Genvoya in HIV: Positive effects predominate in some adults, negative effects in others

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The fixed-dose combination of the drugs elvitegravir, cobicistat, emtricitabine and tenofovir alafenamide has been available under the trade name Genvoya since November 2015 as treatment for adults and adolescents aged over 12 years infected with human immunodeficiency virus type 1 (HIV-1). The German Institute for Quality and Efficiency in Health Care (IQWiG) now examined in an early benefit assessment whether this drug combination offers an added benefit for patients in comparison with the appropriate comparator therapy.

According to the findings, there is a hint of a minor added benefit for pretreated women without indication for a treatment switch, but not for men. Negative effects predominate in treatment-naive adults, irrespective of sex. Hence here IQWiG sees a hint of lesser benefit in comparison with the comparator therapy. There were no data for adolescents.

Subgroups based on age and prior therapy

The Federal Joint Committee (G-BA) distinguished between four groups of patients depending on age (adolescents/adults) and previous treatment (pretreated/treatment-naive). Genvoya was to be compared with efavirenz in combination with two further drugs in treatment-naive patients, and with individual antiretroviral therapy in pretreated patients.

In its dossier, the drug manufacturer additionally distinguished between pretreated patients with and without so-called indication for a treatment switch. This indication exists if the previous treatment has failed or cannot be continued due to side effects.

Pretreated adults: added benefit only for certain women

For pretreated adults, the dossier contained only data for patients without indication for a treatment switch, i.e. patients who could principally continue their previous treatment. The data of a randomized controlled trial of direct comparison showed that severe adverse events occurred less frequently if these patients were taking Genvoya. In men, but not in women, this advantage was outweighed by greater harm in the form of more frequent nervous system disorders, however.

Overall, there is a hint of an added benefit of the new fixed-dose combination in pretreated women (without indication for a treatment switch), but not for pretreated men. IQWiG rated the extent of this added benefit as minor. The dossier contained no data for patients with indication for a treatment switch.

Treatment-naive adults: hint of lesser benefit

Due to a lack of studies of direct comparisons, the manufacturer used results from an adjusted indirect comparison, which was principally suitable for the benefit assessment, for treatment-naive adults. They showed that psychiatric disorders were less common under Genvoya.

However, there were also disadvantages regarding AIDS-defining illnesses, which the comparator drug prevented better. In addition, serious side effects as well as infections and infestations were more

frequent under Genvoya. Since the negative effects more than outweighed the positive effect, a hint of lesser benefit of the new fixed-dose combination in treatment-naive adults was derived from the data.

The added benefit of Genvoya for adolescents could not be assessed because the dossier contained no data for this patient group.

G-BA decides on the extent of added benefit

The 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.

More information: www.iqwig.de/download/A15-61_E … ertung-35a-SGB-V.pdf

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