The scope and future of ISPOR value flower with IRA

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INTRODUCTION

- The Inflation Reduction Act (IRA) of 2022 represents a significant shift in the United States (U.S) healthcare policy, with major implications for the pharmaceutical industry. It focuses on reducing prescription drug prices and improving access to essential medications. To achieve this, the IRA provided Medicare the authority to directly negotiate high expense drug prices with the aim of making treatments more affordable for patients and generating savings for payers.[1]
- Centers for Medicare & Medicaid Services (CMS) will implement a structured approach to set the Maximum Fair Price (MFP) for single-source prescription drugs selected based on their high cost, significant spending by Medicare, and lack of generic or biosimilar alternatives.[1]
- Based on the negotiations, evidence, and analyses, CMS will set an MFP that reflects a balance between the drug's value and affordability. This price must be lower than the current market price and should ensure access for beneficiaries.

OBJECTIVES

- To qualitatively describe the International Society for Pharmacoeconomics and Outcomes Research (ISPOR) value flower and review existing publications on its validity in context of price negotiation
- To identify alignment between the values and criteria for MFP
- To assess evidence gathering strategies for extended values

METHODS

- Desk research was conducted for policy analysis and to identify previous policy analyses.
- MEDLINE, EMBASE and ISPOR presentation database were searched in a targeted manner to identify published literature on IRA and ISPOR value flower.

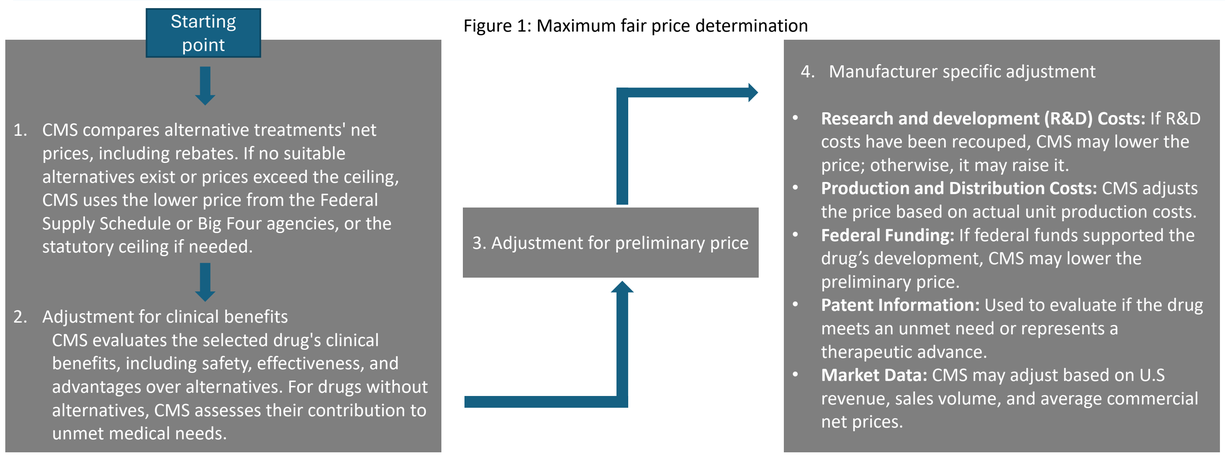
RESULTS

Summary of IRA price negotiation conditions[2]

Eligibility for price negotiation	Eligibility for exclusion	Eligibility for renegotiation
Top 50 expensive Part B and Part D medicines	• Small biotech drugs (<1% of total expenditure for Medicare Part D and Part B, and >=80% of the Medicare expenditure for manufacturer) until 2028 • Products of the manufacturer are acquired after 2021 by another manufacturer or, in the case of an acquisition, before 2025.	• Selected drug (excluding vaccines) with extended-monopoly having 75% market for 11 - 16 years • Long-monopoly drugs having 65% market for at least 16 years. • Standard monopoly drugs having a 40% market.
Approved or licensed under section 505(j) or section 351(a), and not listed as the reference product for a 351(k) product or application	• Biologics that are named reference products for a product approved or under approval in the 351(k) filing • Biologics that are selected in special Social Security Plan for which 106% of the Maximum Fair Price (MFP) will be applicable for such drug and a year during such period	If a selected drug receives a new indication or there is a material change in the factors considered by the Secretary in setting the initial negotiated price.
Single source drugs post 9 years of US Food and Drug Administration (FDA) approval	• Plasma derived products • New formulations include extended-release, higher concentration and change of route of administration of a qualifying drug	A selected drug's negotiated price (or as renegotiated when applicable) will remain in place until a generic or biosimilar is launched, in which case the selected drug's MFP would terminate at the start of the first year that begins 9 months after the generic or biosimilar has entered the market
Single source biologics post 13 years of FDA approval	Drugs below expenditure of $200 million annually (total Part B and Part D)	
Drugs designated for >1 rare disease or condition	Drugs with single orphan drug designation with indication only for the same	

