How EAG Recommendations Affect Reimbursement Decisions in the UK – A Thematic Analysis

HTA384

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SUMMARY

OBJECTIVES

- HTAs are essential for determining reimbursement eligibility of new therapies in the UK, aiding informed health resource allocation
- NICE provides standardized guidelines for HTA dossier submissions, while EAGs critically review clinical and economic evidence for rigorous assessments
- A thematic analysis identified key factors influencing NICEs final negative reimbursement decisions for new therapies in the UK.

METHODS

- HTA dossiers published on the NICE website between 1st January 2022 and 31st December 2023 were reviewed[1].
- Therapies with negative recommendations from NICE were included in the analysis, excluding withdrawn or COVID-19 submissions.
- Key EAG comments and final reasons for negative recommendations were examined, including clinical data quality and methodology, cost-effectiveness, data generalisability to the NHS, comparative effectiveness, and evidence gaps.

FINDINGS

- 16 appraisals received negative recommendations (oncology: 12, sleep apnea: 2, dermatology: 1, depression: 1)
- Key issues were extracted were failure to meet cost-effectiveness, uncertainty in the clinical evidence, uncertainty in survival data, uncertainty in utility data, uncertainty in the model structure, and failure to explore additional scenarios
- End-of life criteria applied to 50% of cases, all assessed against NICEs £20,000 threshold.

BACKGROUND & AIMS

- Heath Technology Assessments (HTAs) play a vital role in determining the reimbursement eligibility of new therapies within the UK healthcare system, supporting informed decision-making for resource allocation.
- The National Institute for Health and Care excellence (NICE) in England provides comprehensive guidelines for the HTA dossiers, establishing standardised requirements for submissions to ensure robust and consistent evaluations. Evidence Assessment Groups (EAGs) conduct in-depth reviews of HTA dossiers submitted to NICE, critically analysing clinical and economic evidence to support transparency and rigour in the assessment process[2]
- A thematic analysis was conducted to identify key factors that significantly impact NICE's final reimbursement decisions, aiming to clarify the criteria that influence outcomes for new therapies in England.
- By narrowing the focus to these specific factors, the review aimed to identify consistent themes in the EAG's critiques and NICE's rationale behind negative recommendations.

METHODS

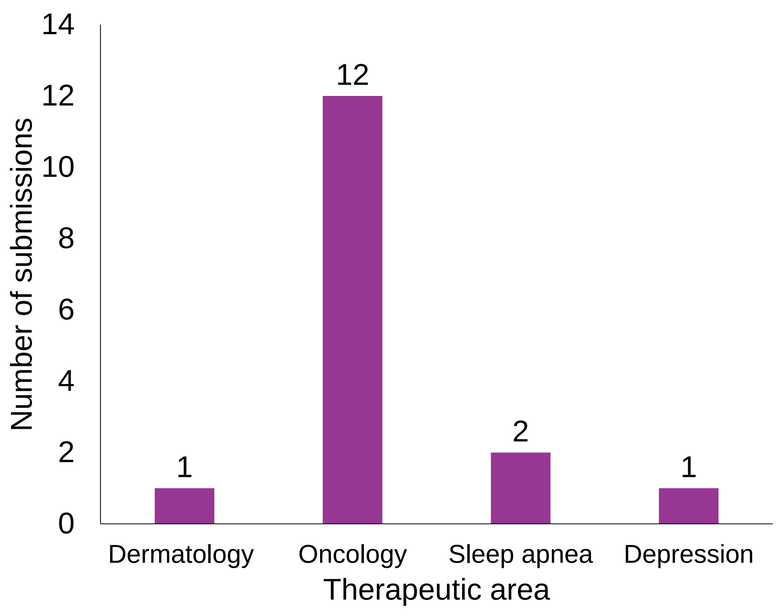
- A targeted review was undertaken to analyse HTA dossiers published on the NICE website between 1st January 2022 and 31st December 2023.
- This review specifically included only those therapies that received a negative recommendation from NICE, with exclusions applied to withdrawn dossiers and those related to COVID-19 treatments to maintain focus on standard evaluations.
- Each dossier was systematically examined, capturing key comments from EAGs alongside NICE's final reasons for issuing a negative recommendation.
- Analysis criteria included:
  - Clinical data quality and methodology
  - Data generalisability to the NHS
  - Evidence gaps
  - Cost-effectiveness

