Ceritinib in advanced lung cancer: No hint of added benefit

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The drug ceritinib (trade name: Zykadia) has been approved since May 2015 for the treatment of adults with non-small cell lung cancer (NSCLC). It is an option when certain changes in the cancer cells (anaplastic lymphoma kinase-positive) stimulate tumour growth and patients have already been pretreated with crizotinib.

The German Institute for Quality and Efficiency in Health Care (IQWiG) examined in a dossier assessment whether ceritinib offers an added benefit over the appropriate comparator therapy. Such an added benefit cannot be derived from the dossier, however, because it contained no data suitable for the assessment.

G-BA distinguished between two research questions

The Federal Joint Committee (G-BA) distinguished between two research questions: In patients who are eligible for chemotherapy with docetaxel or pemetrexed, ceritinib was to be compared with one of these two drugs.

In patients who are not eligible for chemotherapy, the G-BA specified best supportive care (BSC) as appropriate comparator therapy. BSC refers to the therapy that provides the patient with the best possible, individually optimized, supportive treatment to alleviate symptoms and improve the quality of life.

Unadjusted historical comparisons not interpretable

Because there were no studies that tested ceritinib directly against chemotherapy, the manufacturer presented different unadjusted historical comparisons. These were not evaluable, however. One of the reasons was that partly different patient groups were considered (patients pretreated with crizotinib and crizotinib-naive patients). Furthermore, it was not ensured for the data on overall survival that the comparator therapy specified by the G-BA was used.

Irrespective of this, historical comparisons per se have a lower certainty of results, which is why the observed differences have to reach a certain magnitude. However, the effect differences reported in the dossier on ceritinib are so small that they may be caused by systematic bias alone.

The company presented no data for the comparison with BSC. Hence there is no hint of an added benefit for any of the two research questions.

G-BA decides on the extent of added benefit

This 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 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/A15-24_C … ertung_35a_SGB-V.pdf