Beyond the QALY: An Analysis of Uncaptured Benefits in NICE Oncology Technology Appraisals (2023-2025)

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Introduction

There is growing recognition that standard cost-effectiveness analyses may not fully capture all benefits of new medicines.[1–4] Benefits not captured by quality-adjusted life year (QALY) calculations ("uncaptured benefits") have been formally considered within National Institute for Health and Care Excellence (NICE) technology appraisals (TAs) since the February 2022 update to the NICE manual; however, the impact of such benefits on decision-making remains unclear.[5,6]

Objective

To assess the frequency and nature of arguments relating to benefits not captured by the QALY calculation in oncology TAs submitted to the NICE, as well as the supporting evidence submitted and committee receptivity to such arguments.

Methods

- The first TAs to include a section on benefits not captured in the QALY calculation were published in January 2023. All oncology TAs with final draft guidance (FDG) published between 01 January 2023 and 11 June 2025 (N=86) were reviewed, and relevant data were extracted from these documents and the corresponding manufacturers' submissions.
- Acceptance of uncaptured benefits arguments by NICE was defined as explicit acknowledgment by the committee in the FDG that benefits existed beyond those modelled. Rejection was defined as an explicit statement by the committee that no benefits existed beyond those modelled.

Results

- Uncaptured benefits arguments were presented by manufacturers in 50 of 86 TAs (58%), with a year-on-year increase from 12/33 (36%) in 2023 to 17/20 (85%) in the first half of 2025 (**Figure 1**). Acceptance of uncaptured benefits arguments by the committee also increased over this period (**Figure 1**).
- Uncaptured benefit arguments presented were most often related to the wider societal effects, experience of care and unmet needs aspects of the Association of the British Pharmaceutical Industry (ABPI) value elements framework (**Figure 2**).[7] There was no clear trend in acceptance or rejection of specific uncaptured benefits arguments by committees.
- Manufacturers presented no evidence to support the submitted uncaptured benefits arguments in a considerable proportion of TAs (30%, n=15/50). Of the remaining 35 TAs presenting uncaptured benefits arguments, manufacturers presented multiple sources of evidence in the majority of cases (57%, n=20/35). The quality of evidence sources was highly variable across TAs (**Figure 3**).

Impacts of Uncaptured Benefits on the Willingness-To-Pay Threshold

- When the incremental cost-effectiveness ratio (ICER) exceeds £20,000 per QALY, NICE consider several factors when selecting an appropriate WTP threshold (WTPT), including uncaptured benefits. A specific WTPT was defined in 42 TAs included in this review. Although the majority of TAs with a specified WTPT in which uncaptured benefits were accepted by the committee were assigned a WTPT of £30,000 (56%; n=10/18), some (17%; n=3/18) were assigned a WTPT of £20,000 (**Figure 4**). The impact of uncaptured benefits on WTPTs therefore remains unclear and must be considered in the context of other factors, such as uncertainty (explored further in **Poster HTA105 - Determinants of Willingness to Pay Thresholds in NICE Oncology Technology Appraisals).**

Conclusion

While the inclusion of uncaptured benefits arguments in oncology TAs is increasing, committee acceptance remains low. There is substantial variation in the arguments submitted and quality of the supporting evidence submitted. Although acknowledgement of these benefits appears to be increasing, the impact on reimbursement decisions remains unclear due to limited transparency in the decision-making process.

