

Drug Provisions in the Inflation Reduction Act (IRA): A Critical Consideration for All Therapeutics and Channels

Pricing and market access stakeholders have increasingly been tasked with a dynamic equation of market, product, and regional factors that influence pricing and contracting decisions (see examples below). These decisions can be the most critical among an organization's commercialization efforts, but are often made in a vacuum without consideration for other elements that inform access and rebating for target patients.

The passage of the Inflation Reduction Act (IRA) and its associated Drug Provisions have added to that complexity for pricing and market access professionals in the pharmaceutical and biotech industries. We at Triangle Insights by Valeris, believe that every product, regardless of channel distribution, requires a clear strategy to integrate the IRA provisions into their pricing approach, as well as subsequent pull-through to execution. Further, the IRA and evolving policy and access provisions should be considered beyond the traditional pricing and access stakeholders in a fully-integrated and comprehensive market access strategy when approaching launch.

For instance, it is obvious that companies anticipating substantial Medicare utilization for their product(s) must develop a clear strategy to craft a list price that will optimize revenue potential in the face of inflationary penalties (based on ASP in Part B, and AMP for Part D). Less recognized, however, is that companies with meaningful Commercial and Medicare channel utilization may consider the differential in AMPs and in rebating strategies between the channels to blunt the possible penalties incurred due to price increases over CPI-U and the maximum fair price (MFP) that results from negotiations.

As companies consider the implications of the IRA in their launch strategy, it will be important to establish a holistic perspective that optimizes for policy considerations and patient access to establish a multi-channel pricing and access approach. For example, the increase in commercial channel specialty carve-outs alongside "base-case" patient / HUB services are important considerations with implications across channels. Further, active CMMI policy proposals, such as the Accelerating Clinical Evidence Model, create possible opportunities for differential pricing not just based on the approval pathway, but by indication as well. Taken together, these sample considerations highlight the need for holistic, strategic decision-making across the entire organization to optimize access and rebating approaches that drive overall revenue and brand strategy.

Contact Triangle Insights Group and Valeris to leverage our cross-functional team and unique end-to-end market access perspectives to strategize the pricing approach, inform the design (patient services, contracting), and pull through the implications into execution to optimize pricing, market access, and downstream fulfillment. Our team is well-equipped to navigate the core market access considerations (including IRA) and to pull through the strategic implications into an optimized and differentiated pricing strategy and program for your patients.

Key Factors for Pricing and Contracting Decision-Making

Recent legislative changes (e.g., IRA) and CMMI initiatives (e.g., Accelerating Clinical Evidence Model) are anticipated to increase the challenges associated with pricing and contracting, requiring a greater understanding of the following (sample, not exhaustive):

- Clinical Profile vs. Unmet Need
- Book of Business / Channel Distribution
- Patient Population (size, severity, out-of-pocket sensitivity)
- Competitive Intensity

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