Open-angle glaucoma: Poor data for the fixed combination tafluprost/timolol

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The fixed combination of the drugs tafluprost and timolol (trade name: Taptiqom) has been approved in Germany since December 2014 for adults with open-angle glaucoma or increased intraocular pressure (ocular hypertension). The combination therapy is indicated in patients who are insufficiently responsive to topical monotherapy with beta-blockers or prostaglandin analogues, and who would benefit from preservative-free eye drops.

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. However, such an added benefit cannot be derived from the dossier, as the study results are very uncertain and evaluable data on important outcomes are lacking.

Incomplete information on patient groups

In its dossier, the drug manufacturer chose the non-fixed combination of a beta-blocker (timolol) plus a prostaglandin analogue (tafluprost) as the appropriate comparator therapy. For the comparison with the fixed combination, the manufacturer presented a randomized controlled trial including not only patients pretreated with prostaglandin analogues or beta-blockers, but also treatment-naive patients.

The study results are very uncertain for several reasons: For instance, it

is unclear how high the actual proportion of relevant study participants is who received prior monotherapy (prostaglandin analogues or beta-blockers). In addition, patient characteristics and subgroup analyses are lacking for patients pretreated with prostaglandin analogue monotherapy, and no information at all is available on patients pretreated with beta-blocker monotherapy.

In summary, neither positive nor negative effects were determined

In the manufacturer dossier, evaluable data are lacking for important outcomes such as blind spots in the visual field (scotoma), diseases of the ocular surface, improvement or deterioration in visual acuity, and health-related quality of life.

No statistically significant differences between treatment groups were shown with regard to side effects.

Overall, neither positive nor negative effects can be determined for the fixed combination of tafluprost and timolol compared with the non-fixed combination. No added benefit can therefore be derived.

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 Federal Joint Committee (G-BA). After publication of the dossier assessment, the G-BA conducts a commenting procedure and makes a final decision on the extent of added benefit.

An overview of the results of IQWiG's benefit assessment is given by a German-language executive summary. In addition, the website "

http://www.gesundheitsinformation.de, published by IQWiG, provides easily understandable German-language information on tafluprost and timolol.

More information: www.iqwig.de/download/A14-49_T … ertung-35a-SGB-V.pdf

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