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Pembrolizumab in lung cancer: Indication of considerable added benefit

November 22 2016

Pembrolizumab (trade name: Keytruda) was initially introduced for the treatment of melanoma. Since July 2016, the monoclonal antibody has also been available for the treatment of locally advanced or metastatic non-small cell lung cancer (NSCLC) in adults whose tumours express the T-cell receptor ligand PD-L1 and who have received a prior chemotherapy regimen. The German Institute for Quality and Efficiency in Health Care (IQWiG) examined in a dossier assessment whether the drug offers an added benefit over the appropriate comparator therapy also for these patients.

According to the findings, there is an indication of considerable added benefit of pembrolizumab for patients for whom further chemotherapy (with docetaxel or pemetrexed) or nivolumab is an option. For patients for whom these treatments are no longer indicated, however, an added benefit is not proven.

No data for one of two research questions

The Federal Joint Committee (G-BA) distinguished two groups of patients: patients for whom further chemotherapy with docetaxel or pemetrexed or treatment with nivolumab is an option and patients for whom this is not the case. For the first group, data from the KEYNOTE 010 study, which compared pembrolizumab with docetaxel, were available.

To assess an added benefit for the second group, the new drug would

have had to be compared with best supportive care, i.e. care optimized for the individual patient to alleviate symptoms and improve quality of life. Since no such study data were available, there was no hint of an added benefit for this research question.

Advantages in mortality, morbidity and some side effects

The KEYNOTE 010 study showed an indication of considerable added benefit in the patient-relevant outcome "overall survival", a hint of considerable added benefit in the outcome category "morbidity" (alopecia, sore mouth, and peripheral neuropathy), and several hints of lesser harm of major or considerable extent in the category "side effects" from the new drug.

This was offset by hints of considerably greater harm in immune-related side effects. In the overall assessment, these did not raise doubts about the positive effects, however. In summary, there is therefore an indication of considerable added benefit of pembrolizumab in comparison with the appropriate comparator therapy for this research question.

G-BA decides on the extent of added benefit

The 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 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.

Provided by Institute for Quality and Efficiency in Health Care

Citation: Pembrolizumab in lung cancer: Indication of considerable added benefit (2016,