Lurasidone in schizophrenia: Added benefit is not proven

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The drug lurasidone (trade name Latuda) has been available since November 2014 for the treatment of adults with schizophrenia. The German Institute for Quality and Efficiency in Health Care (IQWiG) examined in a dossier assessment whether this new drug offers an added benefit over the appropriate comparator therapy.

According to the findings, an added benefit is not proven: It is uncertain both in the acute treatment and in the prevention of relapse whether the effect lurasidone has on the symptoms of schizophrenia is as good as that of the appropriate comparator therapies.

Acute treatment: studies not conclusive

Lurasidone in the acute treatment was investigated in three comparative studies (RCTs) and compared with risperidone, olanzapine or quetiapine XR. However, the dosages of lurasidone and of the appropriate comparator therapies in the studies deviated from the guideline and the respective Summary of Product Characteristics. It is uncertain whether this led to a potential over- or underestimation of effects. Hence there are doubts about the suitability of the studies for the benefit assessment.

The drug manufacturer based its conclusions on the added benefit of lurasidone for acute treatment solely on a reduction of side effects. These would only be relevant however if it was proven that lurasidone was as effective with regard to schizophrenia symptoms as the

appropriate comparator therapies. This cannot be inferred from the manufacturer dossier.

Prevention of relapse: study objective not achieved

The only comparative study (RCT) on the prevention of relapse was conducted to prove that lurasidone is not inferior to the appropriate comparator therapy (risperidone) in the prevention of relapse. However, this study objective was not achieved.

Moreover, with regard to schizophrenia symptoms, it is uncertain whether the effect of lurasidone is similar in size to the one of risperidone.

Opposing effects for side effects

In the prevention of relapse, lurasidone showed statistically significant effects only in non-serious/non-severe side effects, and these were opposing: On the one hand, vomiting and treatment discontinuations due to side effects were more common. On the other hand, constipation and reproductive system and breast disorders were less common under lurasidone than under risperidone. Neither an advantage nor a disadvantage of lurasidone results from this.

Hence IQWiG concluded for lurasidone in the acute treatment of schizophrenia and in the prevention of relapse: An added benefit has not been proven.

G-BA decides on the extent of added benefit

This 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