

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

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This section provides supplementary information to support the analysis presented in the poster. The analysis was completed on 26 June 2025, and the results reflect the status of HTA decisions as of that date.

Table 1: Overview of drugs indicated for NSCLC and their reimbursement outcomes across the EU4

	Drugs	Indication	FR HAS	DE G-BA	IT AIFA	ES AEMPS
CDx (n=15)	Entrectinib	ROS1 positive, advanced NSCLC	SMR insufficient	No added benefit	Class H	Not recommended
	Capmatinib dihydrochloride monohydrate	Advanced, 14 METex14 skipping' NSCLC	SMR insufficient	No added benefit	Class H	Recommended
	Tepotinib hydrochloride monohydrate	Advanced, 14 METex14 skipping' NSCLC	N/A	No added benefit	Class H	Recommended
	Selpercatinib	Advanced RET fusion positive NSCLC	SMR weak, ASMR V	No added benefit	Class H	Recommended
	Amivantamab	Advanced/ metastatic second-line NSCLC with activating EGFR Exon 20 insertion mutations	SMR insufficient	No added benefit	Class H	Not Recommended
		In combination with carboplatin and pemetrexed for advanced first-line treatment NSCLC Exon 20 insertion mutations	SMR important, ASMR IV	Ongoing	N/A	Ongoing
		In combination with carboplatin and pemetrexed for advanced NSCLC with EGFR Exon 19 deletions or Exon 21 L858R substitution mutations	SMR important, ASMR IV	Ongoing	N/A	Ongoing
		In combination with lazertinib for the first-line treatment advanced NSCLC with EGFR exon 19 deletions or exon 21 L858R substitution mutations	N/A	Ongoing	N/A	Ongoing
	Lorlatinib	ALK-positive advanced second-line NSCLC	SMR weak, ASMR IV	No added benefit	N/A	Recommended
		ALK-positive advanced first-line NSCLC	SMR important, ASMR IV	No added benefit	Class H	Recommended
		ALK positive advanced NSCLC with disease progression	SMR weak, ASMR V	No added benefit	Class H	Recommended
	Sotorasib	Advanced NSCLC with KRAS G12C mutation	SMR weak, ASMR V	No added benefit	Class H	Recommended
	Adagrasib	Advanced NSCLC with KRAS G12C mutation	SMR weak, ASMR V	N/A	Class Cnn	N/A
	Dacomitinib monohydrate	Advanced/ metastatic NSCLC with EGFR activating mutations	SMR important, ASMR V	No added benefit	Class C	Recommended
	Trastuzumab deruxtecan	Advanced NSCLC with activating HER2 mutation	SMR insufficient	No added benefit	N/A	Not recommended
Non-CDx (n=2)	Sugemalimab	Advanced ROS1 positive, NSCLC	N/A	N/A	N/A	N/A
	Tremelimumab	in combination with durvalumab and platinum-based chemotherapy metastatic NSCLC	SMR moderate; ASMR IV	No added benefit	N/A	Recommended

Table 2: Overview of drugs indicated for breast cancer and their reimbursement outcomes across the EU4

	Drugs	Indication	FR HAS	DE G-BA	IT AIFA	ES AEMPS
CDx (n=9)	Alpelisib	In combination with fulvestrant for HR-positive, HER2-negative, advanced/ metastatic breast cancer with a PIK3CA mutation	SMR insufficient	Minor added benefit	Class H	Recommended
		Neoadjuvant treatment of HER2-positive, advanced, inflammatory breast cancer	SMR insufficient	No added benefit	Class H	Recommended
	Pertuzumab;trastuzumab	HER2-positive early breast cancer at high risk of recurrence	SMR insufficient	Minor added benefit	Class H	Not recommended
		In combination with docetaxel for HER2-positive metastatic or locally recurrent unresectable breast cancer	SMR important, ASMR V	No added benefit	Class H	Recommended
	Talazoparib	Advanced or metastatic breast cancer with BRCA mutated HER2 negative	SMR important, ASMR V	Considerable added benefit	Class H	Not recommended
		Unresectable/ metastatic HER2 positive breast cancer (≥ 2 prior treatment)	SMR moderate; ASMR V	Non-quantifiable added benefit	Class H	Recommended with restrictions
	Trastuzumab deruxtecan	Unresectable/metastatic HER2 positive breast cancer, with recurrence within 6 month of adjuvant chemotherapy	SMR important; ASMR III	Ongoing	Class H	Recommended with restrictions
		In combination with fulvestrant for oestrogen receptor ER-positive, HER2-negative locally advanced/ metastatic breast cancer	SMR weak, ASMR V	No added benefit (Sb1) Considerable added benefit (Sb2)	Class Cnn	Ongoing
	Capivasertib	ER positive, HER2-negative, advanced/ metastatic breast cancer with ESR1 mutation	SMR moderate; ASMR V	No added benefit (Sb1) Considerable added benefit (Sb2)	Class Cnn	Ongoing
		In combination with trastuzumab and capecitabine HER2 positive advanced/ metastatic breast cancer	SMR important; ASMR III	Considerable added benefit	Class H	Recommended
	Tucatinib	Unresectable/ metastatic triple-negative breast cancer (≥ 2 prior treatment)	SMR important, ASMR III	Major added benefit	Class H	Recommended with restrictions
		Unresectable / metastatic HR-positive, HER2-negative breast cancer with endocrine-based therapy	SMR important, ASMR IV	Considerable added benefit	Class H	Recommended
		In combination with trastuzumab and capecitabine HER2 positive advanced/ metastatic breast cancer	SMR important; ASMR III	Considerable added benefit	Class H	Recommended
Non-CDx (n=3)	Sacituzumab govitecan	Unresectable / metastatic HR-positive, HER2-negative breast cancer with endocrine-based therapy	SMR important, ASMR IV	Considerable added benefit	Class H	Recommended

Legend: Recommended Recommended with restrictions Not Recommended Ongoing Not available

Abbreviations: AEMPS, Agencia Española de Medicamentos y Productos Sanitarios (Spanish Agency of Medicines and Medical Devices); AIFA, Agenzia Italiana del Farmaco (Italian Medicines Agency); CDx, companion diagnostic; EGFR, epidermal growth factor receptor; EU4, France, Germany, Italy, and Spain; G-BA, Gemeinsamer Bundesausschuss (Federal Joint Committee, Germany); HAS, Haute Autorité de Santé (French National Authority for Health); HTA, health technology assessment; NSCLC, non-small cell lung cancer; Sb, subpopulation.