Figure 1: Frequency and Acceptance of Uncaptured Benefits Arguments Over Time

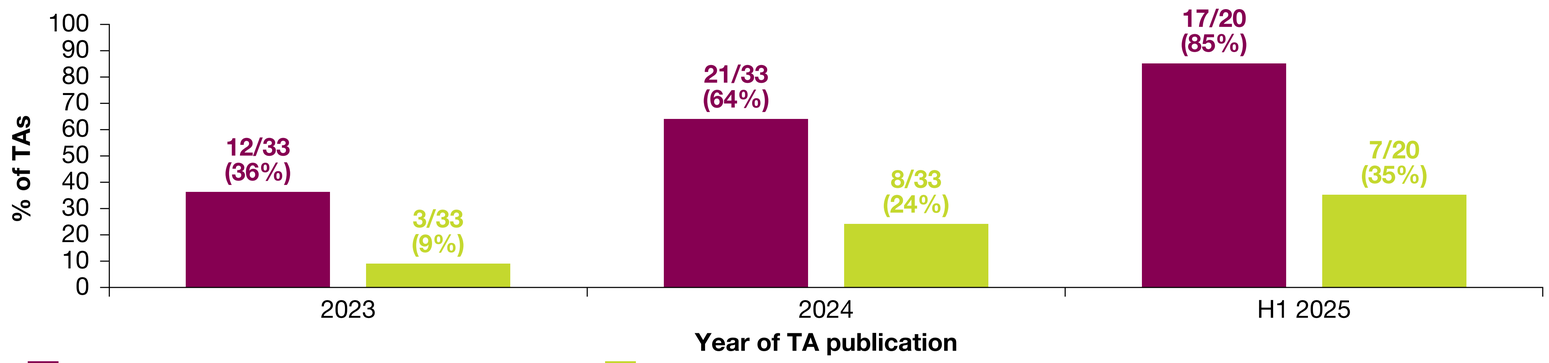
