Crizotinib in bronchial carcinoma: New data not informative

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Crizotinib (trade name: Xalkori) has been available since 2012 for patients with advanced non-small cell lung cancer (bronchial carcinoma) with high activity of the enzyme anaplastic lymphoma kinase (ALK) who have already received another treatment. The drug had already undergone a dossier assessment, but the Federal Joint Committee (G-BA) had limited its decision, which is why the drug manufacturer now submitted a new dossier.

The Institute for Quality and Efficiency in Health Care (IQWiG) has now also assessed this second dossier: It contained new results from a later data cut-off for patients for whom further chemotherapy is an option. These were not interpretable in a meaningful way, however, which was mainly due to the increased proportion of patients who had switched treatment.

Again, the drug manufacturer did not submit any data for further patients. The result of the first dossier assessment is therefore still valid.

87% of the participants in the chemotherapy arm switched to crizotinib

In the study that was decisive already for the first assessment, patients could be switched from the chemotherapy arm to the crizotinib arm of the study under certain conditions such as progression. Such treatment switching causes problems. It was unclear, for example, how long the

patients initially allocated to the chemotherapy arm would have lived if, after progression, they had continued treatment with a different chemotherapy instead of crizotinib.

At the second data cut-off, the proportion of patients who had switched treatment had increased to 87% (first data cut-off: 62%). Thus, the study almost only consisted of one (crizotinib) arm, however, which limited the interpretability of the data considerably further than this was the case at the first data cut-off.

Still advantage in symptoms and quality of life

Due to the increased uncertainty, the second dossier contained no new findings in comparison with the first assessment, which also comprised an addendum. Hence, its results remained unchanged: For patients for whom chemotherapy principally is still an option, there is a hint of a considerable added benefit of crizotinib in comparison with chemotherapy for the outcomes on symptoms and health-related quality of life.

For patients for whom chemotherapy is no longer indicated, also the second dossier contained no data.

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 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.