EE566

Inclusion of Caregiver Quality-of-Life in Economic Evaluations: Global HTA Perspectives and Impact

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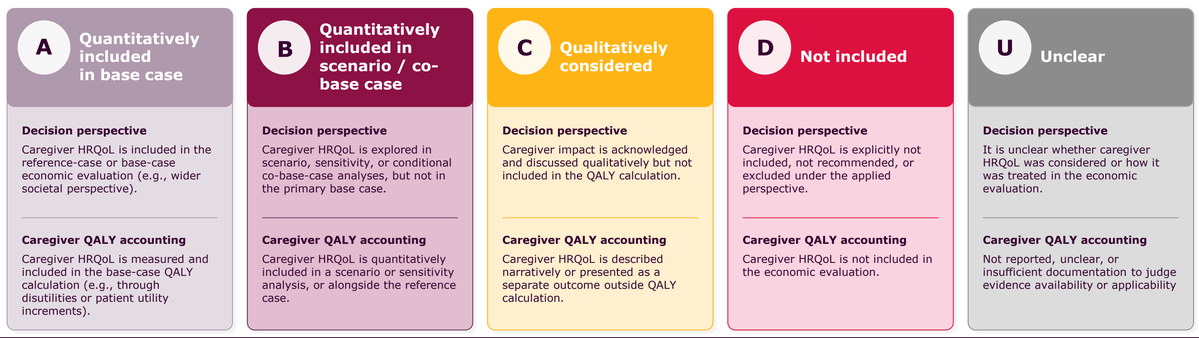
Objectives

In health technology assessments (HTA), inclusion of caregiver health-related quality of life (HRQoL) and associated costs is essential to capture the full societal impact of disease and treatment, as interventions often generate "spillover effects" beyond the patient, particularly for parents of children with (degenerative) rare diseases. Ignoring these effects can systematically undervalue health interventions and lead to suboptimal resource allocation. Yet it is not formally incorporated by many HTA authorities despite its potential to substantially influence the assessment of treatment benefits and value. Consequently, HTA decisions may be informed by an incomplete representation of the overall impact of treatment. This study assessed recent changes in global HTA practices regarding inclusion of caregiver HRQoL in cost-effectiveness analyses and evaluated their impact following the publication of Pennington et al. (2022).[1]

Methods

An AI-assisted targeted review of HTA methodological guidelines and recent assessments was conducted across major agencies in Europe, North America, and Asia-Pacific. We examined whether caregiver HRQoL is included in the reference case or in scenario/sensitivity analyses. Additionally, HTA reports for orphan drugs licensed for patients aged 0-18 years (1 Jan 2022 - 1 Oct 2026) were analysed to assess real-world application and impact on outcomes. All AI-identified HTA reports were reviewed and subsequently assessed by a Kintiga researcher. If multiple (re) assessments were available for the same product, indication and population, these were considered as one unique HTA; with the most recent economic evaluation informing the reimbursement decision/advice and the cut-off date for inclusion. Eligible HTAs were assessed based on their level of caregiver HRQoL inclusion, ranging from A – quantitatively included in the base case, to D – Not included (**figure 1**). HTAs without (publicly available) economic evaluation were excluded.

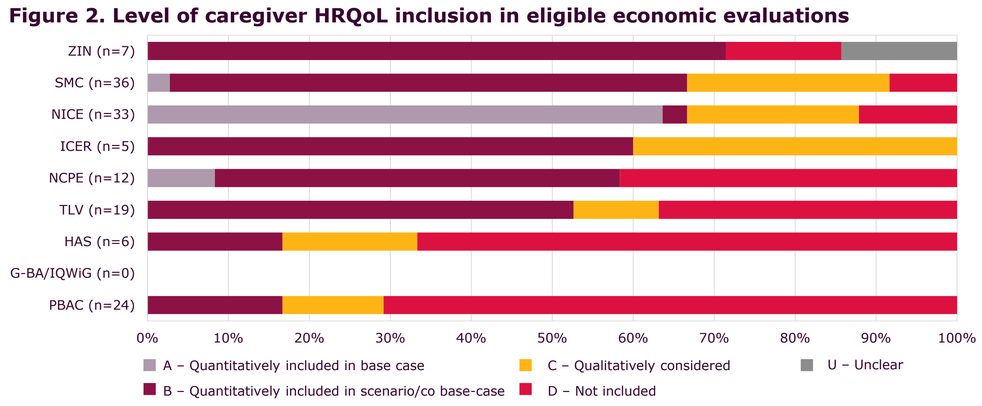
Figure 1. Level of caregiver HRQoL inclusion in economic evaluations – a continuum of approaches in HTA



