



## SUMMARY

- In August 2022, President Biden signed the Inflation Reduction Act (IRA) into law with provisions to improve Medicare through pharmaceutical cost containment measures
- Although the IRA may continue to evolve through rounds of amendments in the coming years, it is likely to lead to significant drug launch price increases and impact pharmaceutical research and development, as manufacturers compensate for reduced long-term revenue potential by focusing on disease areas with limited Medicare exposure

## INTRODUCTION AND OBJECTIVES

- The Inflation Reduction Act (IRA) seeks to limit Medicare spending and patient out of pocket costs. Key provisions include:
  - Top selling Medicare drugs will be eligible for mandatory negotiations if single-source and on market for 9+ years (NDA) or 13+ years (BLA)
  - Once a Medicare beneficiary's annual out of pocket spending exceeds \$2,000 branded drugs will be funded 20% by Medicare, 60% by the health plan, and 20% by the drug manufacturer, and generic will be funded 40% by Medicare and 60% by insurance plans
  - Manufacturers receive penalty rebates if therapy prices are increased at a steeper rate than inflation
- However, the indirect effects of the IRA remain unclear. This policy analysis aims to understand how the Inflation Reduction Act will impact pharmaceutical research and development investment. Specifically, we sought to understand key shifts in investment between categories of therapies (i.e., small molecule vs. biologic), and understand if there are types of therapies that are well insulated to withstand revenue-pressures from the IRA

## METHODS

- The potential research and development impact was assessed based on the key three points of the Inflation Reduction Act regulating biopharma: 1) Medicare Part D \$2,000 out of pocket (OOP) cap, 2) price increase penalties, and 3) minimum price discounts/negotiations

## RESULTS

- We find that the reduced Part D out-of-pocket limit (Figure 1) is expected to result in higher launch prices as manufacturers seek to mitigate the reduced long-term revenue potential, thus warranting greater research and development investment
  - The capped out of pocket costs for Medicare beneficiaries as well as the extended funding of premium subsidies will allow for patients to have lower barriers to access health services that otherwise contain large financial burdens, which, as a result, may incentivize manufacturers to invest in research and development, as there is a guarantee of funding for more costly treatments
- Revenue impact is greater for products that will lose revenue due to reduced market exclusivity time, whereas products with expected long-term competition will lose revenue regardless of exclusivity period length due to decreased sales volume when other products enter the market, likely before the anticipated loss of exclusivity date
- The impact of the Inflation Reduction Act on research and development will vary across products (Figure 3). While for most products the research and development impact may be positive due to the Part D out-of-pocket cap and resulting higher launch prices, the impact will be negative for assets with limited long-term competition expected
- Inflation-based penalties are unlikely to have significant impact on research and development given year-over-year increases seldom exceed inflation

