Afatinib in advanced squamous cell carcinoma of the lung: Added benefit not proven

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Afatinib (trade name: Giotrif) has been approved since April 2016 for the treatment of adults with locally advanced or metastatic non-small cell lung cancer (NSCLC) of squamous histology who have already received chemotherapy. In an early benefit assessment, the German Institute for Quality and Efficiency in Health Care (IQWiG) has now examined whether in these patients this drug offers advantages over the appropriate comparator therapy. According to the findings, an added benefit of afatinib for these patients is not proven.

Requirements for comparator therapy not met

The Federal Joint Committee (G-BA) specified docetaxel or - if no further chemotherapy is indicated for the patients - best supportive care as appropriate comparator therapy. The drug manufacturer presented no data for this second research question.

For the first research question - i.e. patients who can receive further chemotherapy - the manufacturer cited the study LUX-Lung 8. In this study, however, afatinib was not compared with docetaxel, but with erlotinib. The manufacturer did not sufficiently justify the therapeutic equivalence of these two drugs in the treatment of patients with squamous cell carcinoma. IQWiG therefore concluded that there was no comparison with the appropriate comparator therapy that could be assessed.

Indirect comparison without informative value

In addition, the manufacturer conducted an indirect comparison with erlotinib as common comparator, using the LUX-Lung 8 study on the afatinib side, and the TAILOR study on the docetaxel side. However, the manufacturer did not attempt to derive an added benefit from this comparison. The information on study design and on the participants in the TAILOR study was actually inadequate to assess whether both studies were sufficiently similar. In addition, the dosage of docetaxel did not exactly comply with the Summary of Product Characteristics, and only results on overall survival were reported under patient-relevant outcomes.

Hence also from the indirect comparison no conclusion on advantages or disadvantages of afatinib could be derived. IQWiG therefore concluded that an added benefit of afatinib in comparison with the appropriate comparator therapy is not proven.

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.

An overview of the results of IQWiG's benefit assessment is given by a German-language executive summary. In addition, the Website gesundheitsinformation.de, published by IQWiG, provides easily understandable German-language information.

More English-language information will be available soon (Sections 2.1

to 2.5 of the dossier assessment as well as subsequently published health information on informedhealth.org).

More information: www.iqwig.de/download/A16-22_A … ertung-35a-SGB-V.pdf

Provided by Institute for Quality and Efficiency in Health Care

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