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Evaluating the ICER Special Report in the context of Medicare Drug Price Negotiations: Implications for manufacturer pricing and evidence strategies

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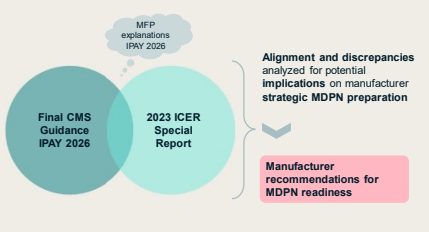
INTRODUCTION

- Under the Inflation Reduction Act (IRA), the Centers for Medicare & Medicaid Services (CMS) implemented the Medicare Drug Price Negotiation (MDPN) program, which allows for price negotiation of a select number of Medicare high-expenditure drugs directly with manufacturers. The maximum fair prices (MFPs) resulting from the 2024 first-cycle negotiations will be implemented in 2026 (i.e. IPAY [initial price applicability year] 2026)[1]
- As part of the legislative specifications under the IRA, CMS released guidance that describes its process to determine the MFP, such as drug information, pricing data, and comparative evidence for the drug versus its therapeutic alternative(s) (TA).[2] Notably, CMS published IPAY 2026 MFP explanations in August 2024[3]
- CMS guidance also provides an opportunity for public and manufacturer evidence submissions. The Institute for Clinical and Economic Review (ICER) independently developed, published, and submitted a Special Report evaluating two of the drugs selected as part of IPAY 2026, apixaban (Eliquis®) and rivaroxaban (Xarelto®).[4] The report used CMS guidance as a foundation to translate evidence into initial prices based on a product's clinical and economic value as compared with that of possible TAs. The Special Report was further cited in the MFP explanations of apixaban and rivaroxaban
- As CMS continues to evaluate product value as part of MDPNs, understanding ICER's approach to comparative evidence assessment and pricing in the context of CMS guidance may inform manufacturers in strategically preparing for future price negotiations

OBJECTIVES

- This analysis aimed to evaluate the ICER Special Report for apixaban and rivaroxaban relative to CMS Guidance for IPAY 2026 to determine potential readiness implications and recommendations for drug manufacturers participating in MDPNs[2,4]

METHODS



RESULTS

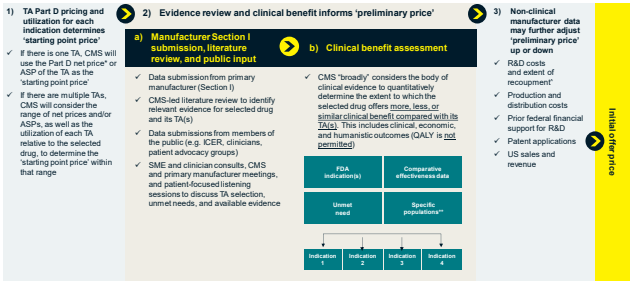
- There are meaningful similarities and differences in CMS' and ICER's methodologies and processes. These factors may influence how the Special Report is utilized and how manufacturers should approach and plan for MDPNs
- Methods are similar in terms of the overall perspective, patient populations, opportunities for and importance of stakeholder input, emphasis on comparative clinical effectiveness, and outcomes assessed
- The main dissimilarities are ICER's more quantitative approach, leveraging a de novo decision analytic model, while CMS employs a broad, qualitative approach to preserve flexibility in negotiations. Other key differences include TA selection, FDA indications considered, and final output of the assessment

Table 1: Comparative evaluation of the CMS MDPN Price Setting Process IPAY 2026 and the 2023 ICER Special Assessment

