HPR83

The Price Is Right or Is It?

Navigating the Inflation Reduction Act (IRA) with Payer Perspectives on Evidence Needs, Fair Market Pricing and Patient Access Implications

Chad Patel, PharmD, Susan Hogue, PharmD, MPH, Denise A Garner, PharmD, Phoenix J Riley , PharmD, MSc, Cristina Masseria, PhD, MSc
AESARA Inc., Chapel Hill, NC USA

CONTACT US

BACKGROUND

In the evolving healthcare landscape, manufacturers must swiftly adapt to Inflation Reduction Act (IRA)-related changes1, including R&D cost considerations.

Understanding how data aligns with IRA requirements, including clinical benefits, unmet needs, patient impacts, and supply-based considerations, is crucial for manufacturers to navigate this dynamic healthcare environment effectively.

OBJECTIVES

To gather payer and policymaker insights to help shape evidence gaps and prioritization for products that meet the requirements for CMS negotiation, as per the Inflation Reduction Act (IRA). To understand how risk will be divested and what the pricing and patient access implications will be given the new legislation.

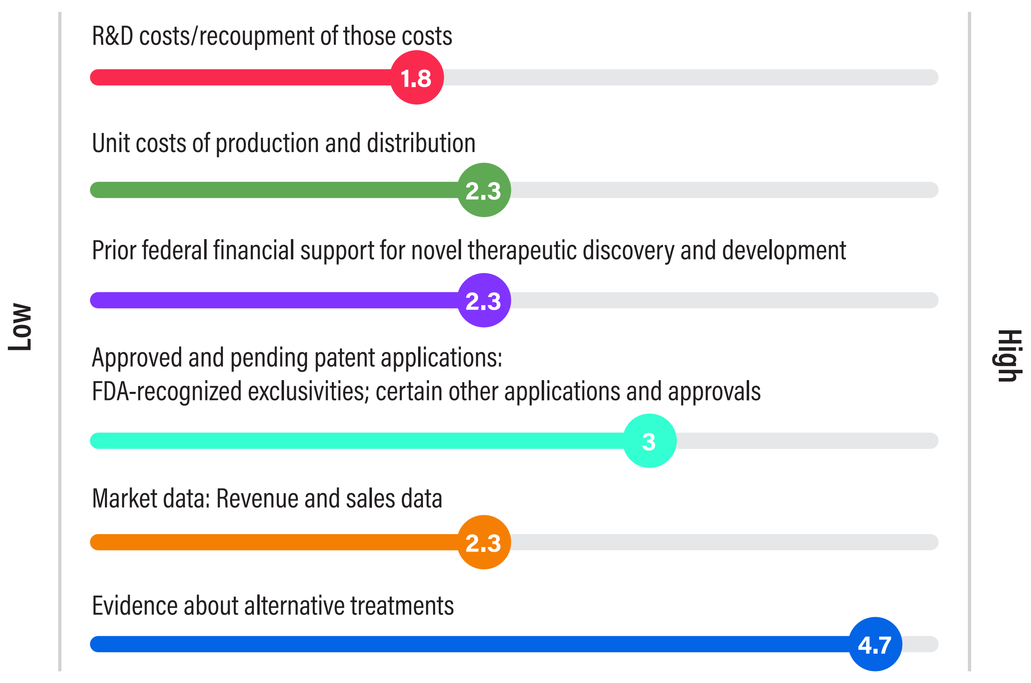
MATERIALS & METHODS

Conduct a mixed-methods approach (e.g., qualitative and quantitative questions) to evaluate access, value, and pricing implications because of IRA from two groups: US payer, and policymakers, and European HTA payer advisors (n=12).

The research focused on 1) Evidence requirements from manufacturers on key data elements as part of negotiation process 2) Payer considerations on cost and patient access implications. Payers rated the key data elements required from manufacturers on a priority scale from (1-low to 7-high) for elements that could be considered for negotiation.

RESULTS

Advisors were polled to rank On a scale of 1 to 7 (1 being lower quality & priority and 7 being higher quality & priority) please rate the value of each of these data elements and types of evidence generation and communication for future decision-making during IRA negotiations?



