# Afatinib: Added benefit in certain mutations confirmed

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Afatinib (trade name: Giotrif) has been approved since September 2013 for the treatment of adult patients with locally advanced or metastatic non-small cell lung cancer (NSCLC) with activating EGF receptor mutations who have not been treated with an EGF receptor tyrosine-kinase inhibitor (EGFR TKI). After a first early benefit assessment in February 2014, the German Institute for Quality and Efficiency in Health Care (IQWiG) now reexamined whether the drug offers an added benefit over the appropriate comparator therapy. The new benefit assessment was conducted because a limitation of the corresponding decision by the Federal Joint Commission (G-BA) expired in May 2015.

The current assessment was based on a new data cut-off of the study already investigated in 2014. Evaluable data were only available for treatment-naive patients in relatively good general condition (ECOG PS 0 or 1). There is still an indication of a major added benefit of afatinib in patients with the EGFR mutation Del19, and a hint of a minor added benefit in patients with L858R mutation. In patients with other EGFR mutations, the Institute now no longer detected an indication, but only a hint of lesser benefit versus the comparator therapy. The pharmaceutical company presented no relevant data for pretreated patients.

**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/A15-17_A … ertung-35a-SGB-V.pdf

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