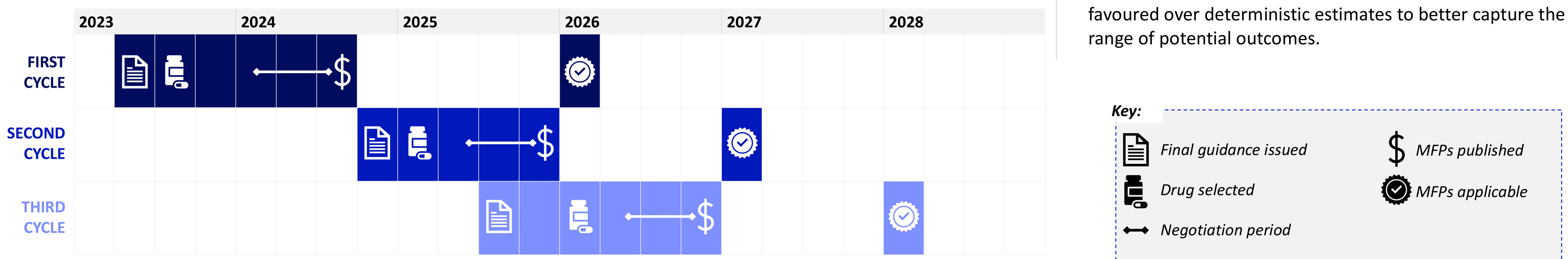
## BACKGROUND

Since 2023, the Centers for Medicare & Medicaid Services (CMS) has conducted two cycles of Medicare Maximum Fair Price (MFP) negotiations (Figure 1), covering 25 drugs in total.<sup>1</sup>

Following publication of the first cycle MFPs in August 2024<sup>1</sup>, we assessed the relationship between publicly available pricing benchmarks and negotiated outcomes. The analysis identified two key predictors: Wholesale Acquisition Cost (WAC) and the lowest Federal Supply Schedule (FSS)/Big Four price, which formed the basis of a predictive model for future MFPs.

The publication of second cycle MFPs in November 2025 expanded the evidence base, enabling refinement of model performance and exploration of emerging pricing drivers under the new administration.<sup>1</sup> The subsequent selection of 15 drugs for the third negotiation cycle in January 2026 provided an opportunity to apply the updated model prospectively.<sup>1</sup>

Figure 1: Medicare negotiation timeline<sup>1</sup>



## OBJECTIVES

- Refine the predictive model using combined first and second cycle MFP outcomes
- Assess the robustness of WAC and lowest FSS/Big Four price as key pricing drivers
- Explore emerging determinants of MFP, including Most Favoured Nation (MFN)-aligned international reference pricing benchmarks
- Apply the updated model to predict third cycle MFPs (Initial Price Applicability Year [IPAY] 2028)

## METHODS

A series of regression analyses were conducted to evaluate the relationship between publicly available pricing variables and published MFPs across the first and second negotiation cycles (n=25).

In addition to 2023/24 WAC and 2023/24 FSS/Big Four prices<sup>2</sup>, three additional candidate variables were explored for inclusion:

- 2023/24 Medicare Part D total spending<sup>3</sup>
- 2023/24 Average price across MFN reference basket
- 2023/24 Lowest price within MFN reference basket

Price data from 2023 were used for first cycle drugs and 2024 for second cycle drugs, reflecting data availability at the time of CMS negotiations. Model inputs for third cycle predictions used 2025 price data.

To account for uncertainty in pricing inputs and inherent variability in list pricing and policy discretion, Monte Carlo simulations were conducted. This probabilistic approach was favoured over deterministic estimates to better capture the range of potential outcomes.

