

# HIV-positive children and adolescents: Added benefit of rilpivirine not proven

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Under the trade name Edurant, rilpivirine as single agent has been approved already since 2011 for adults who are infected with human immunodeficiency virus type 1 (HIV-1). Since November 2015, HIV-1-infected children and adolescents from the age of 12 years have also been allowed to be treated with rilpivirine if they have not received any other antiretroviral therapy before and have no more than 100 000 viral RNA copies/mL in their blood (so-called viral load).

The German Institute for Quality and Efficiency in Health Care (IQWiG) now examined in an early benefit assessment whether the drug has an added benefit for these patients in comparison with the appropriate [comparator therapy](#), i.e. the drug efavirenz in combination with abacavir plus lamivudine. According to the findings, such an added benefit of rilpivirine is not proven.

## Data from one-arm study unsuitable

The manufacturer only presented data from a one-arm rilpivirine study in its dossier. Only in exceptional cases can conclusions on the added benefit of a drug be derived from one-arm studies. This is the case in so-called dramatic effects, i.e. effects regarding patient-relevant outcomes that are so large that they cannot be caused by systematic bias alone. Further sufficiently certain data from other sources from which conclusions on the appropriate comparator therapy can be derived for the same outcomes are additionally required. These preconditions were

not fulfilled here.

## **Manufacturer also did not aim at an indirect comparison**

The manufacturer conducted no search for studies for the appropriate comparator therapy; it planned no indirect comparison. Nevertheless it claimed a non-quantifiable added benefit for its drug. IQWiG did not concur with this conclusion: An added benefit of the drug in comparison with the appropriate comparator therapy for HIV-1-positive children and adolescents is not proven.

Provided by Institute for Quality and Efficiency in Health Care

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