A Comparative Analysis of Reimbursement Patterns for Targeted and Immunotherapies in NSCLC Across EU HTA Bodies

Authors: Gulchehak Kaur[1], Bikramaditya Ghosh[1], Abhra Roy Choudhury[1], Pixy Banerjee[1]
[1]PharmaQuant Insights Pvt. Ltd.

HTA 2

PharmaQuant

Focused Insights, Better outcomes

INTRODUCTION

- Non-small cell lung cancer (NSCLC) is the leading cause of cancer-related mortality worldwide and accounts for over 1.5 million deaths annually.[1]
- Targeted and immunotherapies have transformed the NSCLC treatment landscape, demonstrating superior progression-free survival (PFS) and overall survival (OS) outcomes compared with chemotherapy.[1]
- Therapies approved by the European Medicines Agency (EMA) are evaluated by national health technology assessment (HTA) bodies, whose varying evidence standards, cost-effectiveness thresholds, and healthcare priorities shape reimbursement decisions and patient access across Europe.

OBJECTIVE

- To compare reimbursement decisions in EMA-approved targeted and immunotherapies for NSCLC, assess decision consistency and variability, and identify key factors influencing decisions across United Kingdom (UK) and European HTA bodies.

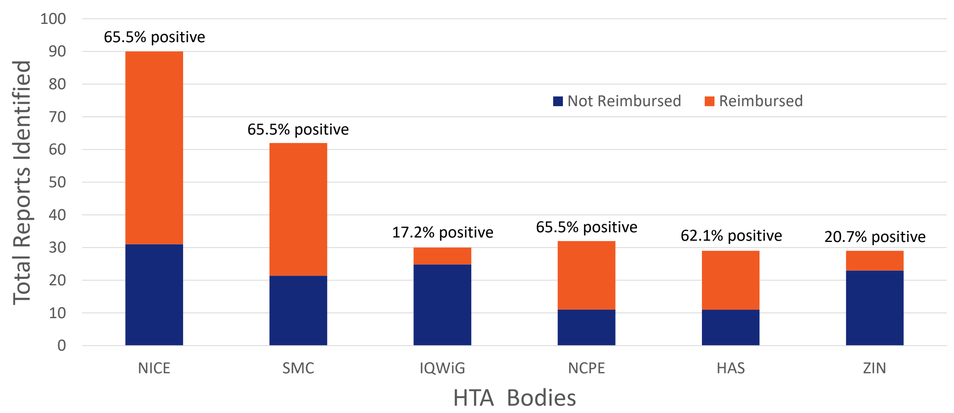
METHODS

- Publicly available HTA reports on EMA-approved targeted and immunotherapies for NSCLC were identified across HTA bodies in the UK, Germany, France, Scotland, the Netherlands, and Ireland.
- Incremental cost-effectiveness ratios (ICERs), willingness-to-pay (WTP) thresholds, and other information concerning decision rationales were all extracted.
- Trends, discrepancies, and alignments between the HTA bodies' decisions and their key drivers were identified.

RESULTS

- The EMA has approved 22 targeted and 7 immunotherapies for NSCLC.
- Positive reimbursement decisions were most often issued by NICE, SMC, and NCPE while greater variation was observed between Germany, France, and the Netherlands (Figure 1).
- Clinical efficacy remains a consistent primary determinant of positive decisions (Table 1).
- NICE, SMC, and NCPE also emphasize cost-effectiveness considerations.
- Of the HTA bodies included, IQWiG most greatly emphasizes head-to-head comparisons with local standards of care (e.g. if no suitable German data exists, IQWiG may conclude no additional benefit was proven despite efficacy shown in global studies).
- Immature trial data and subsequent uncertainty due to strong assumptions and survival extrapolations contributed to negative decisions.

Figure 1. Reimbursement Decisions Across HTA Bodies



Abbreviations: HAS=Haute Autorité de Santé; IQWiG=Institute for Quality and Efficiency in Health Care; NCPE=National Centre for Pharmacoeconomics; NICE=National Institute for Health and Care Excellence; SMC=Scottish Medicines Consortium; ZIN=Zorginstituut Nederland

Table 1. Summary of Key Decision Drivers

	UK	Scotland	Ireland	Germany	France	Netherlands
Positive decision drivers	• ICER below or close to the NICE £50,000 WTP threshold • Relevant model comparators according to biomarker • Biomarker-driven targeting	• Use of Patient Access Schemes (PAS) and flexible managed entry agreements • Cost-effectiveness with discounts • Evidence of unmet need	• Negotiated pricing agreements • Strong clinical rationale for biomarker-targeted therapies	• Trial alignment with German clinical practice • Comparison with current standard of care	• High unmet medical need, especially in advanced and metastatic disease • Improvement in quality of life (QoL) or reduced toxicity	• Cost-effectiveness within Dutch WTP considerations • Negotiated price agreements
Negative decision drivers	• Uncertainty in long-term survival extrapolations • Rare subgroups with limited evidence • Lack of commercial access scheme	• Limited PACE (patient and clinician engagement) case in favour of the new therapy	• Lack of clear survival benefit • Survival outcome extrapolation inconsistencies	• Reliance on surrogate trial endpoints • Non-randomized trial • Lack of biomarker-appropriate comparator data	• Limited or uncertain clinical benefit	• Concerns about long-term affordability or proportionality of benefit vs cost • Uncertainty concerning long-term affordability

CONCLUSION

- Therapies showing robust overall and progression-free survival gains, QoL improvements, acceptable ICERs within country-specific WTP thresholds, and favourable safety profiles received consistent recommendations across HTA bodies.
- Appropriate trial comparator selection based on biomarkers is crucial for a strong submission given the highly specific nature of targeted and immunotherapies and the variation within the NSCLC disease area.
- Commercial or patient access schemes and pricing agreements may support submissions in cases where cost-effectiveness concerns may otherwise lead to a negative reimbursement decision.

REFERENCES

1. Koban MU, Hartmann M, Amexis G, Franco P, Huggins L, Shah I, et al. Targeted Therapies, Novel Antibodies, and Immunotherapies in Advanced Non-Small Cell Lung Cancer: Clinical Evidence and Drug Approval Patterns. Clin Cancer Res. 2024;30(21):4822-33.

Presented at ISPOR Europe 2025; Glasgow, Scotland, UK; November 9-12, 2025