Aclidinium bromide/formoterol in COPD: Added benefit for certain patient groups

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The fixed-dose combination aclidinium bromide/formoterol has been approved since November 2014 for long-term treatment of adults with chronic obstructive pulmonary disease (COPD). The German Institute for Quality and Efficiency in Health Care (IQWiG) examined in a dossier assessment whether this drug combination offers an added benefit over the appropriate comparator therapy.

According to the findings, there is an indication of minor added benefit for adult patients with moderate COPD (grade II). For adults with grade III and fewer than 2 exacerbations (flare-ups) per year, there is proof of considerable added benefit versus the comparator therapy. In contrast, no conclusions can be drawn on greater or lesser benefit for more severely ill patients from the data presented.

Comparator therapy depends on severity and frequency of exacerbations

The Federal Joint Committee (G-BA) specified different appropriate comparator therapies depending on the severity of the disease: From a moderate severity grade (research question 1), the new drug combination was to be compared with a long-acting beta-2 sympathomimetic (such as formoterol) and/or tiotropium. From grade III and at least two flare-ups per year (research question 2), the patients in the comparator arm were to receive additional inhaled corticosteroid.

Three suitable studies with direct comparisons

The drug manufacturer submitted data from three double-blind, randomized controlled approval studies with patients with moderate to severe COPD, in which the drug combination was directly compared with formoterol. In contrast to the G-BA's specifications, all patients included in these studies could continue ongoing treatment with an inhaled corticosteroid, irrespective of their severity grade and the frequency of exacerbations. However, only the data of those patients who were treated in accordance with the G-BA's specifications were included in the analyses presented.

Relevant differences only in the E-RS symptom questionnaire

For patients with COPD grade IV, no evaluable data were available to answer research question 2; for grade III, the differences between the treatment groups were not statistically significant. Hence an added benefit for grade III or IV patients with at least two flare-ups per year is not proven.

Better data were available for research question 1. When asked about their dyspnoea, patients with grade III reported less dyspnoea under the new drug combination than under the control intervention. The difference was too small, however, to derive an added benefit from it.

When symptoms were recorded on a broader basis with the E-RS questionnaire (breathlessness, cough and sputum, chest symptoms), there was an indication of an added benefit for grade II, and proof of an added benefit for grade III. In addition, there was an indication of an added benefit in grade III for the outcome "severe exacerbations". For COPD grade IV patients, there were also no data for research question 1.

In summary, there is an indication of a minor added benefit for patients with moderate severity and proof of a considerable added benefit for patients with COPD grade III and no more than one flare-up per year.

More information: www.iqwig.de/download/A15-06_K … ertung-35a-SGB-V.pdf

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