

# The Use of QALYs in Decision-Making in Europe, Canada, and the US: A Qualitative Review of Methodological Guidance

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## Introduction

The reimbursement of health technologies conventionally depends upon gaining favorable recommendations from HTA agencies, subject to the evaluation of manufacturer-submitted evidence. Economic evaluations, utilizing metrics such as QALYs, are frequently included as part of the submission to support the decision-making process (1). However, some HTA agencies and academics express concerns regarding the use of QALYs in reimbursement decision making highlighting ethical and methodological issues around the accuracy and fairness of QALY calculations, and propose more clinically relevant evaluation measures (2). Currently, the use of QALYs varies among HTA agencies, with some making limited use or forgoing their use entirely. In this review we aimed to explore the extent of their use in more detail, based on HTA guidelines.

## Objectives

The research objectives were to:

1.

Assess and compare the role of QALYs in the reimbursement decision-making process of pharmaceutical products in selected countries within Europe and North America
2.

Capture the rationale for either **prominent**, **limited**, or **non-use of QALYs**, where relevant, by the HTA agency

## Methodology

A qualitative review was conducted focusing on the current use of QALYs in HTA decision-making processes. Countries were selected if they constituted a large pharmaceutical market, and had a well-established HTA process.

Websites for HTA agencies from France (Haute Autorité de Santé), Germany (Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen), Italy (Agenzia Italiana del Farmaco), Spain (Ministerio de Sanidad), the UK (National Institute for Health and Care Excellence), Canada (Canada's Drug Agency), and the US (Institute for Clinical and Economic Review) were searched for information regarding the decision-making process for reimbursement and pricing of pharmaceutical products.

If an economic analysis was performed as part of the assessment, the methodological guidance for conducting such analysis was also reviewed. The review was supplemented by targeted desk research. Information was extracted and reported in Excel®, followed by a thematic analysis to identify key themes among the HTA agencies' use of QALYs.

## Results

The review highlighted structured and rigorous HTA decision-making processes across all countries including the assessment of a broad range of evidence sources and involvement of several stakeholders. However, several differences were identified.

### Primary focus of the decision making

For the UK, Canada, and the US, economic evaluation is included alongside a complete body of clinical evidence supplied as part of the HTA submission.

However, the primary focus of the HTA process in France, Germany, Italy, and Spain is the evaluation of the clinical benefit related to the intervention of interest. In these countries, economic evaluation is performed only upon request, e.g., when a relevant clinical benefit for the new intervention is established, or to support the pricing discussions.

### Type of evaluations

Differences were observed in the recommendations regarding the primary type of economic evaluation within the submission. For France, Germany, and Spain the choice between CUA or CEA is based solely on the outcome of the clinical assessment and the impact on the health-related quality of life. CUA is a priority evaluation for the UK and Canada whereas CEA is a priority for the US. Italy did not specify the preferred type of analysis and highlights the use of combined CUA and CEA. If similar health benefit of intervention versus comparator is established, cost-minimization or cost-comparison analyses can be used as an alternative to CEA or CUA in Spain and the UK.

In addition, budget impact analysis is mandatory in the UK, Germany, and Italy, and cost-consequence analysis, which accounts for a wider impact of interventions, can be considered a complementary evaluation in France and Canada.

### The use of QALYs

The use of QALYs across the HTA bodies is summarized in Table 1. The QALY was found to be a priority metric for reporting the economic evaluation base case results in the UK and Canada. For France, Germany, Italy, and Spain, the use of QALYs is limited, as highlighted by the recommendations regarding the type of economic evaluation. They are often presented alongside additional metrics, such as life years, to provide a wider context of health benefit. However, in the US, QALYs are only used for comparisons with existing literature. The priority metric in the US is the evLYG, intended to mitigate concerns regarding the potential discriminatory effect of cost per QALY.

