ISPOR Europe 2024, Barcelona

Benefit vs Uncertainties: The Potential Impact of Joint Clinical Assessment (JCA) on Market Access and Reimbursement of Novel Drugs

HTA118

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Background & Objective

- In 2025, Joint Clinical Assessment (JCA) for oncology drugs and advanced therapy medicinal products (ATMPs), including gene therapies, will start in the European Union (EU).
- The JCA's goal is to standardize the evaluation of new therapies across EU member states, reducing multiple clinical submissions within member states (MS).
- While the implementation is ongoing, concerns remain regarding potential hurdles and evidence requirements.
- The objective of this work is to summarize the benefits of the JCA process as well as to identify the uncertainties associated with JCA implementation for different stakeholders.

Methods

- A targeted review of publicly available statements and viewpoints was conducted to explore potential benefits and uncertainties associated with JCA. The approach involved:
  - Collecting information from diverse stakeholders, including patients, health authorities, industry representatives, and patients.
  - Analyzing the gathered information to identify key challenges and potential solutions.
- This qualitative analysis aims to synthesize diverse perspectives, offering a comprehensive understanding of the complexities inherent in JCA and its potential to transform existing healthcare assessment systems.

Results

- The search revealed two primary categories of potential considerations for stakeholders with respect to JCA integration across Europe:
  - Methodological aspects relating to the scientific approaches and evidence standards in conducting JCA, including:
    - Handling diverse data types and complex PICOs.
    - Addressing varying levels of evidence quality among countries.
  - Operational aspects that involves practical aspects of implementing and managing the JCA process, such as:
    - Aligning timelines for assessment and decision-making.
    - Integrating JCA with existing national evaluation processes.
    - Managing and allocating resources efficiently.
    - Ensuring timely submission of data from various sources.
    - Facilitating effective communication among stakeholders across multiple countries.

Results (ctd)

- Table 1 presents the methodological and operational aspects of four key stakeholders involved in JCA integration.
- For each stakeholder, the table outlines the anticipated benefits and potential uncertainties within these two primary categories, providing a comprehensive overview of the anticipated JCA acceptance in Europe.
  - Methodologically
    - JCA aims to improve access to medicines, streamline assessment processes, and foster knowledge exchange across EU countries.
  - Operationally
    - JCA promises to reduce administrative burden for health technology developers and promote consistency in clinical assessments. However, significant challenges remain, including meeting stringent evidence requirements across member states, potential procedural ambiguities, and the need to balance European-level assessments with national autonomy.
    - Stakeholders face shorter timeframes for development of evidence submission documents, language barriers, and the need for increased collaboration and investment in new tools to comply with JCA regulations.

Conclusions

- The identified considerations and potential outcomes associated with JCA implementation across Europe underscore the complexity of this system and highlight the need for thoughtful planning and coordination among all stakeholders. To address the various methodological aspects and operational factors, the following strategies could be considered:
  - Enhancing Collaboration and Alignment
    - National agencies/HTA bodies might benefit from collaborating on aligning methodologies and data requirements to streamline efforts and develop expertise in evaluating complex data types.
    - Manufacturers could engage early with HTA bodies to align on evidence generation plans, particularly for rare diseases, and invest in robust real-world data collection and analysis capabilities.
  - Policy and Resource Considerations
    - Ensuring adequate resources and training for national HTA bodies to facilitate a smooth transition to the JCA process.
    - Establish EU wide training programs to support MS.
  - Continuous Improvement
    - All stakeholders should foster open dialogue and collaboration to address the various aspects of JCA implementation.
    - Regular review and refinement of JCA processes based on early experiences and stakeholder feedback could contribute to the system's effectiveness and efficiency.

Table 1: Potential consequences for stakeholders due to challenges in implementing the Joint Clinical Assessment (JCA)

	Stakeholder							
	Patients				National authorities			
Category	Methodological	Ref	Operational	Ref	Methodological	Ref	Operational	Ref
Benefits	Improved access to innovative treatments through standardized assessments across the EU	1, 2, 3	Faster access to new therapies due to streamlined processes	1	Enhanced transparency and consistency in health technology assessment, leading to more equitable healthcare outcomes	2, 4, 7	Reduced duplication of clinical assessments lowers administrative burden for national HTA bodies	2, 4, 5
Uncertainties	Potential inequalities in access to rare disease treatments due to insufficient real-world evidence (RWE) consideration in JCAs	3	Delays in implementation may affect timely access to treatments	2, 3, 6, 7	Aligning different national standards and practices within a unified framework poses significant challenges	4, 6	Significant coordination is required among member states for effective implementation	5, 6

	Stakeholder							
	Payers				Health Technology Developer			
Category	Methodological	Ref	Operational	Ref	Methodological	Ref	Operational	Ref
Benefits	More efficient reimbursement decision-making through a centralized assessment that payers can use as reference	2, 4	Streamlined processes may lead to quicker reimbursement decisions	2, 4	Harmonized assessment process reduces duplication of effort and streamlines submissions across multiple countries	2, 4	• Simplified market entry strategies with a single assessment framework for multiple countries • Potentially lower costs due to reduced need for multiple submissions and assessments	2, 4
Uncertainties	Variability in local healthcare priorities and budgets can affect how JCA findings are appraised at the national level	4, 5	Differences in local healthcare priorities may still require additional national assessments, modifying reimbursement processes	4, 5, 7	Adapting to new evidence requirements, including RWE integration, requires strategic planning from early stages of drug development	4, 5	• Increased administrative burden due to complex documentation requirements for JCAs • Need for local expertise and understanding of diverse national regulations remains critical	4, 5, 6

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