ICER and JCA: Insights for manufacturers in an evolving HTA landscape

Colin Song[1], Melanie Anderson[1], Anne Loos[1]

[1]Wickenstones Ltd, 1 & 3 Kings Meadow, Oxford OX2 0DP, United Kingdom

WICKENSTONES
PARTNERS IN BUILDING VALUE

BACKGROUND

In the United States (US), health technology assessments (HTA) conducted by the Institute for Clinical and Economic Review (ICER) play an advisory role in pricing and reimbursement decision making, with individual payers weighing clinical value, budget impact, and patient needs differently. In the European Union (EU), HTA plays a more central and formalized role, with each member state having its own official HTA body assessing the value of new medicines.

Recently, in 2025, Joint Clinical Assessment (JCA) was introduced to consolidate clinical evaluations across EU member states; however, this has raised concerns about its impact on evidence generation, submission complexity, and launch planning.

This study aims to compare the methodologies and scopes of ICER and JCA to highlight how diverse and evolving HTA submission requirements may impact global market access strategies.

METHODS

Structured examination of ICER and JCA approaches to HTA

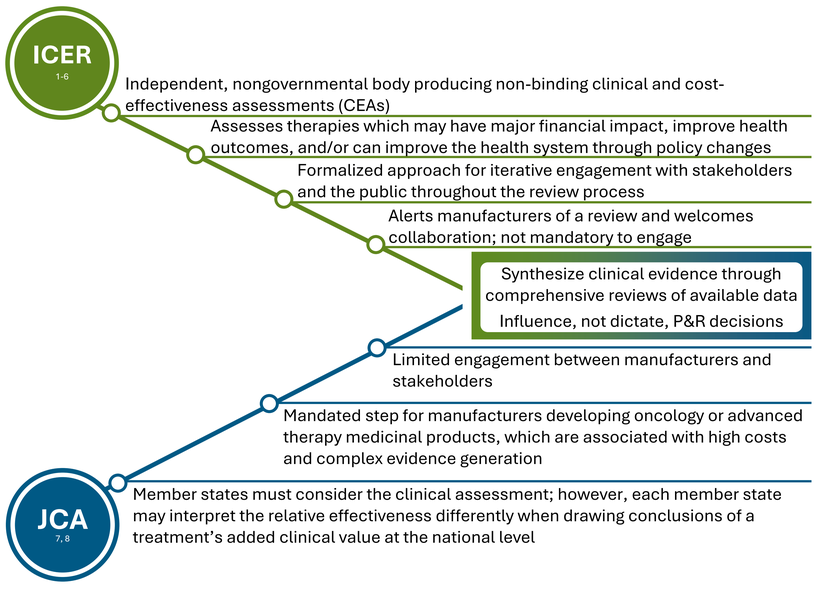
- ► Evidence requirements, review timelines, stakeholder engagement, and assessment scope
- ► Sources included publicly available guidelines and expert commentary

RESULTS

Methodologies of ICER vs JCA (Figure 1)

- ► While both assess clinical effectiveness and influence pricing and reimbursement decisions, there are differences in manufacturer obligation, topic selection, and extent of expert input

Figure 1. Comparison of ICER and JCA methodologies



Abbreviations: CEA, cost-effectiveness assessment; ICER, The Institute for Clinical and Economic Review; JCA, Joint Clinical Assessment; P&R, pricing and reimbursement.

Topic selection priorities of ICER vs JCA (Table 1)