RESULTS

- A total of 16 appraisals received a negative recommendation across 4 different indications, including oncology, n=12; sleep apnoea, n=2; dermatology, n=1; depression, n=1 across 2022 and 2023.
- In oncology, the most common reason cited for negative recommendations, excluding cost-effectiveness, was uncertainty in clinical data and methodology. This was often due the rarity of the disease meaning only single-arm trials were available. The ITCs used to support these trials were often uncertain and survival data was generally immature.

REASON FOR DECISION	NUMBER OF APPRAISALS	RATIONALE
Failure to meet cost-effectiveness	15	Not meeting the threshold is a key determinant in for NICE decision making.
Uncertainty in the source of clinical evidence	8	Uncertainty in clinical evidence is a causative factor of a negative decision. Within our data, the most common piece of uncertainty was generalisability to NHS clinical practice. Immature data and uncertain ITCs were also key in impacting decision making.
Uncertainty in survival data	7	If survival data is used within a NICE appraisal, particularly if it is used in modelling, maturity of data and choice of parametric distributions are key considerations. If data is immature, it needs to be robustly validated by UK clinicians.
Uncertainty in utility data	6	It is important to generate utilities using NICE's preferred methodology, and to be transparent in how they have been generated,
Uncertainty in model structure	4	When designing an economic model for use in a NICE appraisal, it is important that robust long-term evidence is used, and that the model is reflective of UK clinical practice.
Failure to explore additional scenarios	1	If the committee request additional scenarios to be analysed within your appraisal, failure to do so will lead to a great deal of uncertainty and a high chance of a negative decision.

Figure 1: Negative recommendations by therapeutic area



- Of those submissions with a negative recommendation, 25% (n=3/12) were recommended for the Cancer Drugs Fund.
- The two submissions in dermatology and depression had high levels of uncertainty in their clinical evidence and utility data, with limited generalisability to the NHS. Both submissions in sleep apnoea lacked robust clinical evidence and appropriate derivation of utilities, with one failing to produce probabilistic results.
- For the one submission in depression, the company used an excess effect on mortality in their model, which was deemed highly uncertain by the committee.
- End of life criteria was applied to 50% of submissions (n=8/16). Due to high levels of uncertainty, all submissions were assessed against NICE's standard willingness to pay threshold of £20,000.

CONCLUSIONS

- Numerous factors influence reimbursement decisions in the UK. Some of the key negative reimbursement decisions in 2022 and 2023 resulted from failure to meet cost effectiveness, ungeneralisable and immature data within the clinical evidence, and uncertain methods of utility generation.
- When submitting an appraisal to NICE, it is important for manufacturers to consider how their evidence lends itself to how the product is expected to be used in clinical practice, and how robust and mature their long-term or survival data is. Robust validation from UK clinicians can help to mitigate these uncertainties.
- These insights offer valuable information for companies aiming to align with NICE and EAG requirements.

References

1. NICE (2024) *Published guidance, Nice Advice and Quality Standards: Guidance: Nice, NICE website: The National Institute for Health and Care Excellence*. Available at: https://www.nice.org.uk/guidance/published?from=2022-01-01&to=2023-12-11 (Accessed: 11 November 2024).
2. NICE (2024) *Overview: How we develop technology appraisal guidance, NICE*. Available at: https://www.nice.org.uk/about/what-we-do/our-programmes/nice-guidance/technology-appraisal-guidance/overview-how-we-develop-technology-appraisal-guidance (Accessed: 11 November 2024).

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