Aflibercept in AMD: No proof of added benefit

June 5 2013

It is not proven that patients with wet age-related macular degeneration benefit from the new drug aflibercept, as the drug manufacturer did not present any suitable data for a comparison with the current standard therapy in its dossier. This is the conclusion of a dossier assessment by the German IQWiG, Cologne, which was published in March 2013 and for which an English-language extract is now available.

The drug aflibercept (trade name: Eylea) has been approved in Germany since November 2012 for the treatment of wet age-related macular degeneration (AMD). In an early benefit assessment pursuant to the Act on the Reform of the Market for Medicinal Products (AMNOG) the German Institute for Quality and Efficiency in Health Care (IQWiG) examined whether this new drug offers an added benefit over the current standard therapy. Such an added benefit cannot be derived from the dossier, however, as the manufacturer did not submit any suitable data for this comparison.

Patients in control group did not receive approval-compliant treatment

The Federal Joint Committee (G-BA) specified the drug ranibizumab as appropriate comparator therapy. In its dossier the pharmaceutical company cited two approval studies of aflibercept that directly compared aflibercept with ranibizumab. But in these studies, ranibizumab was not used according to its approval status. For instance,

the continuation or discontinuation of treatment was not made dependent on whether the patients had achieved stable visual acuity or not. Although the manufacturer cited other documents in its dossier, these cannot be used for the benefit assessment, as they do not allow any reliable conclusions to be drawn on the comparison of aflibercept and ranibizumab. Overall, no added benefit of aflibercept can be derived from the data presented in the dossier.

G-BA decides on the extent of added benefit

The dossier assessment is part of the overall procedure for early benefit assessments supervised by the G-BA. After publication of the manufacturer's dossier and IQWiG's assessment, the G-BA conducts a commenting procedure, which may provide further information and result in a change to the benefit assessment. The G-BA then decides on the extent of the added benefit, thus completing the early benefit assessment.

Provided by Institute for Quality and Efficiency in Health Care