Maximum fair price determination[1]

Figure 1: Maximum fair price determination



Additional values included in published literature

From 2016 to 2020, only 1% of published cost-effectiveness analyses (CEAs)—30 studies—incorporated at least one novel or social value element in their calculations. Among these, adding patient time costs shifted the cost-effectiveness ratio from above to below the $100,000-per-Quality-adjusted life year (QALY) incremental cost-effectiveness ratio (ICER) threshold in 1 of 6 cases. Similarly, including adherence-improving factors achieved this shift in 4 of 17 cases. However, including other elements such as productivity, equity, family spillover, disease severity, or real option value did not alter ratios significantly.

Productivity and Severity of Disease are the most frequently mentioned and quantified additional elements in CEA, with productivity appearing in almost ~50 articles and severity in over ~40. This suggests a strong focus on these factors in recent evaluations.

Adherence improving factors, equity, and insurance value, though they are still somewhat commonly mentioned, but quantified in limited studies.

Family Spillover, fear of contagion, and real option value are rarely mentioned or quantified[3,4]

Preferences of patients and caregivers on additional value elements

A 2020 study evaluated patient preferences for additional value elements. The findings revealed that traditional values such as survival, costs, and health related quality of life (HRQoL) remained highly rated across both survey rounds. Meanwhile, nontraditional values like value of hope and real option value were also preferred by patients and caregivers. Scientific spillover consistently received high scores, highlighting patient interest in the broader impacts of healthcare innovations.[5]

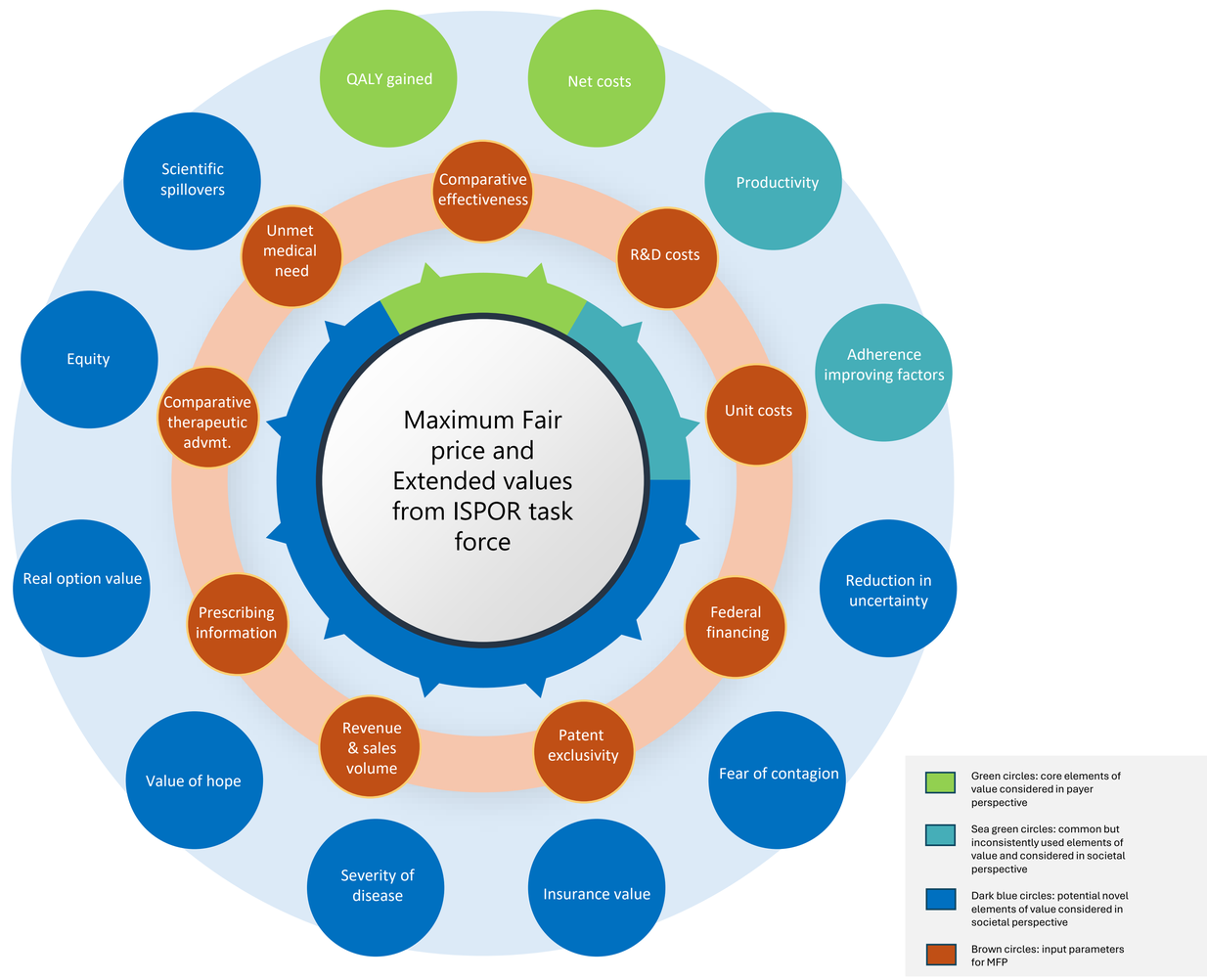
Potential scope of ISPOR value flower with MFP

