KEY POINTS

The New Frontier in EU HTA Regulation Impact on coverage, pricing and risk management for private health insurers

The European Union's Health Technology Assessment Regulation (EU) 2021/2282 (HTAR) came into effect on January 12, 2025. This regulation establishes a framework for EU Member States to collaborate on the assessment of health technologies, including medicines and medical devices, aiming to streamline evaluations and facilitate patient access to innovative healthcare solutions.

While private healthcare funders insurers may not be directly targeted by the regulatory changes they will bring both opportunities and challenges, influencing coverage decisions, pricing models, and risk management strategies. Understanding these implications is crucial for insurers aiming to maintain competitiveness and ensure sustainable offerings in an evolving healthcare landscape.

Introduction of Joint Clinical Assessments

The regulation establishes a new centralised framework for assessing clinical effectiveness and safety at the EU level. 30-day Joint Clinical Assessments (JCAs) are becoming mandatory for:

- Cancer treatments and Advanced Therapy Medicinal Products ATMPs (January 2025)
- Orphan (rare disease) drugs and other high-priority medicines (January 2028)
- High-risk medical devices (2026)
- All new medicinal products (2030)

Key Impacts of the HTAR on Private Health Insurers

As these changes come into effect potential key impacts and associated benefits and challenges of the HTAR for insurers include:

1. Greater Transparency in Health Technology Assessments (HTAs)

Impact: Private insurers will have access to standardised, EU-wide clinical assessments of new medicines and medical devices. This could lead to more consistent decision-making regarding reimbursement and coverage.

Potential Benefit: Reduced uncertainty regarding the effectiveness of new treatments, which may improve insurers' ability to design evidence-based coverage policies.

2. Faster Market Access for New Treatments

Impact: The harmonisation of clinical assessments could accelerate the introduction of innovative health technologies.

Potential Challenge: Insurers may need to adapt pricing models and adjust premium calculations more frequently to accommodate a faster influx of new treatments.

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3. Potential Cost Pressures
Impact: If joint clinical assessments lead to broader adoption of expensive, cutting-edge treatments, private insurers could face higher claims costs.
Potential Challenge: This could translate into higher premiums for policyholders or tighter coverage restrictions on high-cost treatments.

4. Reduced Variability in Reimbursement Policies Across the EU
Impact: Currently, HTA processes vary significantly across EU Member States. The HTAR introduces greater standardisation, which may pressure insurers to align reimbursement policies across multiple markets.
Potential Benefit: Private insurers operating across the EU may find it easier to streamline reimbursement policies, improving administrative efficiency.

5. Need for More Flexible Health Insurance Plans
Impact: With new treatments being introduced faster, insurers may need to design adaptive pricing models and more customisable health plans.
Potential Benefit: Insurers that explore innovative options, such as value-based pricing (already embraced by some iFHP members), may gain a competitive edge.

6. Stronger Patient Advocacy & Demand for Coverage
Impact: As HTAs become more patient-centric, with stakeholders like patient groups being involved in assessments, public demand for reimbursement of high-cost treatments may increase.
Potential Challenge: Insurers may face public pressure to cover treatments deemed effective by the EU's joint HTAs, even if they are costly.

7. Increased Collaboration with Public Healthcare Systems
Impact: Many private health insurers work alongside national healthcare systems. A harmonised HTA process could encourage more public-private collaboration in negotiating prices and coverage policies.
Potential Benefit: Insurers might benefit from joint price negotiations or risk-sharing agreements with governments to manage high-cost treatments.

Global Implications of the EU HTA Regulation
The EU HTA framework is influencing global regulatory agencies and encouraging international harmonisation in clinical assessments and reimbursement policies:

- **United Kingdom:** The National Institute for Health and Care Excellence (NICE) is reviewing joint clinical assessments (JCAs) to align methodologies.
- **United States:** Centralised HTA models are gaining traction as policymakers explore more consistent evaluation methods.
- **Canada:** The Canadian Agency for Drugs and Technologies in Health (CADTH) is refining assessment models based on EU approaches to enhance decision-making efficiency.
- **Australia:** The Pharmaceutical Benefits Advisory Committee (PBAC) and the Medical Services Advisory Committee (MSAC) are evaluating the integration of EU methodologies to improve their processes.

In February 2025, the USA-based Institute for Clinical and Economic Review (ICER), NICE, and Canada's Drug Agency (CDA-AMC) launched the Health Economics Methods Advisory (HEMA) initiative. HEMA aims to advance HTA methodologies, contributing to global alignment and best practices in medical technology evaluation.

Conclusion
The EU HTA Regulation is set to improve transparency, standardise assessments, and enhance efficiency for private health insurers. However, it also introduces cost pressures and new patient expectations. To navigate these changes, insurers must collaborate with policymakers, healthcare providers, and pharmaceutical companies to balance cost management and treatment accessibility. Insurers that swiftly adapt by refining coverage policies, exploring value-based pricing, and investing in flexible health plans could turn these challenges into opportunities, ensuring both financial sustainability and improved healthcare outcomes for policyholders.

Key Resources:

Read more on emerging trends in treatment funding:
International Healthcare Cost Comparison Report 2024

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