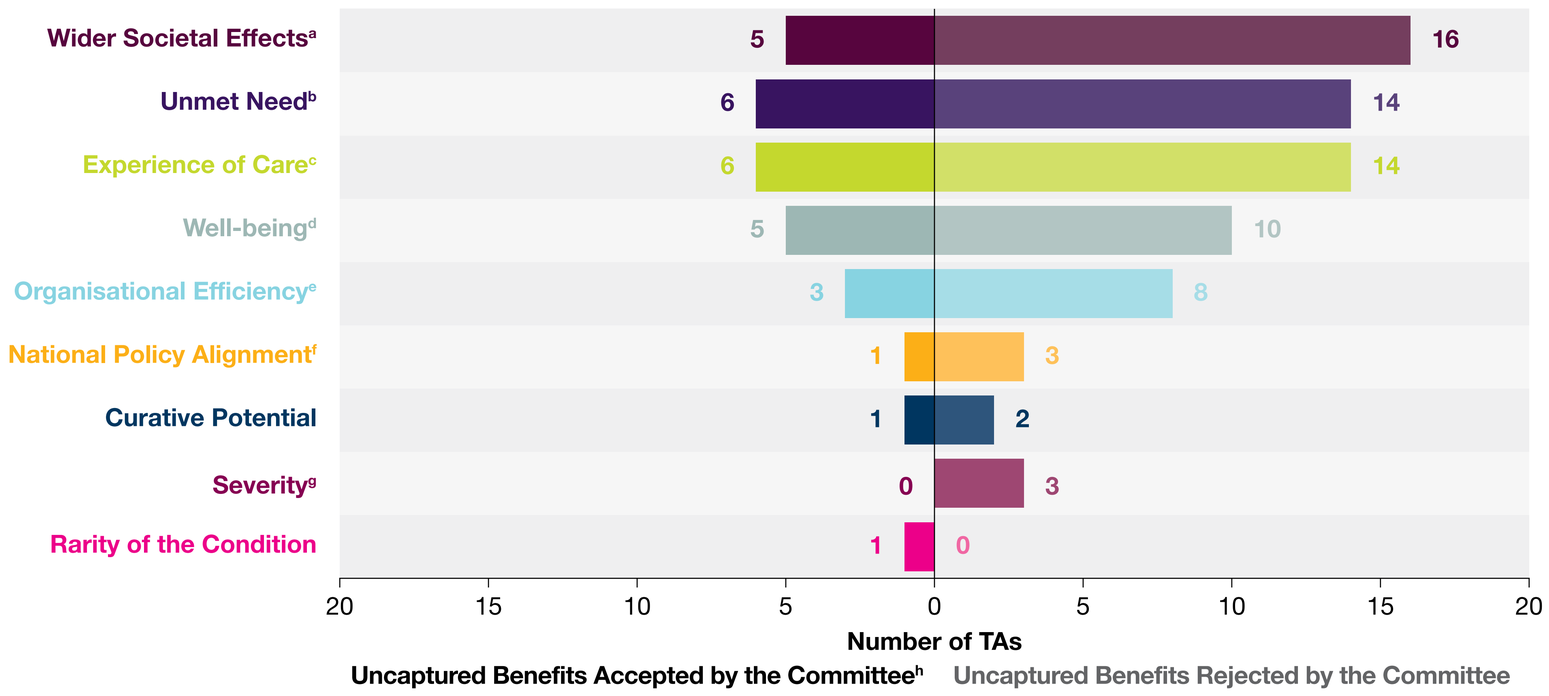
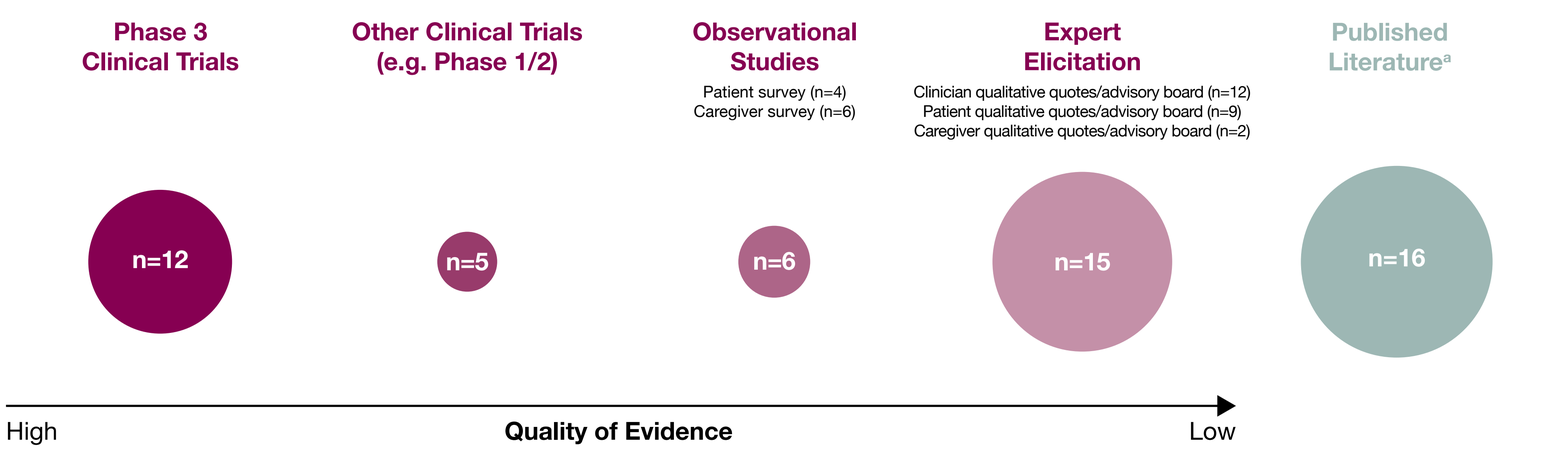