Real option value accounts for potential future applications and benefits of treatments.[6] Similarly, R&D costs in the MFP model is expected to reflect investments in innovation, which may lead to new uses or enhancements of the original treatment, representing the future potential of the initial investment. The CMS may consider the R&D costs and the extent of return on the investments. Therefore, with data on investment and potential newer innovations manufacturer may negotiate with CMS to demonstrate the value creation from R&D cost

Reduction in uncertainty captures patients' preference over treatments with better safety profile and the increased efficacy of the particular treatment.[6] If payer needs to make a reimbursement decision on similar efficacy treatments or on diseases with high treatment related adverse events, better safety profile may reap benefits for the manufacturer during price negotiation to demonstrate the value on unmet needs.

Scientific spillovers capture the broader benefits that an innovative treatment can contribute to R&D and subsequent innovations.[6] CMS may consider comparative therapeutic advancement recognizing treatments that push forward medical science, potentially leading to new advancements. Scientific spillover of treatments may lead to new innovations with related mechanism (pembrolizumab leading anti PD-L1 treatments) leading to patients' access to effective and life-saving treatments. The spillover may also lead to entry of low cost biosimilar and generics in upcoming years post patent expiration, ensuring cost saving for payers. Cumulatively these factors could demonstrate the value with R&D costs, comparative therapeutic advancement, and patent exclusivity.

