Vemurafenib: Result unchanged despite new data

December 18 2013

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) reassessed vemurafenib (trade name: Zelboraf), a drug for the treatment of adults with a certain type of advanced melanoma. The reason for this was that the Federal Joint Committee (G-BA) had limited its decision on the first assessment to one year. This obliged the drug manufacturer to submit a second dossier.

This dossier contained additional and more recent data, but did not provide any new findings. IQWiG therefore still considers there to be an indication of a considerable added benefit of vemurafenib.

Longer survival, but also major side effects

The drug approved since February 2012 can be an option for adults whose melanoma cannot be removed by surgery or has formed secondaries (metastases) and in whose cancer a change (mutation) has occurred in a certain gene (BRAF-V600). G-BA had specified the drug dacarbazine as the appropriate comparator therapy.

In its first AMNOG assessment in June 2012, the Institute concluded that vemurafenib had major advantages in overall survival, but also major disadvantages in the form of side effects. Overall, this resulted in an indication of a considerable added benefit.

Treatments mixed during the course of the study

The manufacturer used the approval study again in its second dossier, and presented additional results from later analysis dates (data cut-offs). However, because of the special design of this study, the risk of bias of the results increased with each data cut-off.

In the first year of the study, patients in whom the disease progressed could be treated with further anti-cancer treatments. They could not switch from dacarbazine to vemurafenib, however. The analysis after this first year was therefore informative for the comparison of vemurafenib and dacarbazine. After this analysis, it was possible to switch from dacarbazine to vemurafenib, which made the results for the comparison of the two treatment options increasingly uncertain. This is the reason why IQWiG did not draw any new conclusions from the later analyses now provided.

Historical comparison is unsuitable

In the second dossier, the manufacturer also added a so-called "historical comparison": Firstly, it compared the survival rates under dacarbazine from other studies with the survival rates under dacarbazine from the approval study. It then related the results of this comparison to the survival rates of vemurafenib (approval study). With regards to the added benefit of vemurafenib, this did not result in any new findings beyond the ones from the approval study. At the most, the historical comparison allows the conclusion that patients in the approval study possibly had a better prognosis than patients in older studies.

Hence the new manufacturer dossier did not contain any new data that would be suitable for describing the added benefit of vemurafenib. Hence the result of the first assessment remains valid.

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.

An overview of the results of IQWiG's benefit assessment is given by a German-language executive summary. In addition, the website gesundheitsinformation.de, published by IQWiG, provides easily understandable and brief German-language information on vemurafenib.

The G-BA website contains both general English-language information on benefit assessment pursuant to §35a Social Code Book (SGB) V and specific German-language information on the assessment of vemurafenib.

Provided by Institute for Quality and Efficiency in Health Care

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