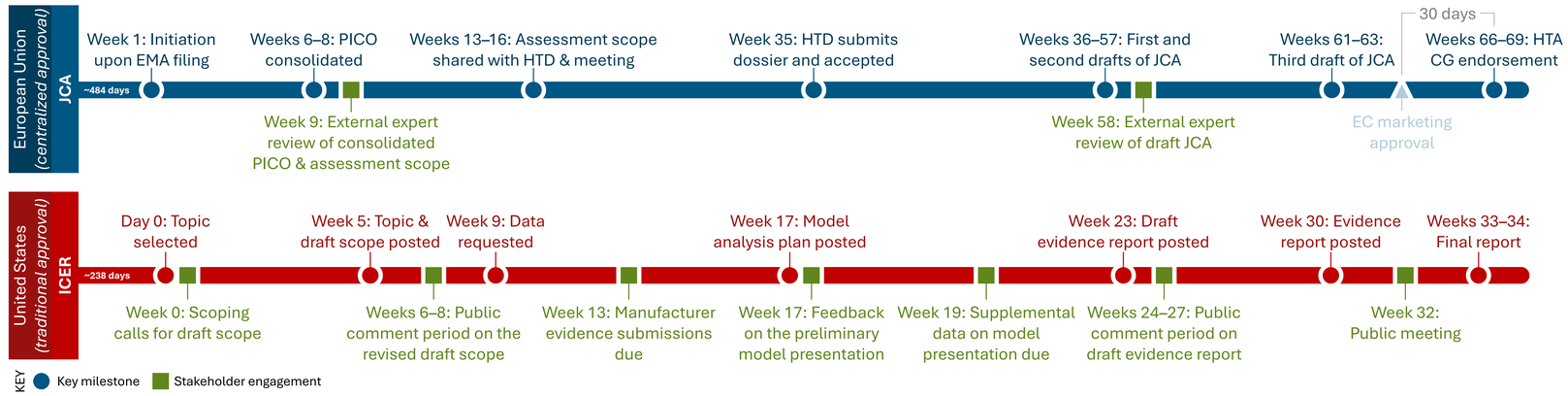
JCA[12]

- ► Will begin with reviewing new oncology medicines and ATMPs with the addition of orphan medicinal products starting in 2028, and all new medicinal products starting in 2030

ICER

- ► Topics are prioritized by impacts on the current landscape, budgets, policy and/or patients[3]
  - Notably, ICER completed only 2 oncology reviews since April 2021. In the US, comparative effectiveness and value assessments carry less weight in oncology, as commercial payers are less likely to manage access using methods like step therapy, relative to other diseases[13-15]

Figure 2. Stakeholder engagement timelines of ICER vs JCA



Abbreviations: CG, Coordination Group; EC, European Commission; EMA, European Medicines Agency; HTA, health technology assessment; HTD, health technology developer; ICER, The Institute for Clinical and Economic Review; JCA, Joint Clinical Assessment; PICO, population, intervention, comparison and outcome.

Timelines of ICER vs JCA (Figure 2)

JCA[9]

- ► In the EU centralized framework, JCA initiates when EMA market authorization filing occurs
- ► JCA and summary reports must be finalized before or at the Commission's decision for market authorization
- ► HTA CG then has 30 days after market approval to endorse the reports

ICER[2, 10]

- ► Selects a topic about 8 months prior to FDA approval to ensure the report aligns with the time for pricing negotiations (PBM P&T committee evaluations, which occur within 90 days of FDA approval)

Table 1. Comparison of ICER's and JCA's topic selection priorities

	JCA (EU)[12, 16]	ICER (US)[3, 13]
Start year	2025	2005
Initial focus	Oncology, ATMPs	Varied; based on policy and clinical impact
Scope expansion	Orphan drugs (2028) and all new drugs (2030)	Selected based on expected implications for care delivery and cost
Oncology review activity	Central, early focus	Only 2 reviews since 2021

Abbreviations: ATMP, advanced therapy medicinal product; EU, European Union; ICER, The Institute for Clinical and Economic Review; JCA, Joint Clinical Assessment; US, United States.

Stakeholders involved in ICER vs JCA (Figure 2)

JCA

- ► Mandatory engagement is limited to reviews of the consolidated assessment scope and revised JCA and summary reports; stakeholders are selected by the HTA Secretariat with expertise across multiple member states[9, 11]
- ► Assessors and co-assessors have the option to further engage stakeholders, if needed[9]

ICER

- ► Formal periods for iterative engagement throughout the entire assessment via written feedback or meeting attendance (draft and revised scope, preliminary model, draft report, and involvement in the public meeting to discuss the evidence report)[5]
- ► Stakeholders providing input may include patients, clinical experts, drugmakers, and insurers[6]

CONCLUSIONS

- ► ICER and JCA have differing timelines and areas of emphasis, reflecting the unique needs and HTA landscapes of their respective geographies.
- ► These differences underscore the divergent evidence requirements and evaluation standards that manufacturers must navigate across global markets.
- ► The findings from this research offer valuable insight into how each framework influences payer expectations, access timelines, and regional decision-making.
- ► Understanding the distinct expectations for engagement with ICER and submission requirements of JCA highlights the need for manufacturers to incorporate global HTA expectations early in a product's lifecycle.