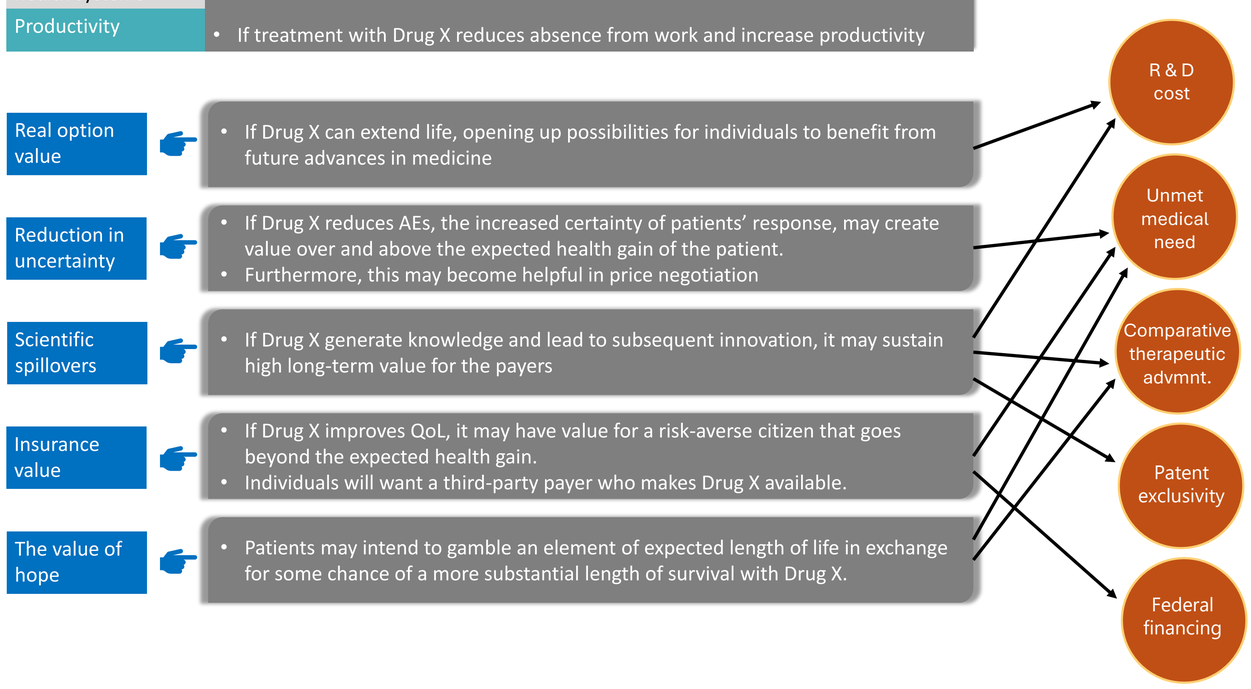
Figure 2: ISPOR value flower and factors in MFP



Potential scope of ISPOR value flower with MFP *continued*..

Figure 3: Scope of extended values in MFP

Traditional Value	Decision makers' objective
Life years gained	• If Drug X contributes to life years gaining for patients suffering from Disease Z
Improvement in QoL	• If Drug X improves the quality of life for patients
Cost-saving within health systems	• The costs averted with treatment with Drug X
Productivity	• If treatment with Drug X reduces absence from work and increase productivity



Insurance value denotes patients' preference for third party payer that enables access to treatments improving quality of life.[6] Federal financing represents governmental support and subsidies that help make treatments affordable and accessible, acting as a form of financial safety net. The CMS is expected to assess the financial support behind a treatment's innovation. Manufacturers may engage in negotiations with CMS, emphasizing the insurance value of a drug by showing that patients feel more confident and secure when federal financing is available for treatment innovations. Manufacturer may also establish that the drug addresses an unmet need in improving quality of life, which is why patients prefer it to be covered by federal support.

Value of hope, although hard to quantify but could be included in broader discussions in MFP setting to inform the psychological benefit for patients in serious conditions who might find new hope through novel treatments.[6] If the negotiated treatment prolongs survival, manufacturer may demonstrate comparative therapeutic advancement and improvement in unmet needs.

Manufacturers may use the additional value elements to better demonstrate the long-term value of negotiated treatments to ensure maximum fair pricing. Refer Figure 3.

CONCLUSION

The ISPOR Value Flower provides a comprehensive framework that captures the full spectrum of a treatment's value, extending beyond traditional clinical and economic metrics to include patient-reported outcomes, patient preferences, and broader societal impacts. By adopting this approach, manufacturers can present a well-rounded value proposition in price negotiations, aligning with both cost containment goals and the objective of improving health outcomes. This holistic framework can support more informed discussions, helping CMS and other stakeholders recognize not only the immediate costs but also the long-term benefits of a treatment. This approach promotes value-based pricing and reimbursement decisions that more accurately reflect the broader impact of medical innovations on patient health and societal well-being. However, incorporating all value elements into economic evaluations could shift their role from purely economic support to broader decision-making, potentially leading to over-reliance on ICER as the final decision-making tool. Manufacturers must be cautious of potential double-counting of value elements, such as improved adherence, which is already reflected in safety and efficacy outcomes. Similarly, including productivity gains as an additional value component could risk overestimating a treatment's cost-effectiveness. Therefore, we recommend careful consideration when including these elements in analyses to avoid inflating the treatment's overall value.

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Keys: CEA, Cost-effectiveness analysis; CMS, Centers for Medicare & Medicaid Services ; FDA, Food and drug administration; HRQoL, health related quality of life ; IRA, Inflation reduction act; MFP, Maximum fair price; ICER, Incremental cost-effectiveness ratio; QALY, Quality adjusted life-year; R&D, Research and development

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