	CMS MDPN Price Setting Process IPAY 2026	2023 ICER Special Assessment
Objective	To create a more efficient and equitable system for prescription drug pricing within Medicare	To provide multiple elements related to drug value to support CMS in translating evidence into initial prices and for assessing counteroffers from drug makers
Approach	Qualitative assessment of the clinical benefit of the selected drug vs its TA(s); designed to preserve flexibility in negotiations, including the ability to consider multiple perspectives, nuanced differences between different drugs, and other factors not captured in a more thoroughly pre-specified quantitative approach	▪ Quantitative de novo decision analytic model that assesses the lifetime health outcomes and costs of the selected drug vs its TA(s) (ICER offers to provide an executable Microsoft Excel® file to CMS) ▪ Report includes sections on qualitative data, in line with CMS guidance, that may not be incorporated into the model
Population(s)	Medicare, 'specific populations' (individuals with disabilities, the elderly, individuals who are terminally ill, children, and other populations relevant to Medicare)	Medicare, subgroups (individuals with disabilities, the elderly, individuals who are terminally ill, children, and other populations relevant to Medicare)**
Perspective(s)	Medicare, societal	Medicare, societal
Indication(s) assessed	All FDA-approved indications for the selected drug are evaluated independently	Evaluates a single, pre-specified indication
TA selection	▪ At the indication level ▪ Branded, generic, or biosimilar ▪ TA(s) within the same drug class are considered first followed by those in different pharmacologic classes ▪ May consider off-label use if included in nationally recognized, evidence-based guidelines and Part D compendia	Not clearly defined; available generic treatment options for the selected indication were included in the analysis
Stakeholder input	▪ Data submission on selected drug and its TA(s) from primary manufacturer (Section I) ▪ Data submissions from members of the public (e.g. ICER, clinicians, patient advocacy groups) ▪ Consult subject matter and clinical experts on TA selection and available evidence ▪ Hold meetings with manufacturers and patient-focused listening sessions regarding unmet need and relevant clinical outcomes	▪ Consults with patients and caregivers regarding unmet need and relevant clinical outcomes ▪ Manufacturers can engage with ICER during report development by providing input during public comment periods, submitting data and evidence, participating in meetings, and responding to draft reports*
Clinical benefit assessment/comparative therapeutic impact	▪ Conducts CMS-led literature review and potentially other relevant internal analytics ▪ CMS "broadly" considers the body of clinical evidence to determine the extent to which the selected drug offers more, less, or similar clinical benefit compared to its TA(s), including: 1) the extent to which the selected drug represents a therapeutic advance vs existing TA(s); 2) FDA-approved prescribing information; 3) comparative effectiveness data, including the effects on 'specific populations'; and 4) the extent to which the selected drug and the TA(s) address unmet medical needs	▪ Conducts an SLR ▪ Conducts NMA(s) using RCT data in the absence of direct head-to-head evidence ▪ ICER assigns an evidence rating for comparative clinical effectiveness to the selected drug vs TA(s) based on ICER's established Evidence Rating Matrix
Evidence reviewed	RCTs, literature reviews, naïve comparisons, ITCs/NMAs, peer-reviewed research, Medicare claims data, expert reports or whitepapers, clinician expertise, real-world evidence, and patient experience	RCTs, high-quality observational studies presenting long-term outcomes and harms
Outcomes considered	▪ Patient-centered outcomes and patient experience data ▪ Certain cost-effectiveness measures (QALY is not permitted^) ▪ Changes to productivity, independence, and QoL to the extent that these outcomes correspond with a direct impact on individuals taking the drug ▪ May consider the caregiver perspective, changes in symptoms, or other factors important to the patient	▪ Patient-important outcomes and AEs ▪ QoL (evLY†) ▪ Medicare-specific healthcare costs ▪ Productivity changes and other non-intervention indirect costs (societal perspective)
Output	Preliminary price (considers the price that CMS pays for TA[s] and non-clinical manufacturer data)	Maximum annualized price premiums at various cost-effectiveness thresholds ($/evLY†) for the selected drug relative to the prices that CMS pays for TA(s)

