Cabazitaxel can offer an advantage in certain patients

May 29 2012

Cabazitaxel (trade name: Jevtana) has been approved since March 2011 in men with metastatic prostate cancer who no longer respond to conventional therapy with hormone blockers and have already been pre-treated with the cytostatic drug docetaxel. 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 cabazitaxel offers an added benefit compared with the present standard therapy.

In patients aged 65 years or older and for whom further treatment with docetaxel is no longer an option, IQWiG found an indication of a considerable added benefit of cabazitaxel due to better survival prospects. In patients younger than 65 years, the data provide a "hint" of an added benefit; however, its extent cannot be precisely classified. An added benefit is not proven in patients who can still be treated with docetaxel, as adequate data are lacking.

Separate assessment for two groups of patients

In accordance with the specifications of the Federal Joint Committee (G-BA), IQWiG separately assessed the drug in two groups of patients. The G-BA has specified different appropriate comparator therapies for the two groups.

The "best supportive care population" contains patients for whom further

treatment with docetaxel is no longer an option. The appropriate comparator therapy for this group is palliative treatment with dexamethasone, prednisone, prednisolone or methylprednisolone, as well as "best supportive care".

"Best supportive care" means the therapy that provides the patient with the best possible individually optimized supportive treatment to alleviate symptoms (e.g. suitable pain therapy) and improve quality of life.

The "docetaxel-retherapy population" comprises patients for whom docetaxel is still an option. The appropriate comparator therapy for this patient population is docetaxel in combination with prednisone or prednisolone.

Cabazitaxel can improve survival prospects

One study (TROPIC), which considered patient-relevant outcomes and provided relevant data, was included in the assessment of added benefit in the "best supportive care population". This study compared treatment with cabazitaxel versus mitoxantrone, in each case combined with prednisone and "best supportive care". In this context, mitoxantrone was regarded as a component of "best supportive care" for the assessment.

As IQWiG found, cabazitaxel can increase survival time, but the results vary with the age of patients. In patients aged 65 years or older, an indication of a major added benefit can be inferred with regard to overall survival. One can also assume an increase in survival time due to treatment with cabazitaxel in under 65-year-olds; however, the extent of this increase cannot be clearly determined, as the evidence base is less reliable here. In this age group, the data therefore only provide a "hint" of an added benefit, for which the extent cannot be quantified. The study also investigated the pain-relieving effect of the interventions as an aspect of the consequences of disease (morbidity). However, no relevant

difference between the two treatment groups was shown. No data were available on health-related quality of life.

Also indication of greater harm due to severe side effects

In the "best supportive care population", the data also provide indications of greater harm in the form of side effects (adverse events). For example, severe adverse events, such as severe diarrhoea, anaemia or neutropenia, occurred more often in the cabazitaxel group. IQWiG classifies the extent of this greater harm as considerable for these outcomes. There is even an indication of major harm for the category "serious adverse events"; these are adverse events that, for example, lead to hospital admission, are life-threatening or fatal.

In the overall consideration of greater benefit (increase in survival time) and greater harm, IQWiG concludes that the data provide an indication of a considerable added benefit in patients aged 65 years or older. In under 65-year-olds, the data provide a "hint" of an unquantifiable, and, at most, considerable added benefit.

Added benefit in the docetaxel-retherapy population not proven

The drug manufacturer did not present data for the "docetaxel-retherapy population" in the dossier, and explained why docetaxel was not regarded as an appropriate comparator therapy. However, IQWIG does not follow this line of argument. An added benefit in the second patient group specified by the G-BA is therefore not proven.

G-BA decides on the extent of added benefit

The procedure for inferring the overall conclusion on the extent of added benefit is a proposal from IQWiG. The G-BA, which has opened a formal commenting procedure, decides on the extent of added benefit.

More information: www.gesundheitsinformation.de/

Provided by Institute for Quality and Efficiency in Health Care