Aflibercept in macular oedema after BRVO: No hint of added benefit

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Since February 2015, aflibercept (trade name Eylea) has been available also for patients with impaired vision due to macular oedema that follows blockage of branch veins of the central retinal vein (branch retinal vein occlusion, BRVO). The German Institute for Quality and Efficiency in Health Care (IQWiG) examined in a dossier assessment whether this drug offers an added benefit over the appropriate comparator therapy. Such an added benefit cannot be derived from the dossier because it contained no data relevant for the assessment.

Manufacturer considered only the comparison with ranibizumab to be adequate

The Federal Joint Committee (G-BA) had specified the drug ranibizumab or grid laser therapy as appropriate comparator therapy. The drug manufacturer accepted only ranibizumab, but not laser therapy.

There has been no study so far that has tested aflibercept against ranibizumab. One randomized controlled trial is available for the comparison with grid laser therapy (VIBRANT), but the study population of this study does not comply with the approval population, i. e. aflibercept was not used as recommended in the approval.

Apart from the fact that the VIBRANT study is unsuitable for the benefit assessment because of this, the manufacturer also did not use it because it rejected grid laser therapy as comparator therapy. As a

consequence, the company claimed no added benefit for aflibercept.

Already fourth dossier assessment of the drug

In 2013 and 2014, IQWiG assessed aflibercept already three times for therapeutic indications in the eye according to the Act on the Reform of the Market for Medicinal Products (AMNOG). The researchers concluded in all three cases that no hint of added benefit can be derived from the dossiers. In these three therapeutic indications, however, the pharmaceutical company had claimed that its drug has an advantage in comparison with conventional treatments.

G-BA decides on the extent of added benefit

This dossier assessment is part of the early benefit assessment according to 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/A15-11_K … ertung-35a-SGB-V.pdf

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