Aflibercept in diabetic macular oedema: Added benefit not proven

December 15 2014

Since August 2014, aflibercept (trade name Eylea) has been available also for patients with visual impairment due to diabetic macular oedema (DMO). 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.

According to the findings, an added benefit in this therapeutic indication is not proven: The data showed no relevant differences between the treatment groups for patients in whom the fovea centralis is also affected. The drug manufacturer did not submit any data for other patients.

IQWiG already assessed aflibercept twice, in 2013 and in 2014, for therapeutic indications of the eye. In both cases, it concluded that an added benefit is not proven.

G-BA specifies appropriate comparator therapy

High blood glucose levels over a long period of time can lead to oedema in the retina of the eye. The fovea centralis, a small pit in the back of the eye, is the part of most acute vision. The area around the fovea is known as the macula or "yellow spot". An oedema in the macula can impair visual acuity and even result in blindness.

The Federal Joint Committee (G-BA) differentiated between two groups

of patients for the assessment, and specified an appropriate comparator therapy for each of them: If the fovea is affected, aflibercept was to be compared with the drug ranibizumab. If the fovea is not affected, aflibercept was to be compared with focal/grid laser photocoagulation.

Studies suitable for indirect comparison

The manufacturer did not submit any direct comparative study for the first patient group, but results from an adjusted indirect comparison. These were four randomized controlled trials (RCTs) in total in which either aflibercept or ranibizumab were tested against laser photocoagulation.

The design of the studies and the patients investigated were sufficiently similar for the results to be used for an indirect comparison. However, these data showed no statistically significant differences between the aflibercept and the ranibizumab group in any of the patient-relevant outcomes, i.e. neither for visual acuity, nor for side effects or quality of life. Hence an added benefit of aflibercept is not proven for patients in whom the oedema affects the fovea.

Since the manufacturer presented no data for the second patient group (fovea not affected), there is also no proof of added benefit for this Group.

More information: www.iqwig.de/download/A14-32_A … ertung-35a-SGB-V.pdf

Provided by Institute for Quality and Efficiency in Health Care