Figure 2: Categories of Uncaptured Benefits Arguments Presented Across TAs



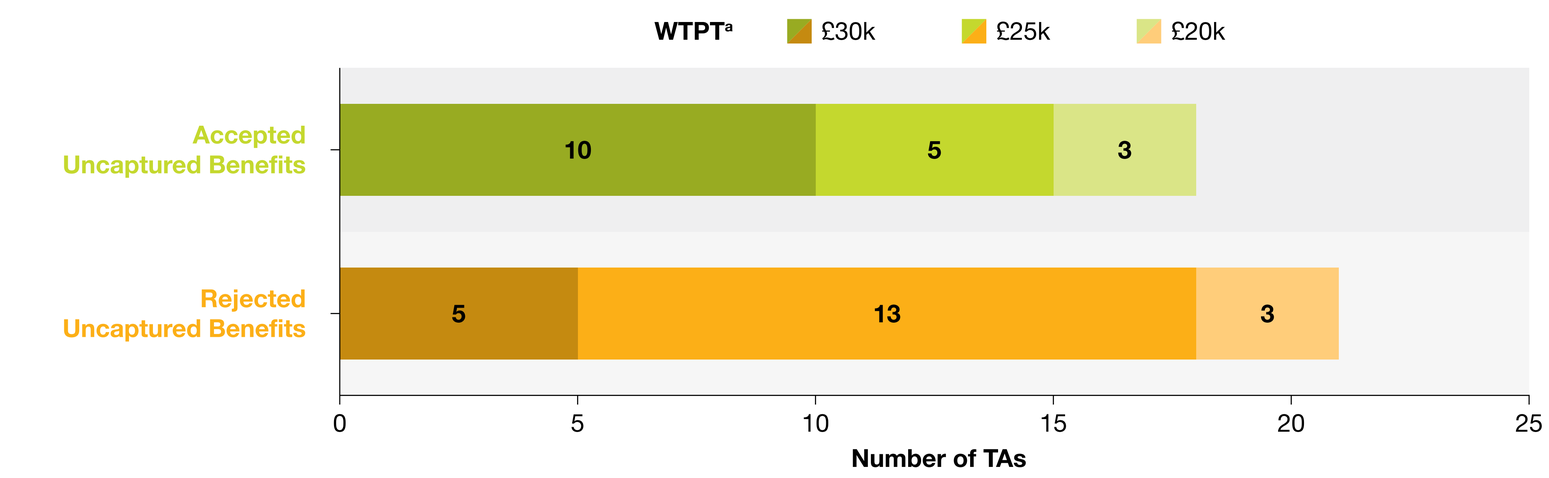
Footnotes: [a]Wider Societal Effects: productivity, caregiver QoL. [b]Unmet Need: addressing a very high unmet need, possibility to benefit from future treatments. [c]Experience of Care: number of hospital visits/appointments, easier administration, reduced adverse events. [d]Well-being: reduced anxiety, increased hope. [e]Organisational Efficiency: number of hospital visits/appointments, NHS capacity issues. [f]National Policy Alignment: sustainability benefits. [g]Severity has been formally included in the QALY calculation through the severity modifier since 2022. [h]In some TAs (n=4) the committee did not accept the uncaptured benefits argument submitted by the company but did accept an uncaptured benefits argument raised by clinician or patient stakeholders during the appraisal process. The data included included in this figure specifically relate to the uncaptured benefits argument submitted by the company.

Figure 3: Evidence Used to Support the Presented Uncaptured Benefits Arguments



Footnotes: [a]The quality of evidence presented in published literature is highly variable and may be high or low depending on the characteristics of the presented study.

Figure 4: Impact of Uncaptured Benefits Arguments on WTP thresholds



Footnotes: [a]Some appraisals did not report an ICER threshold or did not require one.

Abbreviations:

ABPI: Association of the British Pharmaceutical Industry; **FDG:** final draft guidance; **ICER:** incremental cost-effectiveness ratio; **ISPOR:** International Society of Pharmacoeconomics Outcomes Research; **NHS:** National Health Service; **NICE:** National Institute for Health and Care Excellence; **QALY:** quality-adjusted life year; **QoL:** quality of life; **TAs:** technology appraisals; **UK:** United Kingdom; **WTP:** willingness-to-pay; **WTPT:** willingness-to-pay threshold.

References:

[1]Health Economics Methods Advisory (2025). Available at: https://hemamethods.org/2025/03/18/health-economics-methods-advisory-group-selects-first-area-for-study-assessing-treatment-benefits-appropriate-to-consider-in-hta-decision-making/ [Last accessed 29 Aug 25]; [2]Lakdawalla D. et al. Value Health 2018;21(2):131–9; [3]Neumann P. et al. Value Health 2022;25(4):558–65; [4]Shafrin J. et al. Forum Health Econ Policy 2024;27(1):29–116; [5]NICE (2025). NICE health technology evaluations: the manual. Available at: https://www.nice.org.uk/process/pmg36/resources/nice-health-technology-evaluations-the-manual-pdf-72286779244741 [Last accessed 27 Aug 2025]; [6]Atkinson E. et al. HTA193. Presented at ISPOR Europe, 12–15 November 2023. Copenhagen, Denmark; [7]The Association of the British Pharmaceutical Industry (2020). Available at: https://www.abpi.org.uk/media/ikrh0oqz/abpi-extended-value-appraisal-proposal-for-the-nice-methods-review.pdf [Last accessed 29 Aug 25].

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