Fingolimod in multiple sclerosis: No hint of added benefit in new therapeutic indication

March 8 2016

Since its approval in 2011, the multiple sclerosis drug fingolimod (Gilenya) has already undergone three early benefit assessments, all of which were mainly based on the approval study TRANSFORMS. After a new modification of the therapeutic indication by the regulatory authorities, the Federal Joint Committee (G-BA) again commissioned the German Institute for Quality and Efficiency in Health Care (IQWiG) to examine the added benefit of the drug in accordance with the Act on the Reform of the Market for Medicinal Products (AMNOG).

This assessment exclusively dealt with patients with highly active relapsing remitting multiple sclerosis (RRMS) who have not responded to a full and adequate course with at least one other disease-modifying treatment. According to the current assessment, an added benefit of fingolimod in comparison with the appropriate comparator therapies is not proven for these patients.

Therapeutic indication modified again

In October 2015, the therapeutic indication of fingolimod was modified again. Hence a new assessment became necessary that only dealt with patients with highly active RRMS despite full previous treatment with at least one disease-modifying therapy (e.g. interferon beta or glatiramer acetate). Previous diagnostic criteria for "highly active" were eliminated, and prior therapy no longer had to have a minimum duration of one year.

Previous assessments had resulted in an added benefit in comparison with the comparator therapy interferon beta for two patient groups: those with rapidly evolving severe RRMS and those who have not yet received full previous treatment with interferon beta. The current assessment has not dealt with these two therapeutic indications: On the one hand, the modified therapeutic indication does not relate to patients with rapidly evolving RRMS. On the other, due to the modification of the therapeutic indication, fingolimod is no longer approved for patients who have not yet received full treatment with interferon beta.

Data availability unchanged

For the newly defined patient group, the drug manufacturer in its dossier only presented data from the approval study TRANSFORMS that it had already submitted in a previous procedure. Neither the elimination of the diagnostic criteria nor the change in the minimum duration of a full previous treatment had influenced this definition.

Added benefit not proven in the new therapeutic indication

Hence the result concurs with the assessment from 2014 on this therapeutic indication: There was no hint of greater benefit or harm of fingolimod in comparison with the appropriate comparator therapy for any of the patient-relevant outcomes investigated.

The result remains the same: An added benefit of fingolimod in comparison with the appropriate comparator therapies is not proven for patients with highly active RRMS despite full previous treatment with at least one disease-modifying therapy.

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.

An overview of the results of IQWiG's benefit assessment is given by a German-language executive summary. In addition, the Website gesundheitsinformation.de, published by IQWiG, provides easily understandable German-language Information.

More information: Shailendra R Singh et al. Nociceptin/OrphaninFQ (N/OFQ) modulates immunopathology and airway hyperresponsiveness representing a novel target for the treatment of asthma, *British Journal of Pharmacology* (2016). DOI: 10.1111/bph.13416

Provided by Institute for Quality and Efficiency in Health Care