Inclusion of caregiver HRQoL in paediatric, orphan drug HTAs (2022-2026)

Of the 216 identified potentially relevant HTAs, 142 met the eligibility criteria and 23 reported ICERs with and without inclusion of caregiver HRQoL. The extent to which caregiver HRQoL was incorporated varied substantially across HTA bodies. Quantitative inclusion in the base case was most common in NICE assessments (58%), whereas most other agencies included caregiver HRQoL primarily in alternative analyses, or did not include it quantitatively. This indicates that observed practice broadly reflected agency guidance, although consideration remained inconsistent within agencies. For TLV and HAS, real-world HTA practice appeared more conservative than methodological guidance, with relatively limited quantitative caregiver HRQOL inclusion (TLV: 53%; HAS: 17%) despite its permitted use in the base case (**figure 2**). Across the assessments reporting comparative ICERs, inclusion of caregiver HRQoL generally increased incremental QALYs and improved cost-effectiveness. However, impact ranged considerably, from a maximum ICER reduction of 66% (NCPE, givinostat), to a slight ICER increase of 6% (SMC, fosdenopterin; HAS, atidarsagene autotemcel). **Figure 3** shows the maximum ICER changes of HTAs reporting ICERs with and without caregiver HRQoL.

Figure 2. Level of caregiver HRQoL inclusion in eligible economic evaluations



Results

HTA guidelines

Since January 2022, several agencies, including NICE (2022, 2026), SMC (2022), NCPE/HIQA (2025), ZIN (2024), G-BA/IQWiG (2023, 2025) and ICER (2025), updated their guidance for conducting economic evaluations.[2-8] ZIN now mandates the inclusion of caregiver HRQoL in scenario analyses where relevant and HIQA explicitly mentions family/caregiver health spillovers as a secondary analysis, while ICER permits a societal co-base alongside the healthcare perspective.[4,5,8] The updates from NICE and G-BA have not resulted in changes regarding carer HRQoL inclusion, although NICE now explicitly requires the manufacturer to "show that the condition is associated with a substantial effect on carer's health-related quality of life and how the technology affects carers".[2]

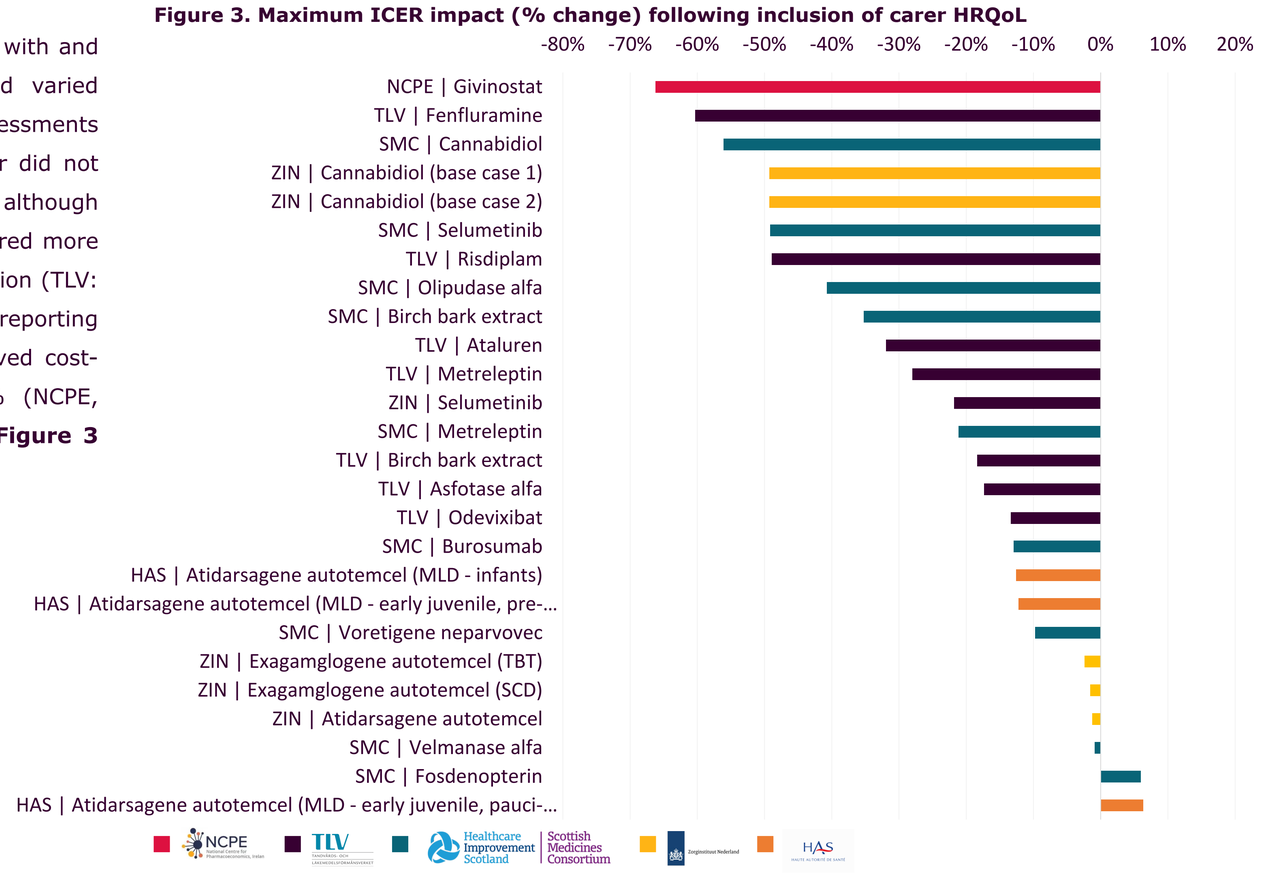
Overall, 5/9 (56%) of the included HTA bodies consider caregiver HRQoL in alternative analyses such as scenario's, sensitivity analyses, or as secondary co-base case (SMC, NCPE, ZIN, ICER, PBAC) and 3/9 (33%) consider it in the base case, if relevant (NICE, TLV, HAS). The guideline of one institute (11%) suggests it may be considered in the institute's report (IQWiG). **Table 1** provides an overview of the identified guidelines.