## RESULTS

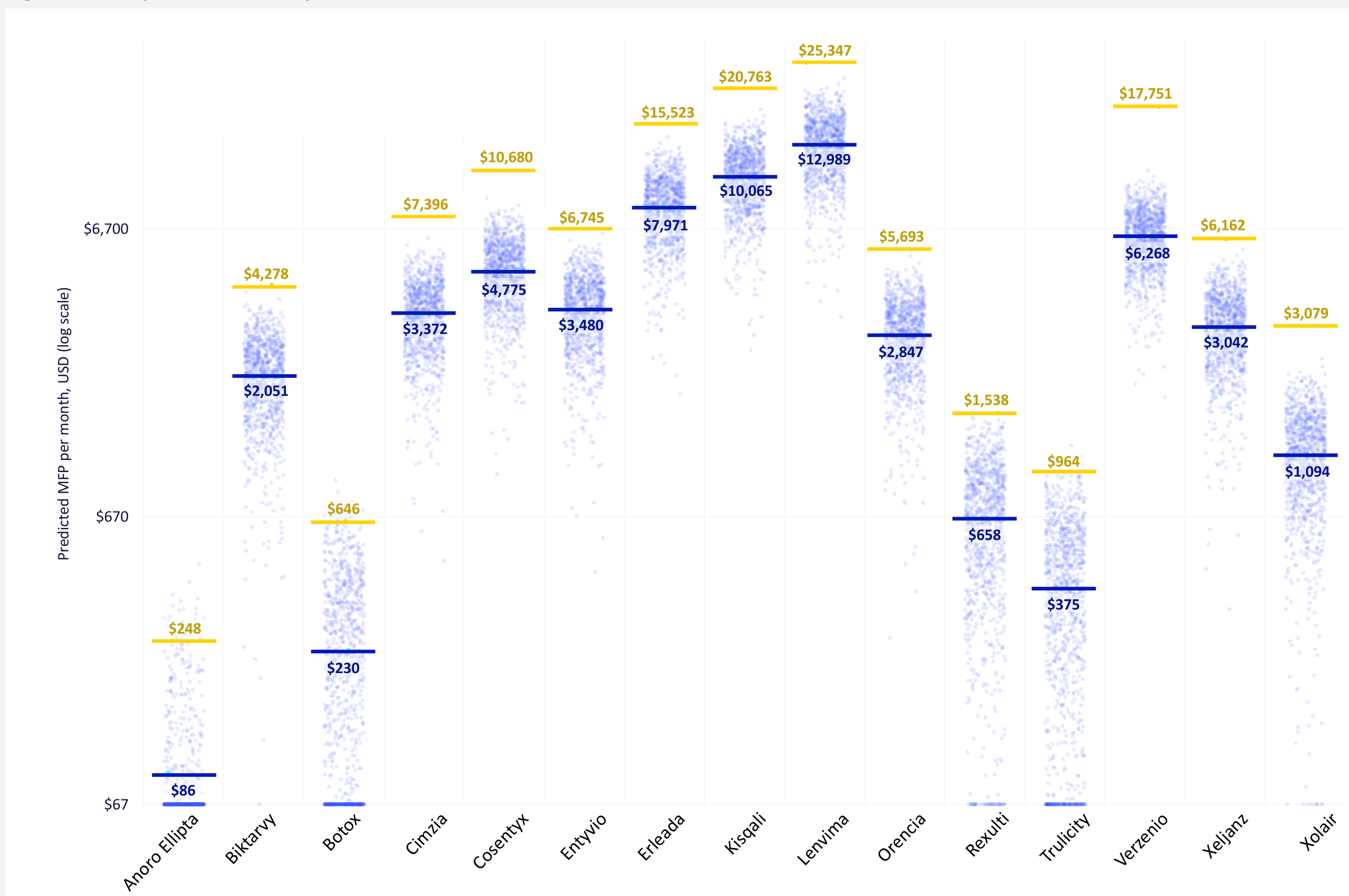
### Model refinement and robustness of key pricing drivers

- The updated regression model, incorporating combined first- and second-cycle data, explained **97% of the variance in MFP outcomes** ( $R^2=0.97$ ). **WAC** ( $p<0.0001$ ) and **lowest FSS/Big Four price** ( $p<0.001$ ) remained strong, stable predictors across both negotiation cycles
- Three additional variables were evaluated for incremental predictive value:
  - **Medicare Part D total spending** ( $p=0.8$ ) and **average MFN basket price** ( $p=0.3$ ) showed no meaningful association with MFP outcomes
  - **Lowest MFN basket price** ( $p=0.09$ ) showed a positive directional relationship, indicating borderline statistical significance at the 10% level and suggesting emerging relevance as a pricing anchor

### MFP predictions for third cycle drugs

Applying the two-variable model, the predictions suggest a mean MFP **56% below** than 2025 WAC and **8% below** the 2025 lowest FSS/Big 4 price (Figure 2)

Figure 2: MFP predictions – outputs from the Monte Carlo simulation\*



\*Note that a price floor of \$67 was applied, equivalent to the lowest price observed across all model input variables in the regression dataset

### Lowest MFN basket price as an MFP driver

- To assess the influence of the **lowest MFN basket price** on predictions, a sensitivity analysis was conducted comparing the **two-variable model** with a **three-variable model** incorporating this additional variable
- Predictions were **broadly consistent** across both models, with outputs closely aligned across most drugs (Figure 3)
- The three-variable model predicted MFPs that were on average **4.8% lower**, suggesting that the lowest MFN basket price may exert a directional influence on MFP outcomes that warrants further investigation

Figure 3: Two-variable vs. three-variable model sensitivity analysis



## CONCLUSIONS

Combining outcomes from both negotiation cycles confirms WAC and FSS/Big Four prices remain robust, stable predictors of MFP. The refined model offers a practical, evidence-based tool to anticipate MFPs in the third and future cycles.

The lowest MFN basket price shows early signals of influence and warrants re-evaluation as additional data emerge and MFN-aligned policies continue to evolve, potentially strengthening its role as a pricing anchor.

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### References

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