Umeclidinium for symptom relief in COPD: Added benefit not proven

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Umeclidinium bromide (umeclidinium for short) has been approved since 2014 as a maintenance bronchodilator treatment in adults with chronic obstructive pulmonary disease (COPD) and was initially only available in combination with vilanterol. It has been available also as a single agent since 2016. The German Institute for Quality and Efficiency in Health Care (IQWiG) now examined in an early benefit assessment whether this single agent offers patients an added benefit over the appropriate comparator therapy.

As in 2015 for the combination therapy, the Institute concluded that an added benefit in comparison with the appropriate comparator therapy is not proven for umeclidinium.

Comparator therapy depends on severity grade

The Federal Joint Committee (G-BA) distinguished between two research questions based on the severity of the COPD: Patients with a moderate severity grade were to receive a long-acting beta-2 sympathomimetic and/or a long-acting anticholinergic as comparator therapy. Patients with more severe COPD were to receive an additional inhaled corticosteroid in the comparator arm.

No significant differences in moderate severity

For the first research question, the drug manufacturer submitted data from a suitable study, in which the long-acting anticholinergic

tiotropium bromide was used in the comparator arm. For those patients who, in accordance with the G-BA specifications, had received no long-term treatment with inhaled corticosteroids, no significant difference between the 2 study arms was shown for any of the patient-relevant outcomes, including all-cause mortality, COPD symptoms or side effects.

No data were available for higher severity grades

The manufacturer submitted no study data for patients with a higher severity grade, i.e. smaller lung capacity and at least two exacerbations (flare-ups) per year.

An added benefit of umeclidinium in comparison with the appropriate comparator therapy is therefore not proven for these two research questions.

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.

Provided by Institute for Quality and Efficiency in Health Care

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