Table 1. Consideration of caregiver HRQoL in HTA guidelines

Country	HTA body	Caregiver HRQoL inclusion – guideline interpretation		
		Base case (A)	Scenario (B)	Notes
England	NICE	✓		"**All health effects**, whether for patients or, when relevant, carers"[2]
Scotland	SMC		✓	"If appropriate data on utilities/QALYs for carers or other groups other than the patients affected is provided as additional evidence this will need to be **presented separately** from the primary QALY analysis as it is outside the perspective adopted by the SMC"[3]
Ireland	NCPE		✓	"Consideration can also be given to the incorporation of the impacts on family and caregiver health (otherwise referred to as health spillovers) in economic evaluations of health technologies, as part of a **secondary analysis**"[4]
Netherlands	ZIN		✓	"The quality of life of caregivers should be considered in a **scenario analysis** if the duration of caregiving and/or the caregiver's quality of life is affected by the intervention"*[5]
Sweden	TLV	✓		"[…] societal-economic perspective. This means, among other things, that **all relevant costs and benefits** of treatment and illness, regardless of who bears them (region, municipality, state, patient, or relative), must be considered."**[9]
France	HAS	✓		"The reference case analysis should be based on a collective perspective, **covering all of the people or institutions affected (in terms of health effects or cost)** by the production of an intervention within the scope of the overall patient care"[10]
Germany	G-BA / IQWiG	?	?	"Interventions can also have consequences for those indirectly affected, for example, relatives and carers. If appropriate, **these consequences can also be considered** within the framework of the Institute's reports"[6,7]
USA	ICER		✓	"In addition [to the base case] each analysis should include an analysis using a **modified societal perspective**, which will include costs and outcomes beyond direct health care impacts.[8]
Australia	PBAC		✓	"[…] where the beneficiaries of health or other relevant outcomes are broader than the treated patient population (eg community, carers, dependants), include these as **supplementary analyses**"[11]

*While adopting a societal perspective, caregiver QoL falls outside the scope of ZIN's base case, **As of October 1st 2026, TLV introduced a new guideline

Figure 3. Maximum ICER impact (% change) following inclusion of carer HRQoL



Note: The 0% axis represents the analysis excluding caregiver HRQoL, which is used as reference point; whenever multiple scenarios including caregiver HRQoL were presented, the scenario with the largest impact was included in this figure

Conclusion

Global HTA guidance and practice regarding caregiver HRQoL remain heterogeneous. Although caregiver effects are increasingly recognised, they are often restricted to scenario analyses or omitted from economic evaluations. Where quantified, caregiver HRQoL can materially affect cost-effectiveness estimates, although both the magnitude and direction of the impact depend on the modelling approach. Greater methodological consistency and comparability are needed to support appropriate consideration of caregiver health effects and HRQoL, particularly in paediatric rare diseases with substantial family burden. This requires progress across the evidence-to-HTA pathway, including development of suitable and standardised preference-based measures, routine measurement in clinical studies, and clearer and consistently applied HTA guidance on methodological choices such as additive vs. disutility approaches, the caregiver QALY trap, and the number of caregivers included.

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