Abbreviations: ATMP, advanced therapy medicinal product; CG, coordination group; EMA, European Medicines Agency; EU, European Union; FDA, Food and Drug Administration; HTA, health technology assessment; ICER, The Institute for Clinical and Economic Review; JCA, Joint Clinical Assessment; PBM, pharmacy benefit manager; P&T, pharmacy and therapeutics; US, United States.

REFERENCES

1. Review TIfCaE. Demonstrate the Full Value of Your Medicines The Institute for Clinical and Economic Review: The Institute for Clinical and Economic Review; 2025 [Available from: https://icer.org/work-with-icer/manufacturers/#:~:text=While%20ICER's%20core%20expertise%20lies,ICER's%20complete%20Manufacturer%20Engagement%20Guide].
2. Thokala P, Carlson JJ, Drummond M. HTA'd in the USA: A Comparison of ICER in the United States with NICE in England and Wales. J Manag Care Spec Pharm. 2020;26(9):1162-70.
3. Review TIfCaE. Topic Selection The Institute for Clinical and Economic Review: The Institute for Clinical and Economic Review; 2025 [Available from: https://icer.org/our-approach/methods-process/value-assessment-framework/topic-selection/].
4. Pyenson B, Buzby E, Sawhney T. The Utility of ICER Reports for Private Payer Budgeting: Budget Impact Analyses. 2019.
5. Review TIfCaE. Manufacturer Engagement Guide. The Institute for Clinical and Economic Review; 2024.
6. Review TIfCaE. Methods & Process The Institute for Clinical and Economic Review: The Institute for Clinical and Economic Review; 2025 [Available from: https://icer.org/our-approach/methods-process/].
7. Group HTAC. Guidance on outcomes for joint clinical assessments European Commission: European Commission; 2024 [Available from: https://health.ec.europa.eu/document/download/a70a62c7-325c-401e-ba42-66174b656ab8_en?filename=hta_outcomes_jca_guidance_en.pdf].
8. Medicine TAfR. JOINT CLINICAL ASSESSMENT FOR ADVANCED THERAPY MEDICINAL PRODUCTS: Learnings from National HTA Reviews and Methodological Recommendations The Alliance for Regenerative Medicine; 2023.
9. Group HTAC. Procedural guidance for JCA medicinal products European Commission: European Commission; 2024 [Available from: https://health.ec.europa.eu/document/download/0929cd01-619d-4456-a1c4-d8e33f9e36bf_en?filename=hta_jca_mp_procedural-guidance_en.pdf].
10. Technology MMI. What is the timeline for formulary decisions? 2025. In: The Essentials of Market Access: How to Build a Strong Commercialization Strategy for Your Pharmacy Benefit Therapy [Internet]. Managed Markets Insight & Technology: Managed Markets Insight & Technology; [7]. Available from: https://www.mmitnetwork.com/what-is-the-timeline-for-formulary-decisions/#:~:text=the%20timeline%20for-,formulary%20decisions?,for%20Your%20Pharmacy%20Benefit%20Therapy.
11. Falla E, Kullnigg A, van Engen A. IQVIA: IQVIA. 2024. [cited 2025]. Available from: https://www.iqvia.com/blogs/2024/03/the-first-step-on-a-long-road-ahead-a-deep-dive-into-the-jca-implementing-act.
12. Group HTAC. Scientific specifications of medicinal products subject to joint clinical assessments European Commission: European Commission; 2024 [Available from: https://health.ec.europa.eu/document/download/48974c78-1c37-4cf9-9fc9-a630fee9baac_en?filename=hta_mp_jca_sc-specifications_en.pdf].
13. Review TIfCaE. Assessments The Institute for Clinical and Economic Review: The Institute for Clinical and Economic Review; 2025 [Available from: https://icer.org/explore-our-research/assessments/].
14. Wang A, Halbert RJ, Baerwaldt T, Nordyke RJ. US payer perspectives on evidence for formulary decision making. Am J Manag Care. 2012;18(5 Spec No. 2):SP71-6.
15. Runyan A, Yi J, Honcz J. The evolution of payer management of oncology drugs in the United States between 2017 and 2022. J Manag Care Spec Pharm. 2023;29(10):1138-49.
16. Commission E. Joint Clinical Assessments European Commission: European Commission; 2025 [Available from: https://health.ec.europa.eu/health-technology-assessment/implementation-regulation-health-technology-assessment/joint-clinical-assessments_en].

Presented at: ISPOR 2025; Montréal, Québec, Canada; May 13–16th 2025