Nivolumab in renal cell cancer: Indication of added benefit

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Nivolumab has been approved since April 2016 as a checkpoint inhibitor for the treatment of adults with advanced renal cell cancer who have already undergone prior therapy. In an early benefit assessment, the German Institute for Quality and Efficiency in Health Care (IQWiG) has now examined whether in these patients this monoclonal antibody offers advantages over the appropriate comparator therapy.

According to the findings, for patients with a high Memorial Sloan-Kettering Cancer Center (MSKCC) score, that is, an unfavourable prognosis, the data provide an indication of a major added benefit. In patients with a favourable or intermediate prognosis, the added benefit is considerable.

Approval study stopped early due to survival advantage

On the basis of prior therapy, the Federal Joint Committee (G-BA) distinguished between two cases: In patients who had not been treated with temsirolimus, everolimus was to be the appropriate comparator therapy. If temsirolimus had been the prior therapy, nivolumab was to be compared with sunitinib. The manufacturer did not present data on this second research question, so that an added benefit of nivolumab is not proven here.

For the first research question, the manufacturer cited the approval study CA209-025, which included patients with advanced or metastatic renal cell cancer who had previously received one or two antiangiogenic

therapies or up to three systemic therapies. After an interim analysis the study was stopped early, as a clear advantage of nivolumab for overall survival became apparent.

Advantages also for morbidity and side effects

The effect on the outcome "overall survival" is modified by the MSKCC score, which counts the risk factors for deterioration of disease: In patients with an unfavourable prognosis, the data provide an indication of an added benefit of nivolumab for overall survival; in contrast, no indication or hint of an added benefit is shown for this outcome in patients with a favourable or intermediate score.

The new drug also shows advantages over the comparator therapy for two morbidity outcomes (symptoms and health status), as well as for several outcomes of the category "side effects" (discontinuation due to adverse events, severe adverse events, and specific adverse events).

Overall, in patients with a favourable or intermediate MSKCC score, the data provide an indication of a considerable added benefit of nivolumab over everolimus; in patients with an unfavourable prognosis the data even provide an indication of a major added benefit here. An added benefit is not proven in patients with prior temsirolimus therapy.

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 Federal Joint Committee (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.