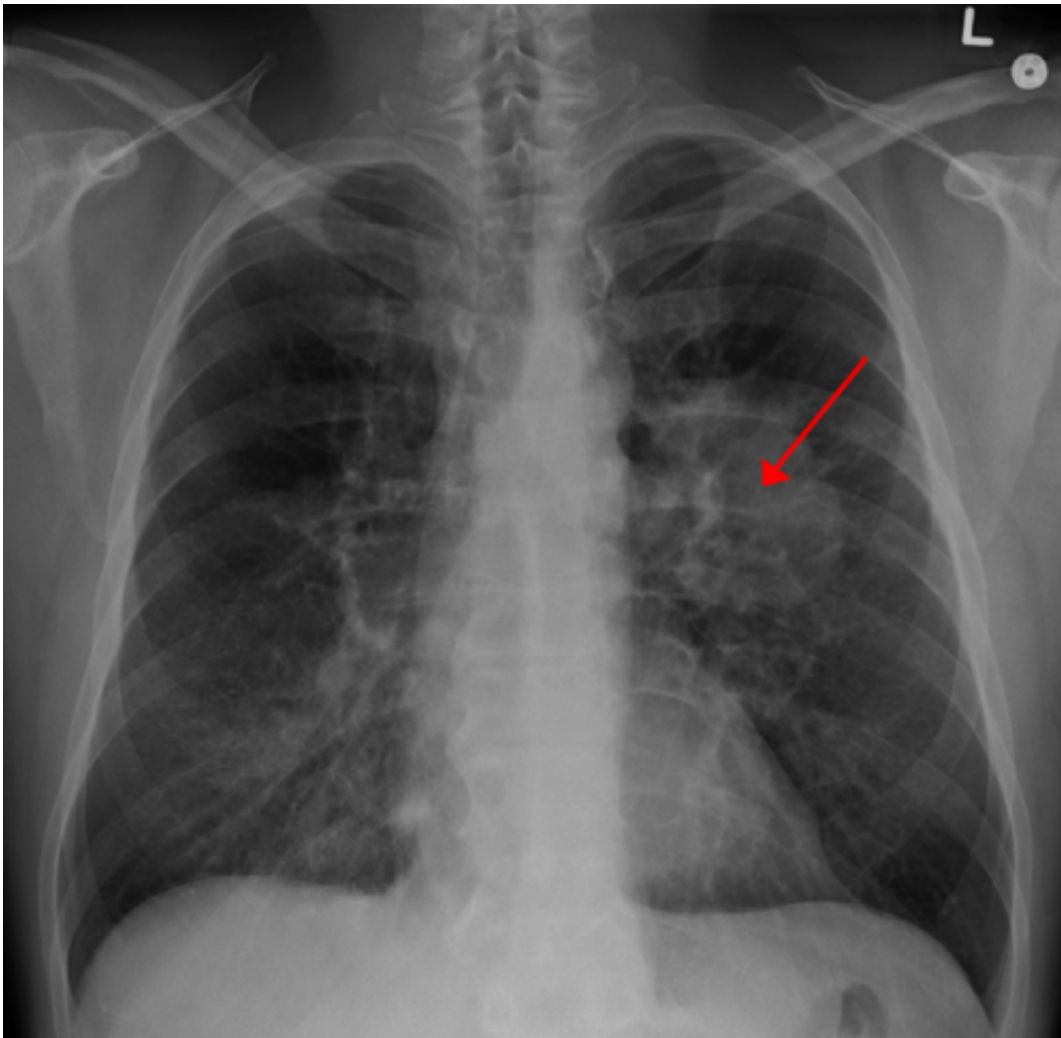


# Pembrolizumab in metastatic NSCLC: Now added benefit for subpopulations

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Lung CA seen on CXR. Credit: [CC BY-SA 4.0](https://creativecommons.org/licenses/by-sa/4.0/) James Heilman, MD/Wikipedia

In early July, the German Institute for Quality and Efficiency in Health Care (IQWiG) conducted two early benefit assessments to investigate whether certain drug combinations with pembrolizumab have advantages in comparison with the respective appropriate comparator therapy for patients with metastatic squamous or non-squamous non-small cell lung cancer (NSCLC). Due to a contradictory presentation of the operationalization of the key outcome "overall survival" in the drug manufacturer's dossiers, the presented data were not interpretable, however.

The manufacturer resolved the contradictions in the subsequent commenting procedure: It had conducted correct analyses on [overall survival](#), but had provided a wrong presentation in the dossiers. IQWiG was now able to include these analyses in two addenda to the original assessments: An added benefit was shown for specific subpopulations.

## **Gene expression influences the results**

In both commissions, the Federal Joint Committee (G-BA) had distinguished between two groups of patients, i.e. those whose tumours express the T-cell receptor ligand PD-L1 with over 50 per cent, and those with a PD-L1 expression of under 50 per cent. In one of the commissions, the data additionally suggested a modification of the results by sex.

Overall, there is now proof of major added benefit for women and an indication of minor added benefit for men in the first-line treatment of non-squamous NSCLC without EGFR or ALK-positive tumour mutations with PD-L1 expression below 50 per cent. If PD-L1 expression is above 50 per cent, there is a hint of a major added benefit for women, whereas for men, there is a hint of lesser benefit in comparison with the appropriate comparator therapy.

In first-line treatment of squamous NSCLC, however, sex does not influence the results of treatment with pembrolizumab. There is an indication of major added benefit in PD-L1 expression below 50 per cent. An added benefit is not proven for men or women with PD-L1 expression above 50 per cent.

## **G-BA decides on the extent of added benefit**

The dossier assessments are part of the early benefit [assessment](#) according to the Act on the Reform of the Market for Medicinal Products (AMNOG) supervised by the G-BA. After publication of the manufacturer dossiers and the IQWiG dossier assessments, the manufacturer submitted additional information in the commenting procedure. The G-BA subsequently commissioned IQWiG to assess this information. IQWiG now presents this assessment in the form of two addenda. The G-BA makes final decisions on the extent of added benefit.

Provided by Institute for Quality and Efficiency in Health Care

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