



# Reexamine the effect of the Inflation Reduction Act



## Has your real-world data and evidence-generation strategy helped or hindered your response to health-care related Inflation Reduction Act policies?

The Inflation Reduction Act (IRA) profoundly impacted the life sciences industry – prompting companies to reevaluate their pipeline therapies and investment strategies. As the initial implementation stages of the IRA are now underway, the Medicare price negotiation program is drawing significant attention.

In the fall of 2023, the Centers for Medicare & Medicaid Services (CMS) selected 10 Part D medications for price negotiations; the new prices will take effect in 2026. CMS will select 15 additional medications in 2025 and 2026 and will increase its selection to 20 medications each year from both Medicare Part D and B, starting in 2027. While CMS is setting the terms for negotiation, real-world data (RWD) and evidence give you the opportunity to take greater control of the value narrative across the whole product lifecycle.

To prepare for the price negotiation program, consider how your organization will answer the following questions:

- What insights do you need about the demographic that will soon be eligible for Medicare?
- What gaps must you address, or what evidence must you strengthen, to approach negotiations with a comprehensive understanding of your market and a robust case for value, safety and comparative effectiveness?
- How can you apply RWD to share the impact of your products in real-world clinical practice and further validate your clinical trial results?
- How can you more effectively present your case to payers, pharmacy benefit managers and employers to secure formulary inclusion and establish appropriate access guidelines?
- How can you ensure that leaders in your organization recognize and value the data and analytical infrastructure required to support your evidence-generation efforts?



Incorporate one of the largest Medicare Advantage populations in your analyses for wider reach and broader study generalizability.

With medical and pharmacy claims sourced from a large national Medicare Advantage (MA) payer, Optum® provides data specific to the Medicare population for more meaningful analyses on the costs and outcomes associated with your product.

**16.1M** Medicare Advantage with Part D lives in our claims data set of more than 84 million unique patient lives

**17+** Years of longitudinal patient data for better visibility into the patient journey

**100%** Closed claims system, containing all claims for a given eligibility period, for greater coverage of patient care

## Maximize product value in price negotiations with data

Strengthening your evidence is essential when entering price negotiations. How you modernize these discussions is particularly important for products that have been on the market for years. Relying solely on clinical trial data from 10–15 years ago no longer provides the full picture.

High-quality, foundational patient data form the backbone of all evidence-generation studies. By using RWD, you can present a more updated snapshot of your product that includes current usage patterns and health outcomes. Accessing source data from Optum can help construct a compelling argument for a price that most accurately reflects your product's value.

### Consider this two-pronged approach:

- 1 Conduct comparative effectiveness, outcomes-focused, unmet need and/or other health economics and outcomes research (HEOR) studies to build a case and demonstrate to CMS why your product's price is fair and justified.
- 2 Once the negotiation process is complete: acknowledge the price outcome from CMS, then pivot your strategy as needed. Ask yourself:
  - How can you gain market share in other areas to offset any potential financial losses? Do you invest more in a specific disease area, pursue a different indication or formulation for an existing product, etc.?
  - How should you prepare to position the rest of your portfolio?
  - Do you need to make any changes to your pipeline priorities? Who should be involved in these decisions, and what evidence should support these strategic choices?
  - How do you continue innovating and keeping shareholders satisfied?



### Connect with us today

Learn more about our real-world data and evidence generation solutions at [optum.com/life-sciences](https://optum.com/life-sciences).

# Optum



### More than just data: services to support your efforts

Your researchers aren't alone. Our data scientists and analytics staff are here to help you navigate our RWD and get the most out of your investments.

Partner with our dedicated researchers for additional support, including literature reviews, economic modeling, gap analysis of your IRA dossier and identification of data and study types that can help strengthen your value story.

- ✓ Health economics and outcomes research
- ✓ Value-based arrangements and financial modeling
- ✓ Epidemiology and post-approval safety studies
- ✓ Commercial analytics and market access