Market access

US inflation reduction act: pipeline considerations

A risk exposure framework for drug developers

The US Inflation Reduction Act (IRA) represents the most significant reform to US healthcare access since the Affordable Care Act (2010). It aims to provide financial relief, lower drug costs for seniors and strengthen Medicare.

These changes to the US market access landscape, specifically the ability for Medicare to negotiate drug prices, have widespread impact on drug manufacturers' revenues and pipeline ROI. Mitigating risk is key and can only be achieved through an in-depth understanding of the new regulations and their complex nuances.

Anticipating and planning for a competitive advantage

Our expert team developed a framework to analyze pipeline assets for IRA risk exposure, using five criteria to assess asset-level risk, prioritize investments, and forecast overall pipeline risk and revenue potential.

Criteria	Relevance for IRA risk	Weighting
Medicare patient population	Risk if product targets patients over 65, leading to significant Medicare spend and price negotiation eligibility.	30%
Small molecule/pill penalty risk	Risk if product is a small molecule, which becomes eligible for maximum fair price (MFP) price negotiations 4 years sooner than biologics.	30%
Disease area/ landscape risk	Risk if product is in a competitive area with high innovation, preventing dominance and hitting spend thresholds.	15%
Value differentiation risk	Risk if product lacks strong value differentiation during CMS price negotiations.	15%
Multiple indication strategy risk	Risk if product relies on multiple indications, reducing time for revenue generation and commercial value.	10%

We tested the framework with five hypothetical product profiles, assessing IRA-related risk using the criteria and weighted scores to guide investment decisions and risk-mitigation strategies.

Product profile 1	
Description	An oral orphan drug used to treat a rare disease that primarily affects patients over the age of 65. First-in-class treatment for single indication with no comparable therapeutic on the market.
IRA Risk	• High risk due to Medicare spend, small molecule penalty and low-innovation of disease area • Orphan drug exemption
Weighted risk score	• 4.0 (exempt as orphan drug)
Recommendations	• Maintain single indication to keep orphan drug exemption

Product profile 2	
Description	An oral treatment for a disease affecting a small patient population, mostly > 65 years. A few competitors are on the market, but this treatment demonstrates superior efficacy.
IRA Risk	• High risk due to Medicare spend, small molecule penalty and therapeutic landscape • Neutral risk for value differentiation due to superior efficacy
Weighted risk score	• 4.3
Recommendations	• Focus on value differentiation; develop a strong evidence generation plan • Identify the value proposition for clinical and payer stakeholders to support MFP negotiations
Product profile 3	
Description	An infused treatment in a large disease area, with average age of patient >35 years. In a crowded market, this product provides slight, but non-inferior improvements over standard of care.
IRA Risk	• High risk due to low value differentiation • Low risk due to Medicare spend, biologic status and therapeutic landscape
Weighted risk score	• 2.0
Recommendations	• Not at risk from Medicare price negotiations under IRA. Proceed with development as planned
Product profile 4	
Description	An oral treatment for a large disease that also has a high proportion of patients > 65 years. The product is entering a crowded market with minimal differentiation and affordable generics readily available.
IRA Risk	• High risk due to Medicare spend, small molecule penalty and low value differentiation • Neutral risk due to multiple indication strategy • Low risk for therapeutic landscape
Weighted risk score	• 4.2
Recommendations	• Engage early with clinical and patient experts to identify unmet needs and generate evidence to demonstrate value • Conduct payer research to gather key economic evidence (such as cost offsets) during clinical development or through real-world evidence (RWE) • Target subpopulations where Profile #4 exhibits differential value, to mitigate the impact of the large Medicare patient population • Develop a robust RWE strategy to leverage if selected for maximum fair price (MFP) negotiations
Product profile 5	
Description	An oral oncology treatment for cancer patients > 65 years. The product offers slight improvement over the limited in-market treatment options. Several products are in pipeline to address the current unmet need.
IRA Risk	• High risk due to Medicare spend, small molecule penalty, low value differentiation and multiple indication strategy • Low risk due to therapeutic landscape
Weighted risk score	• 4.4
Recommendations	• Identify the optimal patient population • Develop robust evidence, including real-world data, to demonstrate strong value differentiation in the chosen patient population and key subgroups

Partner with us to minimize access challenges and maximize product success

Through in-depth understanding of the IRA, early strategic planning and ongoing communication with regulators, we provide insights to drive critical decisions and generate the complete evidence solution that will move your product forward, successfully.

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