Findings showed CER focused on existing therapeutic alternatives and in specific (e.g., CMS-Medicare) populations were given the highest priority ranking; unmet needs also ranked as a high priority. Advisors shared the highest quality data element would be comparative effectiveness, how a product addresses unmet need, and how a product differentiates from standard of care therapies are critical needs.

Additionally, the submission of real-world evidence will help determine maximum fair price (MFP) and allow product differentiation. Advisors noted that skepticism will likely exist with RWE however it is still important that manufacturers submit it.

> "When you participate in mock exercises, you see that RWD is going to be important as launch trials occurred many years in the past. There may not be H2H trials against the appropriate comparator, therefore choice of comparator is extremely important for price and clinical evidence."

CONSIDERATIONS

EVIDENCE CONSIDERATIONS

1. The importance of safety and efficacy differentiation will be core components in drug pricing negotiations. Advisors shared that CMS is sensitive to safety considerations, and this can influence their decisions.
2. Additionally, CMS will focus on clinical guidelines which may include generics, brands, and off-label products if SoC includes both types of products. Advisors recommended to consider extracting savings, establishing value for costs, and total cost of care.
3. Important to present information in a very succinct way to differentiate your product, whether it be in safety, efficacy, adherence, etc.

MANUFACTURER CONSIDERATIONS

1. Publish in credible, high-quality peer-reviewed journals and how this evidence fits into clinical guidelines.
2. Generate data in specific populations where their product is different
   a. Safety differences (e.g., bleed rates) that translate to lower costs of care
3. Focus on clinical meaningful differences and impact to total costs of care
   a. Entresto reduced hospitalizations and lowered total cost of care
   b. Improvement in patient-related outcomes may not be as impactful (e.g. less lesions in plaque psoriasis)

> "In scenarios, company present their case, what they don't tend to do is acknowledge the counterarguments and address them well. The key here is communicating it effectively. Word limits are a restraint, but it's a good opportunity to create good top line summaries."
>
> Senior Policy Maker

PLAN CONSIDERATIONS

Payer advisors stated plans are currently working on the following strategies:

1. Engaging cross-functionally including with pharmacy, actuaries, finance, etc. to mitigate risk and develop prevention strategies.
2. Analyzing what categories will become much leaner.
3. Observing the spillover effects in commercial plans where some manufacturers are already offering 60-80% discounts.
4. Divesting risk by potentially creating more formulary restrictions.
5. Watching competitor plans to ensure they are properly tracking risk.
6. Advisors noted future implications of new legislation could lead to reduction in Medicare Part D plans given the potential for lower margins and less profits in certain markets which would provide less insurance choices for patients.

CONCLUSIONS

Our research findings identified key evidence areas for manufacturers to immediately restructure data requirements to include highest priority data elements and to be able to synthesize and communicate these evidence packages to maximize successful submissions as part of IRA negotiations. Manufacturers are advised to focus on data validation, comparative effectiveness, safety, and efficacy differentiation, and consider the nuances of different therapeutic areas like oncology. The participants acknowledge that the process may evolve over time, and rigorous data presentation is key to success in these negotiations. These research findings underscore the complexity of the pharmaceutical pricing landscape, with an emphasis on risk management, data quality, and differentiation as crucial elements for success in negotiations with CMS and other stakeholders.

Future Direction and Next Steps

1. Success in CMS and drug manufacturer negotiations relies on innovative strategies and a robust evidence package, including publications, real-world data, and comparators, to substantiate a drug's value.
2. Effective communication of the evidence will be critical given the word limits of the evidence package submissions to demonstrate meaningful differentiation.
3. Negotiations under IRA will entail a significant increase in liability, requiring an actuarial approach. Organizations are seeking cost-cutting measures, margin protection, and potential formulary restrictions to mitigate risk while monitoring competitor plans.
4. Companies need a versatile approach involving standardized framework on the implication of IRA across the drug portfolio, effective real-world evidence utilization and generate differentiation versus appropriate comparators for success in future Medicare drug program negotiations.

REFERENCES

1. Medicare Drug Price Negotiation Program: Revised Guidance, Implementation of Sections 1191 – 1198 of the Social Security Act for Initial Price Applicability Year 2026. Accessed online on October 19, 2023: https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf

CONTACT

For further correspondence please contact Chad Patel at chad.patel@aesara.com