Necitumumab in NSCLC: Indication of minor added benefit for patients with metastases

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The monoclonal antibody necitumumab has been approved since February 2016 for the treatment of patients with locally advanced or metastatic epidermal growth factor receptor (EGFR) expressing non-small cell lung cancer (NSCLC) who have not received prior chemotherapy for this condition. The drug is used in combination with gemcitabine and cisplatin.

In an early benefit assessment, the German Institute for Quality and Efficiency in Health Care (IQWiG) now examined the advantages and disadvantages of this combination. According to the findings, there is an indication of a minor added benefit of necitumumab in combination with gemcitabine and cisplatin in comparison with the appropriate comparator therapy cisplatin in combination with a third-generation cytostatic agent for patients with metastases. It is unclear whether the observed effects are transferable to patients without metastases.

Study only in patients with metastases

The benefit assessment was based on the study SQUIRE. Patients whose NSCLC did not express the EGFR also participated in this study, however. Their data were excluded from the analysis to comply with the Summary of Product Characteristics of necitumumab. All patients had stage IV of the disease, i.e. had metastases. Based on this study, no conclusions can be drawn on an added benefit for patients with locally

advanced NSCLC (stage IIIB).

Survival advantage, but also disadvantages

There was an indication of considerable added benefit of the combination therapy with necitumumab in comparison with the comparator therapy in the outcome "overall survival". In the morbidity outcome "symptoms", the effect was influenced by ethnicity; there was no hint of an added benefit for the main ethnicity in the health care area (Caucasians). In the outcome category "side effects", the new treatment was associated with disadvantages of different extent, some of which only applied to subgroups.

Transferability to patients without metastases unclear

In the overall consideration, these negative effects did not outweigh the advantage in overall survival, but led to a downgrading of the extent. Hence an indication of a minor added benefit of necitumumab in combination with gemcitabine and cisplatin in comparison with the appropriate comparator therapy remains for patients with metastatic NSCLC. It remains unclear in how far these conclusions are transferable to patients with locally advanced, not yet metastatic NSCLC.

G-BA decides on the extent of added benefit

The dossier assessment is part of the early benefit assessment according to the Act on the Reform of the Market for Medicinal Products (AMNOG) supervised by the Federal Joint Committee (G-BA). After publication of the dossier assessment, the G-BA conducts a commenting procedure and makes a final decision on the extent of the added benefit.

More information: www.iqwig.de/download/A16-17_N … ertung-35a-SGB-V.pdf