Figure 1 | Part D Out-of-Pocket Cost-Sharing Breakdown, Starting in 2025

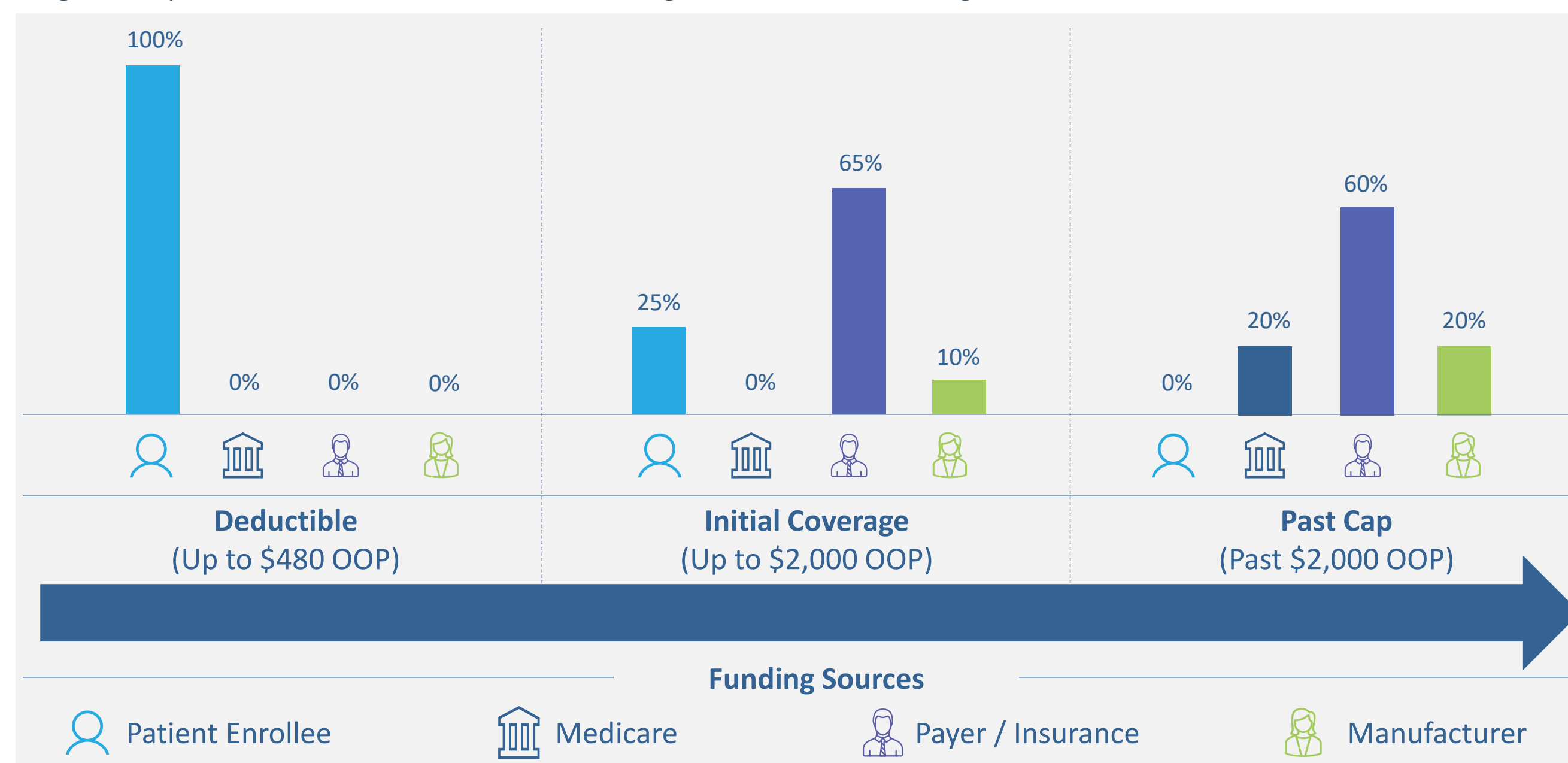
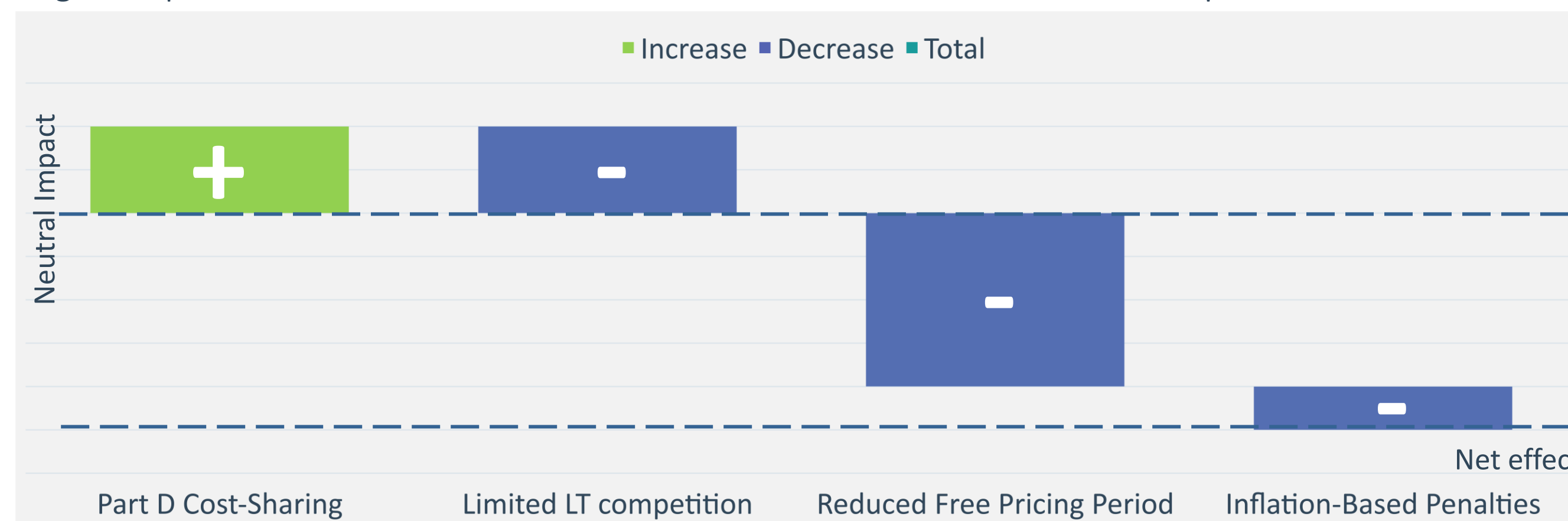


Figure 2 | Timeline of Medicare Negotiation Implementation



Figure 3 | Cumulative Effect of the Inflation Reduction Act on Research and Development Investment



## DISCUSSION & CONCLUSION

- Although many aspects of the IRA will be inflationary on biopharma prices, which could stimulate R&D, the curbing of any long-term pricing upside balances this effect
- IRA price negotiation rules incentivize research and development in therapies treating conditions with limited Medicare exposure and low cost of goods sold
- Long-term forecasting and investment must consider the impact of the Inflation Reduction Act on the Medicare and commercial markets, as many of the top selling Medicare drugs today will be at or near their loss of exclusivity date by the time discounts take hold (Figure 2). Forecasts for future blockbusters will need to account for new price pressure leading up to the loss of exclusivity (LoE) date
- The Inflation Reduction Act is certain to be challenged in court, and the development of the legislation can be expected to impact future trends in biopharmaceutical investment in research and development
- A key uncertainty is if and how payers will react to higher launch prices with stricter access restrictions, further impacting profitability and, indirectly, research and development

## REFERENCES

- Medicare Drug Price Negotiation Program: Initial Memorandum, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026, and Solicitation of Comments.