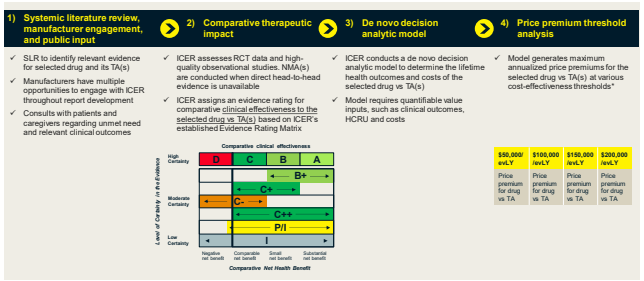
Key: AE, adverse event; CMS, Centers for Medicare & Medicaid Services; evLY, equal value life year; FDA, Food and Drug Administration; ICER, Institute for Clinical and Economic Review; IPAY, initial price applicability year; ITC, indirect treatment comparison; MDPN, Medicare Drug Price Negotiation; NMA, network meta-analysis; QALY, quality-adjusted life year; QoL, quality of life; RCT, randomized controlled trial; SLR, systematic literature review; TA, therapeutic alternative.
Notes: Green = similar. ^ CMS holds the position that QALYs undervalue life extension for individuals who are elderly, disabled, or terminally ill compared to individuals who are younger, nondisabled, or not terminally ill. ** Subgroups were not captured in the decision analytic model. ^ ICER manufacturer engagement guidelines may differ for the Special Report. † ICER states that the evLY is a nondiscriminatory alternative to the QALY and has provided CMS with rationale for why the evLY is consistent with the IRA and will be helpful to CMS in its deliberations.

Figure 1: CMS MDPN Price Setting Process IPAY 2026



Key: ASP, average sales price; CMS, Centers for Medicare & Medicaid Services; DIR, direct and indirect remuneration; FDA, Food and Drug Administration; ICER, Institute for Clinical and Economic Review; IPAY, initial price applicability year; MDPN, Medicare Drug Price Negotiations; PBM, pharmacy benefit manager; PDE, prescription drug event; QALY, quality-adjusted life year; R&D, research and development; TA, therapeutic alternative.
Notes: This figure is informed by CMS Guidance IPAY 2026 and is for illustrative purposes only. Some information has been omitted. Please see the CMS guidance for full methodology.
* Includes all price concessions received by any Part D plan or PBM on behalf of the Part D plan by using PDE data and detailed DIR report data. ** Individuals with disabilities, the elderly, individuals who are terminally ill, children, and other populations relevant to Medicare. ^ Global and US total lifetime revenue.

Figure 2: 2023 ICER Special Assessment



Key: A, superior; B, incremental; B+, incremental or better; C, comparable; C+, comparable or incremental; C++, comparable or better; C-, comparable or inferior; CMS, Centers for Medicare & Medicaid Services; D, negative; evLY, equal value life year; HCRU, healthcare resource utilization; I, insufficient; ICER, Institute for Clinical and Economic Review; P/I, promising but inconclusive; RCT, randomized controlled trial; SLR, systematic literature review; TA, therapeutic alternative.
Note: This figure is informed by the 2023 ICER Special Report and is for illustrative purposes only. Some information has been omitted. Please see the ICER Special Report for full methodology.
* The most commonly used cost-effectiveness thresholds in the US are utilized, as well as a wider range, to provide CMS with additional pricing points for consideration.

