Inflation Reduction Act: Assessment of Impact on Oncology Therapies

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Introduction

On August 16, 2022, Congress passed the Inflation Reduction Act (IRA). The landmark law contains significant reforms to the federal reimbursement of pharmaceutical products in the United States, where drug prices have long been significantly higher than in other developed nations. For the first time, the IRA grants the Centers for Medicare & Medicaid Services (CMS) the authority to negotiate drug prices directly with manufacturers, who must pay an excise tax on drugs if they do not comply with the regulations. The IRA also limits drug price increases and shifts the cost burden of high-expenditure Medicare Part D drugs to manufacturers and payers instead of the government (See Table 1).

Beyond the effects on individual drugs, the IRA will strongly influence manufacturer portfolio management decisions. Most notably, it favors biologics over small molecules. Biologics are subject to negotiations after 13 years on the market compared to 9 years on the market for small molecules. Launch sequencing will likely also be impacted. The common strategy of launching oncology drugs in smaller or later line indications while trials to support earlier line use are conducted is no longer optimal because the negotiation clock starts ticking upon launch.

Objectives

The aim of this study is to understand how the behaviors of key stakeholders will likely change in order to navigate the new and evolving landscape in a post-IRA era. Additionally, the study evaluates situations that oncology manufacturers may face and provides recommendations on how manufacturers could adapt or adjust their market access strategies.

Methods

Through secondary research and primary research with key stakeholders, we analyzed the new policy changes and interpreted the evolving market access landscape to identify implications for pricing and reimbursement in the US. Secondary research included analyst reports, company commentary, financial reports and news releases. Qualitative research with subject matter experts was performed to understand the unique challenges presented by the IRA and potential stakeholder responses. Interviewees included experts from manufacturers, law firms specializing in health policy and former payers.

Results

Our research evaluated potential impact of the IRA on oncology manufacturers across three potential scenarios:

Scenario 1: Manufacturer's Own Product Selected for Price Negotiation

The likelihood of negotiation rises over time. Ten high-expenditure Part D drugs will face a reduced "negotiated" price from Medicare in 2026, rising to 20 Part B and D drugs in 2028 and thereafter (See Figure 1). The IRA mandates a minimum cut of 25% to selected drugs' non-federal average manufacturer price if they have been on the market less than 12 years, a 35% cut for those on the market 12-16 years, and a 60% cut after more than 16 years on the market.

CMS cannot accept a price higher than the ceiling price established by the aforementioned discounts, and it may seek larger concessions. The scope for manufacturer counteroffers varies based on the agency's methodology for arriving at its initial offer (See Table 2). Most notably, there is potential to engage CMS on its choice of therapeutic alternatives if the agency makes an aggressive offer using reference-based pricing. CMS may adjust its offer based on the price of therapeutic comparators if the negotiated product offers a relatively superior or inferior clinical benefit, so there is scope to challenge the agency's clinical justification and sources of evidence.

Manufacturers can prepare for negotiations in advance by ensuring their medications meet unmet needs and are well supported by comparative effectiveness studies and real-world data in the Medicare patient population. However, unlike certain European markets, CMS cannot use evidence that treats extending the life of people from certain populations (elderly, disabled, terminally ill) as of lower value than others. This includes certain uses of Quality-Adjusted Life Years, a common metric that is valued by international HTA agencies. It is unclear how often CMS will attempt to obtain a price below the ceiling price, but reference-based pricing is likely to be deployed to justify large price cuts in situations where the therapeutic alternative(s) are perceived as clinically equivalent and considerably cheaper than the selected drug.

Scenario 2: Competitor Product Selected for Price Negotiation

Competitors of negotiated drugs may face pressure from private payers to match the net price that CMS obtains for negotiated drugs. To combat this, manufacturers need to show their products are differentiated from the negotiated products. Once again, the need for strong evidence to support comparative effectiveness claims is paramount. However, payers may be constrained in their ability to prefer products in protected classes, such as oncology. They may also be wary of restricting access to new medications in a manner that reduces patient/provider choice and competition levels within the pharmaceutical industry.

