Fingolimod in RRMS: Indication of added benefit in certain patients

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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) reassessed fingolimod (trade name: Gilenya), a drug for the treatment of adults with highly active relapsing remitting multiple sclerosis (RRMS). The Federal Joint Committee (G-BA) had limited its decision on the first assessment from 2012 to three years because it considered the certainty of the data as insufficient. This obliged the drug manufacturer to submit a second dossier.

It did not submit any new studies, but reanalysed studies that were already available. On this basis, IQWiG reached different conclusions: From the data, an added benefit was now derived for two instead of only one of a total of three patient groups. IQWiG now found an indication where it had found a hint before.

Indication instead of hint in severe course of disease

One study - the approval study TRANSFORMS - was decisive also for the new dossier assessment. The manufacturer presented new analyses with a more detailed differentiation between subgroups for two patient groups.

On the basis of the new analyses, there was an indication, and no longer a hint of an added benefit in patients with rapidly evolving severe RRMS. The extent of this added benefit depends on sex, however: It is considerable in women, and minor in men. While adverse events in the

form of influenza-like symptoms are less frequent and certain adverse events (severe adverse events) occur more often in both sexes, only women have fewer relapses under fingolimod.

Added benefit for further patient group

The new analyses of TRANSFORMS showed that fingolimod has advantages for patients with highly active RRMS that has not been fully treated with interferon beta. In contrast, no added benefit had resulted from the first dossier.

Since both the annualized relapse rate is lower and adverse events in the form of influenza-like symptoms occur less frequently, IQWiG sees an indication of considerable added benefit in comparison with the appropriate comparator therapy.

Still no evaluable data for one group

However, also the new dossier contained no evaluable data for patients with highly active RRMS who have already received full previous treatment with interferon beta (IFN-β1a). The results of an indirect comparison again presented by the manufacturer are still unsuitable because the majority of the patients in the studies on the appropriate comparator therapy had not been fully pretreated.

Now added benefit for two thirds of the approval population

Overall, the current assessment showed an added benefit for approximately two thirds of all patients for whom fingolimod was approved in 2011. However, this assessment only referred to the therapeutic indication of the first approval from 2011, not to the indication "highly active RRMS with pretreatments other than interferon

beta", which was also approved in 2014 and assessed according to AMNOG.

G-BA decides on the extent of added benefit

This dossier assessment is part of the early benefit assessment according to 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/A15-12_F … ertung-35a-SGB-V.pdf

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