Impact of Companion Diagnostics (CDx) on Reimbursement Outcomes of Breast Cancer and NSCLC Therapies

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Background

+ Precision medicine has revolutionised oncology by tailoring treatment based on patients' genomics.
+ Companion diagnostics (CDx) - in vitro tests developed alongside targeted therapies - play a critical role in identifying patients most likely to benefit, thereby supporting more effective and personalised treatment strategies.

Objectives

This study aimed to:

+ Assess the impact of CDx on health technology assessment (HTA) and reimbursement outcomes for breast cancer and non-small cell lung cancer (NSCLC) (excluding generics).
+ Focus on drugs approved by the European Medicines Agency (EMA) between 2019 and 2024 and the corresponding HTA/ reimbursement decisions across four key European markets: France (HAS), Germany (G-BA), Italy (AIFA), and Spain (AEMPS).

Methods

1 Drug Selection

Identified drugs approved by the EMA between 2019-2024, noting any CDx requirements.

2 Indication Filtering

Shortlisted drugs with approved indications in breast and NSCLC cancer.

3 HTA and Reimbursement Analysis

Analysed HTAs and reimbursement decisions in France, Germany, Italy, and Spain.

4 Final Dataset

30 approved indications across 19 drugs were assessed[1].

Results

+ The analysis was completed on 26 June 2025, and results reflect the status of HTA decisions as of that date[1-6].
+ The majority of indications required a CDx as specified in the EMA label; however, HTA decisions for these CDx-associated indications varied significantly across countries (Figure 1) (Figure 2).
+ In NSCLC, French HTA decisions for CDx indications were mixed (Figure 1).
+ In Germany, all NSCLC indications- CDx and non-CDx- received either a "no-added benefit" rating or were still pending (Figure 1).
+ Italy approved only CDx-linked indications, whereas Spain mainly issued positive recommendations for all NSCLC (Figure 1).
+ In breast cancer, Italy showed consistent reimbursement outcomes regardless of CDx status (Figure 2).
+ Germany and France favoured non-CDx indications, while Spain issued mostly positive recommendations across all indications (Figure 2).

Figure 1. Overview of reimbursement outcomes for NSCLC indications with CDx and non-CDx requirements across France, Germany, Italy, and Spain (n=17)