Still, the bar for developing second or third or fourth to market drugs is likely to rise. Unless clearly differentiated from the standard of care, they may face the specter of large discounts soon after launch in order to maintain coverage and access, particularly if competing in a negotiated drug class.

Scenario 3: Shifting Incentives in Combination Therapy Prescription

The IRA may result in unintended consequences for combination therapies that utilize drugs across both Medicare Part B and Part D. Specifically, the redesign of the Medicare Part D program includes shifting cost sharing responsibilities, increased access to benefits and subsidies, a lower out-of-pocket (OOP) cap, as well as a co-pay smoothing option for beneficiaries as means to improving patient affordability of necessary therapies.

The improved patient affordability of Part D drugs following the Part D redesign could drive providers to develop prescribing preferences for Part D products over Part B products with higher OOP costs and potentially higher abandonment rates. However, if payers start deploying utilization management tactics due to increasing Part D product uptake, providers may respond by preferring less managed, Part B products. The future impact on combination therapies remains uncertain, so key stakeholders in the pharmaceutical industry should engage with CMS directly by providing comments around the potential complications facing combination therapies spanning both Medicare benefits.

Table 1: Impact of the IRA on Key Selected Stakeholders by Provision

Provision	Pharmaceutical Industry	Payers	Providers
Medicare Drug Price Negotiation	Lower Medicare Drug Prices Shifting R&D (and M&A) Priorities	Increased Leverage	Lower Reimbursement of Negotiated Part B Drugs
Inflation Rebates	Hampers Ability to Take Price Increases May Results in Higher Launch Prices	Lower Price Increases	No Significant Impact
Part D Redesign	Potential Positive Impact: Improved Patient Affordability and Less Rx Abandonment Potential Negative Impact: Manufacturer Responsibility for Cost Share in Catastrophic Phase	Cost Sharing in Catastrophic Phase Cap on Premium Increases	Improved Patient Affordability

KEY: Potential Positive Impact on Stakeholder | Neutral or Unclear Impact on Stakeholder | Potential Negative Impact in Stakeholder

Conclusion

The IRA brings profound changes to the pharmaceutical industry in the US, as well as globally, as it fundamentally impacts pharmaceutical research, development, and commercialization activities. In the new world of the IRA, manufacturers should start planning and acting differently. More specifically, manufacturers should understand the type of evidence and thresholds needed to convince payers of meaningful superiority to their competitors at launch, particularly in a negotiated drug class. In the launch phase, communicating the value story effectively and the impact of the product's clinical differentiation more concretely will be critical. Lastly, manufacturers should plan proactively by designing evidence-driven market access strategies that take into account the potential impact of IRA on stakeholders within the healthcare value chain.

Figure 1: Medicare High-expenditure Oncology Products in 2020

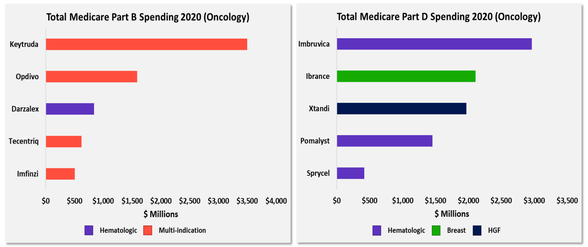

Table 2: CMS Negotiation Approaches and Potential for Counteroffers

	Ceiling Price	Lowest Federal Price	Reference-based Pricing
Description	Minimum mandatory cut, as stated in the IRA (25%, rising to 60%)	Lowest price paid by four federal agencies	CMS offer based on comparative effectiveness and price of the therapeutic alternatives
Scenario	Default price if CMS does not push for a larger concession	If no therapeutic alternatives and an agency pays less than the ceiling price	May be deployed to aggressively lower prices in competitive TAs
Scope for Counteroffer	None	Minimal	Significant

References

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