### The rationale for (non-)use of QALYs

The rationale for use, or non-use, of QALYs is not well reported within the guidelines. Spanish guidelines briefly mention the benefits associated with QALYs, highlighting comparability between evaluations using the same measure. In contrast, both Germany and the US prominently state perceived limitations of QALYs, citing the existing literature or highlighting the potential discriminatory effect of QALYs. In Germany and the US, explicit cost-per-QALY decisions are restricted or prohibited, particularly within federal governmental programs.








### Decision modifiers




The use of decision modifiers, metrics aimed at addressing the challenges associated with QALYs, remains limited within the reviewed HTA guidelines. Of the countries assessed, only the UK incorporates a severity modifier in economic evaluation, introduced in 2022, which assigns a higher weighting to QALYs for treatments targeting severe diseases. In the US, the assessment process includes absolute and proportional shortfall calculations for evLYGs and QALYs to aid the decision-making process or benchmark with published literature, respectively, but these are excluded from the economic evaluation. In contrast, the HTA guidelines in France and Canada explicitly state that all health outcomes should be weighted equally.

### The use of willingness-to-pay thresholds

Table 1 summarizes the range of thresholds identified. Values, or the range of values, were reported only for the UK and US, where they support reimbursement decisions. No formal guidelines exist for the other reviewed countries. Spanish HTA reports refer to an estimated threshold following a scoping review of literature (3), but it is not used in the decision-making process. Importantly, the Spanish HTA process is currently under review with the intention to align with the European Union Joint Clinical Assessment process (4).

Table 1: The use of QALYs and WTP during HTA process

| Country   | Is QALY a priority metric in the base case? | Rationale   | Does a formal WTP threshold exist? | Rationale  |
|---|---|---|------------------------------------|--|
|  France (5)    |   | QALYs used when HRQoL is a major consequence of the intervention; otherwise, the evaluated health outcome is LYs  |                                    | No formal guidelines or references that specify WTP threshold  |
|  Germany (6)  |   | Economic evaluation supports pricing of new interventions, but QALYs in CUA apply only if QoL impact is demonstrated in the clinical benefit assessment |                                    |  |
|  Italy (7)   |   | QALY listed as one of the outcomes of economic evaluation; used alongside other metrics such as LYs   |                                    |  |
|  Spain (8)   |   | CUA, with health benefit reported in QALYs, listed as a first choice evaluation for medicines that provide a relevant additional clinical benefit       |                                    | No formal guidelines, however, reports refer to estimated threshold from the literature (€22,000 to €25,000/QALY)  |
|  UK (9)      |   | QALYs are a priority measure for CUA used to evaluate most interventions  |                                    | WTP threshold of £20,000 to £30,000 per QALY gained, or £100,000 per QALY gained for highly specialized technologies   |
|  Canada (10) |   | QALYs are a priority measure for CUA used to evaluate most interventions  |                                    | No formal guidelines or references that specify WTP threshold  |
|  US (11)     |   | evLYGs highlighted as a priority measure, QALYs included for comparison with other academic and global frameworks                                       |                                    | Results reported for thresholds of \$50,000, \$100,000, \$150,000, and \$200,000 for all assessments to accommodate the needs of decision makers across the US |

 Prominent use of QALYs     Non-use of QALYs     Limited use of QALYs

## Conclusion

The review highlighted a lack of standardized approach to the use of QALYs during the assessment of new technologies across the countries evaluated. None of the countries' HTA guidelines elaborate on their position and rationale regarding QALY use or non-use. The HTA processes in France, Germany, Italy, and Spain emphasize demonstration of clinical benefits, and these countries can be considered low utilizers of the QALY.

Furthermore, no explicit decision modifiers are used within economic evaluation outside of the UK. This variation highlights the lack of harmonization in HTA processes across countries, underscoring the need for transparent criteria, particularly in the application of QALYs and decision modifiers.

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### Abbreviations

|   |                                  |
|---|----------------------------------|
| CEA, cost-effectiveness analysis        | LY, life year                    |
| CUA, cost-utility analysis              | QALY, quality-adjusted life year |
| evLYG, equal value of life years gained | QoL, quality of life             |
| HRQoL, health-related quality of life   | WTP, willingness to pay          |
| HTA, health technology assessment       |                                  |