

NIVEN BIOPHARMA
EXECUTIVE BRIEF

ISSUE 001
JULY 2026

Interpreting the First Joint Clinical Assessment Reports

Strategic implications for national HTA

EXECUTIVE BRIEF

One medicine can generate multiple evidence positions

Interpret evidence positions and value scenarios at the PICO level, not the product level

The PICO, not the product,
is the strategic unit of interpretation

EXECUTIVE BRIEF

The JCA reports explain the assessment. The next step is determining the implications

Understanding the assessment:

- Assessment methodology
- Evidence appraisal
- Assessor rationale
- Product-level conclusions

Interpreting the implications:

- National HTA strategy
- PICO-level interpretation
- Country-specific opportunity and challenge
- Evidence beyond the JCA

Pricing and reimbursement

EXECUTIVE BRIEF

Every PICO tells a different strategic story

Interpret each PICO independently. Every evidence position may create a different opportunity or challenge within national HTA systems

<i>Evidence position by PICO</i>	RELATIVE CLINICAL ADVANTAGE ESTABLISHED	RELATIVE CLINICAL ADVANTAGE UNCERTAIN	NO DEMONSTRATED RELATIVE IMPROVEMENT	NOT ASSESSABLE
				
<i>Strategic question</i>	How can this evidence be translated into a compelling national HTA case?	Which uncertainties are most likely to matter to individual HTA bodies?	Is there still a compelling value proposition within specific national contexts?	Does the absence of an assessment create a challenge, or an opportunity within national HTA?
	<i>Robust comparative evidence of improvement</i>	<i>Directionally favourable evidence, weakened by material uncertainty</i>	<i>Comparative evidence shows similar or worse outcomes</i>	<i>Evidence relevant to national HTA lies outside the JCA remit</i>

EXECUTIVE BRIEF

Three signals for future submissions

Early JCAs already reveal recurring signals for future submissions, that extend beyond individual products

OBSERVATIONS:

1. Orphan medicines are being assessed using the same evidentiary expectations as other medicines
2. Unanchored indirect comparisons continue to attract substantial uncertainty
3. Clinical uncertainty is being characterized explicitly and systematically.

WHAT THIS MEANS FOR DEVELOPERS:

- High unmet need is unlikely to offset limitations in comparative evidence*
- Address disconnected evidence networks as early as possible in development*
- Prepare for uncertainty to be interpreted differently across national HTA systems*

EXECUTIVE BRIEF

The JCA is only part of the national HTA story

National HTA bodies will continue to consider evidence and decision criteria that sit beyond the scope of the JCA

Assessment domain	Sources of variation at the national level:
Economic Value	Degree of added value, cost-effectiveness, budget impact, affordability
Policy priorities	Unmet need, disease severity, innovation, societal priorities, orphan and pediatric policies, public health
Acceptability of evidence	Different willingness to accept data from single-arm trials, indirect treatment comparisons, higher uncertainty, immature data

The JCA harmonizes parts of the assessment, not the decision

Three questions every company should ask:

1

Which PICOs create the greatest national opportunity or challenge?

2

Which recurring JCA signals should influence our evidence strategy?

3

What evidence beyond the JCA will shape national HTA decisions?