HTA30

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A case study in PICO

What we might consider for JCA

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Background

- The development of joint clinical assessments (JCA) often requires the use of multiple population, intervention, comparator, and outcomes (PICO) frameworks.
- This case-study aims to provide insights for optimizing the adoption processes of new drugs in the European Economic Area (EEA) by comparing country-specific health technology assessment (HTA) reports for a target product across Scandinavian countries and Finland and analyzing variations in the elements of the PICO framework.

Methods

- A retrospective analysis of HTA reports from Denmark, Finland, Norway, and Sweden was conducted to identify a single oncology drug evaluated for the same indication across all four countries within a three-year timeframe.
- The PICO framework elements deemed relevant by each HTA agency were extracted and subjected to comparative analysis.
- This methodological approach facilitated the examination of potential variations in HTA practices among the selected countries, specifically in the context of oncology drug assessments.

Results

- The assessment of polatuzumab-vedotin as first-line treatment for patients with diffuse large B-cell lymphoma (DLBCL) was selected. The clinical evidence is mainly informed by the POLARIX trial. EU authorization was granted on May 24, 2022. HTA decisions followed in 2022 (Finland, Norway, Sweden) and 2023 (Denmark).
- Differences were observed in the population and outcomes elements of the PICO framework (Figure 1). The intervention and comparator elements of the PICO framework showed no differences, likely due to the rarity of the disease. For more common diseases with multiple treatment options, it is likely that comparators will vary across countries, reflecting differences in the standard of care.
- Regarding the population element, agencies in Finland, Norway, and Sweden considered the trial population as relevant, while in Denmark the analysis was restricted to a subgroup that better represented eligible patients according to clinical expert opinion.
- In terms of outcomes, variations were found in the methods used in economic models for estimating long-term progression-free survival and overall survival. Different utility weights were used to estimate health-related quality of life.

Figure 1. Overview of the PICO framework for the assessment of polatuzumab-vedotin as first-line treatment for DLBCL in Denmark, Finland, Norway and Sweden

		Denmark[2]	Finland[3]	Norway[4]	Sweden[5]
Population		Adult patients (<80 years) with previously untreated DLBCL, with IPI scores 3-5	Adult patients (<80 years) with previously untreated DLBCL, with IPI scores 2-5	Adult patients (<80 years) with previously untreated DLBCL, with IPI scores 2-5	Adult patients (<80 years) with previously untreated DLBCL, with IPI scores 2-5
Intervention		Polatuzumab vedotin + R-CHP	Polatuzumab vedotin + R-CHP	Polatuzumab vedotin + R-CHP	Polatuzumab vedotin + R-CHP
Comparator		R-CHOP	R-CHOP	R-CHOP	R-CHOP
Outcomes	PFS	Long-term extrapolation: Generalized gamma	Long-term extrapolation: Generalized gamma	Long-term extrapolation: Generalized gamma with MCM	Long-term extrapolation: Generalized gamma. No PFS benefit after month 42.
	OS	Long-term extrapolation: Log-logistic. No OS gain	Long-term extrapolation: Generalized gamma with MCM	Long-term extrapolation: Generalized gamma with MCM	No OS gain
	Safety	Grade 3-5 AEs from POLARIX trial that occurred in more than 2% of patients	Grade 3-5 AEs from POLARIX trial that occurred in more than 2% of patients	Grade 3-5 AEs from POLARIX trial that occurred in more than 2% of patients	Not available
	QoL	Utility weights from the POLARIX trial	Utility weights from the GOYA trial	Utility weights from the POLARIX trial	Average of utility weights from the POLARIX and GOYA trials

Legend: Different from other countries; Similar to one other country; Similar to at least two other countries; Information not available in HTA report

Conclusions

- Demographic differences and different economic evaluation methodologies influenced the variations in the population and outcomes elements of the PICO framework.
- Variations may also be expected for the comparator based on the standard of care in each country.
- While JCA focuses on clinical aspects, national HTA agencies still consider both clinical and economic values in their recommendations for the adoption of new drugs.
- By disaggregating the clinical and economic evaluations, JCA challenges traditional assessment approaches where the clinical value might have a direct impact on the economic value.
- Manufactures should be prepared to use innovative approaches to present multiple PICO frameworks for JCA and equip country teams to translate the above country appraisal of clinical value into local economic evidence. This comprehensive approach ensures a thorough evaluation and assessment of a drug's overall value.

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Abbreviations

AE: Adverse event; DLBCL: Diffuse large B-cell lymphoma; EEA: European Economic Area; HTA: Health technology assessment; IPI: International Prognostic Index; JCA: Joint clinical assessment; OS: Overall survival; PFS: Progression-free survival; PICO: Population, intervention, comparator, and outcomes; QoL: Quality of life; R-CHOP: Rituximab, cyclophosphamide, doxorubicin, vincristine and prednisone; R-CHP: Rituximab, cyclophosphamide, doxorubicin and prednisone ; SAE: Serious adverse event

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