Secukinumab in ankylosing spondylitis or psoriatic arthritis: Added benefit not proven

March 18 2016

Secukinumab (trade name: Cosentyx) has been approved since November 2015 for adults with active ankylosing spondylitis or psoriatic arthritis. For patients with plaque psoriasis, the drug already underwent an early benefit assessment according to the Act on the Reform of the Market for Medicinal Products (AMNOG) in 2015.

The Federal Joint Committee (G-BA) now commissioned the German Institute for Quality and Efficiency in Health Care (IQWiG) to conduct a dossier assessment also for the new therapeutic indications. Since the manufacturer cited no suitable studies in its dossier, an added benefit of secukinumab in comparison with the appropriate comparator therapies is not proven.

No studies for direct comparison

According to the G-BA, the monoclonal antibody secukinumab had to be compared with one of four TNF? inhibitors.

Since the manufacturer presented no studies on these comparisons in its dossier, an added benefit of secukinumab in comparison with the appropriate comparator therapies for patients with active ankylosing spondylitis or psoriatic arthritis is not proven. This result concurs with the assessment of the manufacturer.

Indirect comparison: Manufacturer referred to

unpublished analyses

Since studies of direct comparisons were lacking, the manufacturer conducted an unsystematic literature search for both therapeutic indications to find out whether an indirect comparison would be possible. According to the manufacturer, no relevant data from studies on the appropriate comparator therapy were found in this search. This approach cannot be checked because the manufacturer did not disclose the inclusion criteria, the search itself or its results.

In addition, the manufacturer enclosed two unpublished indirect comparisons (network meta-analyses) in its dossier. Based on these analyses, the manufacturer also stated that no indirect comparison was possible. However, it did not process the analyses for the present benefit assessment and therefore did not present them in the publicly available part of the dossier.

Overall, it remained unclear whether an indirect comparison would have been possible and suitable for the derivation of greater or lesser benefit.

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: www.iqwig.de/download/A15-53_S … ertung-35a-SGB-V.pdf