Abiraterone: Indication of considerable added benefit in certain patients

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Abiraterone (trade name: Zytiga) has been approved since September 2011 for men with metastatic prostate cancer that is no longer responsive to hormone therapy and progresses further during or after therapy 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 abiraterone offers an added benefit compared with the present standard therapy.

IQWiG finds an indication of a considerable added benefit of abiraterone in patients who are not eligible for further treatment with docetaxel. In contrast, an added benefit is not proven in patients who can still be treated with docetaxel, as the dossier submitted by the drug manufacturer provides inadequate information for this group of patients.

Separate assessment for two groups of patients

In accordance with the specifications of the Federal Joint Committee (G-BA), IQWiG separately assessed abiraterone 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 who are not eligible for further treatment with docetaxel. 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. adequate pain therapy) and improve quality of life.

The "docetaxel-retherapy population" comprises patients who are still eligible for further treatment with docetaxel. The appropriate comparator therapy for this patient population is docetaxel in combination with prednisone or prednisolone.

Indication of increase in survival and delay in consequences of disease

One study (COU-AA-301), which considers patient-relevant outcomes and provides relevant data, was included in the assessment of added benefit in the "best supportive care population". This study compared treatment with abiraterone versus placebo, in each case combined with prednisone and "best supportive care".

IQWiG finds an indication of an added benefit in patients treated with abiraterone: the above study provides indications that abiraterone can prolong survival and delay consequences of prostate cancer, such as fractures or operations due to bone metastases. In addition, the "time to pain progression" was prolonged in study participants receiving abiraterone.

IQWiG classifies the extent of this added benefit as "considerable". The corresponding legal ordinance has specified three grades to determine the extent of added benefit: "minor", "considerable" and "major".

The study data presented on health-related quality of life assessments cannot be used; an added benefit of abiraterone is therefore not proven for this outcome.

The indications of advantages for abiraterone are not accompanied by proof of greater harm.

Added benefit in the docetaxel-retherapy population not proven

The manufacturer presented inadequate data for the "docetaxel-retherapy population". The required search in trial registries was missing in the dossier. Moreover, studies presented by the manufacturer, such as indirect comparisons and one-arm studies, cannot be used due to deficits in methods and content. An added benefit in this patient group 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.

Provided by Institute for Quality and Efficiency in Health Care