Comparative Analysis of HTA Guidelines on Indirect Costs and Caregiver Utilities: Japan vs. Four European Countries

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RWD151

Objectives

- This study compares the preferences of Japan and four European Health Technology Assessment (HTA) bodies regarding the inclusion of indirect costs and caregiver burden in health economic evaluations (HEEs) used to support drug reimbursement decisions

Methods

- Official guidance documents were identified through a targeted review of HTA agency websites in Japan (Center for Outcomes Research and Economic Evaluation for Health, C2H), Germany (IQWiG), France (HAS), Sweden (TLV), and the UK (NICE). Each was analysed for its approach to incorporating indirect costs and caregiver utilities in HEEs

Results

- All results are summarized in **Table 1**
- C2H and three European HTA bodies (NICE, IQWiG, HAS) exclude indirect costs from the base-case and allow them only in supplementary analyses
- C2H is more restrictive, permitting only productivity losses directly attributable to the evaluated intervention (e.g., impact on length of hospital stay), while productivity gains from improved health should be excluded. Furthermore, productivity losses can be included only when supported by Japanese data
- In contrast, TLV mandates a societal perspective, requiring all relevant indirect costs in base-case analyses
- All five HTA bodies permit caregiver utilities, but under different conditions. In Japan, they are allowed only in additional analyses from an extended public payer perspective, whereas NICE expects their inclusion when caregiver impact is clinically relevant

Table.1 Caregiver utilities and indirect costs – pharmacoeconomic guidelines from Japan and 4 European countries

Country (HTA body)	Japan (C2H)[1]	England & Wales (NICE)[2]	France (HAS-CEESP)[3,4]	Germany (IQWiG/G-BA)[5,6]	Sweden (TLV)[7-9]
Perspective	**Public payer**	**Healthcare system (NHS and PSS)**	**Collective or healthcare system**	**Restricted societal (SHI-insured)**	**Societal**
Costs to be included in base-case	**Direct medical**	**Direct medical**	**Direct medical and non-medical**	**Direct/non-medical (reimbursable) + patient**	**Direct and indirect costs**
Inclusion of indirect costs	**S Scenario only** • Excluded from base-case • Productivity can be included only in additional analysis, and only if: a. directly caused by the intervention (e.g., treatment-related shortening of hospital stay), and b. supported by Japanese data	**S Scenario only** • Excluded from base-case • Productivity costs can be presented as a scenario analysis	**S Scenario only** • Excluded from base-case • If relevant, indirect costs may be included in supplemental analysis • The losses of resources considered in the analyses are generally, losses of productivity, due to a total stoppage (absenteeism) or partial reduction of the productive activity of the population analysed	**S Scenario only** • Excluded from base-case • Productivity losses (handled primarily on the cost side) due to incapacity to work, occupational invalidity, and premature death or the reduced productivity can be included in additional analysis from extended perspective (e.g. societal perspective)	**✓ Required** • Societal perspective is standard; relevant indirect costs are required in the base-case
Inclusion of caregiver burden	**S Scenario only** • Caregiver-influenced QOL may be considered only in additional analyses from the public healthcare + long-term care payer perspectives and if actual data exist	**✓ Required** • Caregiver utilities should be included when carer impact is considered clinically relevant	**✓ Optional** • According to guidance "when the evaluated intervention has consequences on the health of other individuals, the population analysed may be extended to those individuals."	**? Restricted** • Only if considered appropriate by HTA body and included in framework perspective	**? Unclear** • Official guidance documents do not comment on inclusion of caregiver burden into base-case analysis • However, HTA reports suggest that caregiver utilities can be included in scenario analysis

Conclusions

- While all HTA bodies reviewed accept the inclusion of indirect costs and caregiver utilities, Japan adopts a notably more conservative and prescriptive stance. The C2H's strict limitations—particularly the requirement for Japanese data and narrow definitions of allowable indirect costs—highlight the need for localized evidence planning
- For global manufacturers, this underscores the importance of early engagement and tailored modelling to meet Japan's specific expectations, ensuring submissions are both compliant and compelling in a highly structured HTA environment

Abbreviations:
C2H, Center for Outcomes Research and Economic Evaluation for Health; CEESP, Commission d'Évaluation Économique et de Santé Publique; G-BA, Gemeinsamer Bundesausschuss; HAS, Haute Autorité de Santé; HTA, health technology assessment; IQWiG, Institut für Qualität und Wirtschaftlichkeit im Gesundheitswesen; NICE, National Institute for Health and Care Excellence; QOL, quality of life: SHI, statutory health insurance; TLV, Tandvårds- och läkemedelsförmånsverket

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