Figure 3: Potential MDPN readiness implications and manufacturer recommendations

Consideration	Implication	Manufacturer recommendation
▪ The ICER Special Assessment aligns with CMS' Price Setting Process on several key factors, such as the emphasis on comparative clinical effectiveness, and adheres to guidelines regarding public data submission for MDPNs (e.g. excludes the use of QALYs, provides rationale for the use of evLY) *It is important to note that the ICER Special Report includes sections on qualitative data, in line with CMS guidance, that may not be incorporated into the model*	CMS is likely to review and consider the ICER Special Report for the 'clinical benefit assessment' in some capacity – likely where methodology and outcomes align. This is further supported by the citing of the report in MPF explanations	✓ Assess, generate and publish comparative effectiveness data that align with methods and outcomes shared across CMS' Price Setting Process and the ICER Special Assessment ✓ Identify areas of the ICER Special Report that can validate or be refuted by manufacturer data submissions during MDPNs ✓ Engage with ICER during report development to ensure all relevant evidence is considered (including qualitative data)
▪ ICER's methods are more quantitative, utilizing a decision analytic model, while CMS employs a qualitative approach to preserve flexibility in negotiations ▪ The modified societal perspective from ICER's model aligns with the value elements considered as a part of CMS' process	▪ CMS' approach may allow for the consideration of value elements not adequately captured in quantitative models ▪ CMS may leverage quantitative values from the ICER Special Report (NMA results, evidence ratings, evLY for unmet need) or the ICER executable Microsoft Excel® model (if shared) as a starting point or foundation for their assessment	✓ Generate and communicate evidence that demonstrates the additional value of the selected drug beyond what is captured in ICER's model (e.g. patient experience data, adherence rates, benefits for 'specific populations') ✓ Consider that ICER's societal perspective may better reflect the selected drugs overall value from a MDPN standpoint ✓ Consider conducting an NMA or developing comparative RWE to understand best practices and limitations, prepare for engagements with CMS and ICER, and plan for potential outcomes and evidence ratings
▪ ICER's Special Assessment generates maximum premium prices at commonly accepted cost-effectiveness thresholds ($/evLY), while CMS' Price Setting Process generates an initial offer price *It is important to note that both processes consider the price that CMS pays for the selected drug relative to the price it pays for TA(s); however, selected TAs and indications assessed may differ*	As CMS does not transparently present the exact calculations and evidence ratings used for generating its initial offer price, it is unclear how and whether ICER's premium price threshold analysis will inform CMS' initial offer price	✓ If leveraged by CMS, understand what ICER's price premium threshold analysis illustrates, what evidence it considers, and any potential limitations. Prepare response if applicable
Other key considerations: ▪ Methodology differences regarding TA selection and indication assessment ▪ Importance of stakeholder perspective and feedback	▪ TA selection and indication(s) assessed may differ across ICER's and CMS' evaluations ▪ CMS and ICER are likely to align on patient-centric outcomes and stakeholder perspectives	✓ Anticipate potential influence of ICER's Special Report on CMS' TA selection and clinical benefit assessment for the relevant indication and TAs ✓ Consider key stakeholder perspectives (i.e. patients, caregivers, and clinicians) when generating and disseminating evidence-related unmet need, clinical endpoints, and relevant TAs

Key: CMS, Centers for Medicare & Medicaid Services; evLY, equal value life year; FDA, Food and Drug Administration; ICER, Institute for Clinical and Economic Review; MDPN, Medicare Drug Price Negotiation; MFP, maximum fair price; NMA, network meta-analysis; QALY, quality-adjusted life year; RWE, real-world evidence; TA, therapeutic alternative.

LIMITATIONS

- CMS does not transparently present how the initial offer price is established during MDPNs. This uncertainty should be considered when reviewing the results and conclusions of the present analysis
- The present analysis aims to highlight key information from CMS Guidance IPAY 2026 and the 2023 ICER Special Report. It is not comprehensive, and some information has been omitted
- CMS has published updated guidance since this analysis was conducted. While the overall process is expected to remain unchanged, it is unclear how any updates may impact the recommendations mentioned herein
- Only one ICER Special Report was available at the time of the analysis. The full context and considerations of future reports may not be fully represented

CONCLUSIONS

- The ICER Special Assessment aligns with CMS' MDPN Price Setting Process, with certain limitations
- Given that CMS cited the ICER Special Report in MFP explanations, manufacturers should consider the findings of this analysis when developing their evidence and negotiation strategies
- Future analyses are needed to understand ICER's potential impact within the context of evolving CMS Guidance and its influence on final pricing

REFERENCES

1. H.R. 2022. https://www.congress.gov/bill/117th-congress/house-bill/5376/text. Accessed 24 January 2025. **2.** CMS. https://www.cms.gov/files/document/revised-medicare-drug-price-negotiation-program-guidance-june-2023.pdf. Accessed 24 March 2025. **3.** MFP Explanations. https://www.cms.gov/inflation-reduction-act-and-medicare/medicare-drug-price-negotiation. Accessed 24 March 2025. **4.** ICER. https://icer.org/wp-content/uploads/2023/09/ICER_NVAF_Medicare_Assessment_100223.pdf. Accessed 24 March 2025.

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