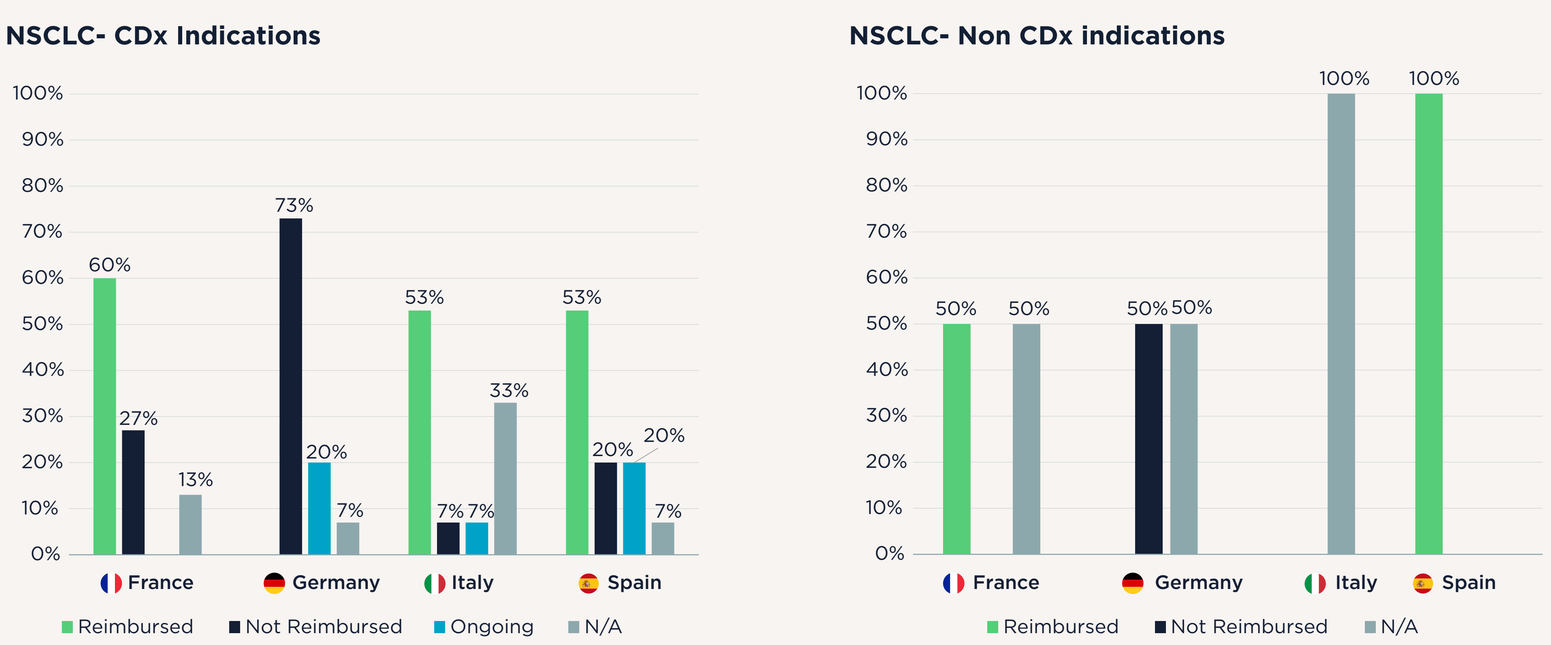
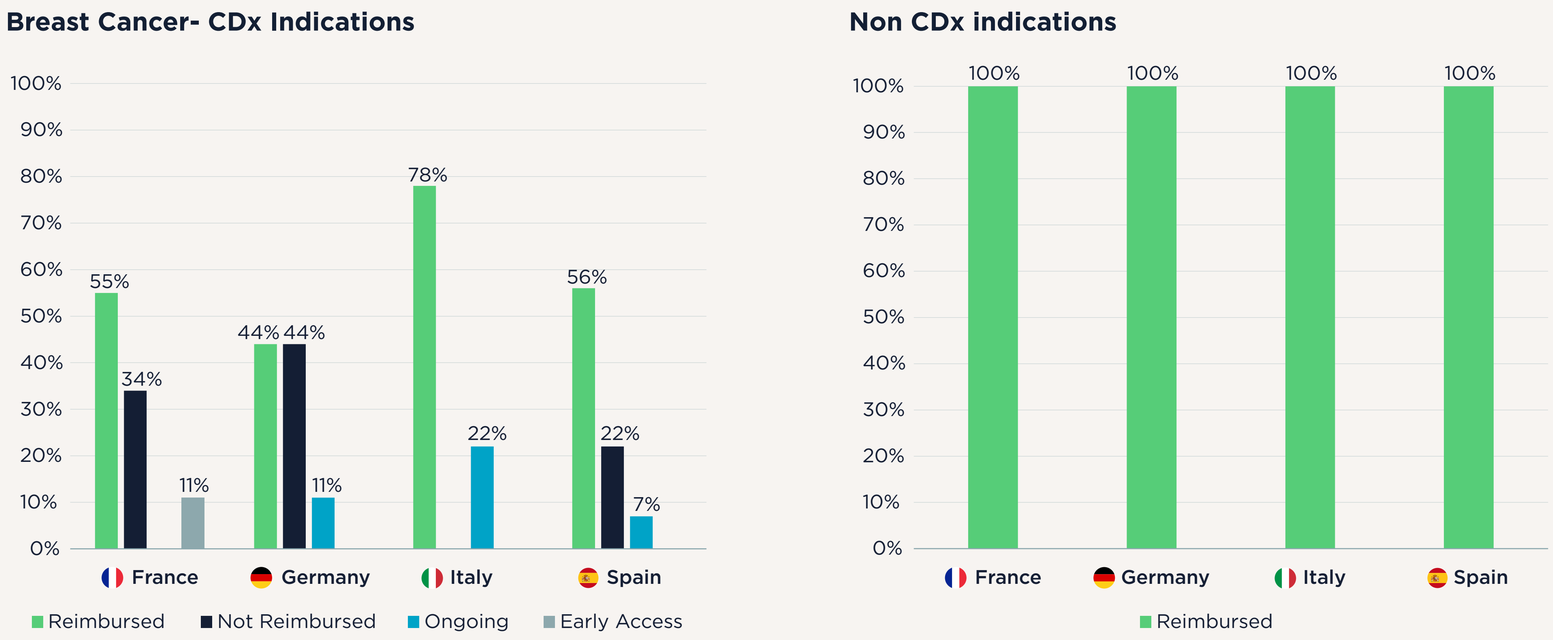


Figure 2. Overview of reimbursement outcomes for breast cancer indications with CDx and non-CDx requirements across France, Germany, Italy, and Spain (n=12)



Notes: 1. One indication was excluded from the analysis following an EMA update, with reimbursement outcomes based on the revised indication. 2. For two indications, G-BA split the population into four subgroups with varying ratings. As three received "no added benefit" and only one "considerable added benefit," the table reflects the majority rating.

Conclusion

+ Reimbursement patterns for CDx-linked therapies varied across countries reflecting differences in national regulations and approaches to CDx reimbursement.
+ This variability complicates decision-making and adds to the unpredictability of CDx therapy reimbursement, which is likely shaped by evolving European and country-specific precision medicine policies.

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Abbreviations:
CDx - Companion Diagnostics
HTA - Health Technology Assessment
NSCLC - Non-Small Cell Lung Cancer
EMA - European Medicines Agency
HAS - French National Authority for Health
G-BA - Federal Joint Committee
AIFA - Italian Medicines Agency
AEMPS - Spanish Agency of Medicines and Medical Products