Nivolumab in head and neck squamous cell carcinoma: Added benefit for specific patients

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Nivolumab (trade name: Opdivo) has been approved since June 2017 for adults with squamous cell carcinoma of the head and neck. The drug is an option if platinum-based chemotherapy is not sufficiently effective against this form of cancer. In recent years, nivolumab has repeatedly been subject to early benefit assessments conducted by the Institute for Quality and Efficiency in Health Care (IQWiG) for other oncological indications. IQWiG has now investigated whether the drug has an added benefit for patients in the new therapeutic indication.

According to the findings, there is an indication of considerable added benefit for patients who have progressed during platinum-based chemotherapy or up to six months after completion of this treatment. No data were available for patients with later progression. Hence for these patients, an added benefit of nivolumab in comparison with the appropriate comparator therapy is not proven.

Data from a randomized trial

The Federal Joint Committee (G-BA) specified individual drug treatment chosen by the physician as appropriate comparator therapy. This treatment may consist of chemotherapy, radiotherapy or surgery. In case of drug treatment, the respective approval has to be considered.

The drug manufacturer presented data from the study CA209-141, in

which patients received either nivolumab or another drug. Whether this drug was cetuximab, methotrexate or docetaxel, was specified by the investigator before randomization. The study only included patients for whom surgery or radiation was no longer an option and who had progressed during or shortly after platinum-based chemotherapy because their cancer had become resistant to this treatment.

In Germany, however, cetuximab and docetaxel are not approved for monotherapy in the therapeutic indication; hence only about half of the study participants in total (those for whom the investigator had specified methotrexate) were treated in compliance with the G-BA's specifications. Only the data of these patients were included in the assessment.

No added benefit proven for patients with later progression

According to the approval, nivolumab can also be prescribed for patients who have progressed more than half a year after platinum-based therapy and who could also receive further treatment with this type of chemotherapy. The manufacturer did not present any data for this case because its study only included patients with earlier progression. Hence an added benefit is not proven for adults with squamous cell carcinoma of the head and neck with disease progression occurring more than six months after completion of platinum-based therapy.

Positive effects outweigh negative effects in early progression

The data of the study subpopulation with progression during or up to six months after platinum-based therapy resulted in an indication of considerable added benefit for the outcome "overall survival". In

addition, there was a hint of notably lesser harm in comparison with methotrexate for an outcome in the category of side effects, namely the overall rate of severe adverse events.

Non-serious adverse events were partly less common, partly more common than in the comparator arm, with some of the data not being usable. None of these findings calls the positive effects into question. In the overall consideration, there is therefore an indication of considerable added benefit of nivolumab for adult patients with progression occurring during or up to six months after platinum-based therapy.

More information: www.iqwig.de/en/projects-resul … ode-book-v.7900.html

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