Secukinumab in plaque psoriasis: Manufacturer dossier provided no hint of an added benefit

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Secukinumab (trade name: Cosentyx) has been approved since January 2015 for adults with moderate to severe plaque psoriasis. The German Institute for Quality and Efficiency in Health Care (IQWiG) examined in a dossier assessment whether this drug offers an added benefit over the appropriate comparator therapy. Such an added benefit cannot be derived from the dossier, however: In patients who are candidates for systemic treatment, an indirect comparison provided no suitable data because the minimum study duration had not been reached. In adults in whom other systemic treatments have been unsuccessful or unsuitable, the results from a direct comparison showed no statistically significant differences in comparison with the comparator group.

Study duration too short

The drug manufacturer presented an indirect comparison with methotrexate as comparator therapy for adults with plaque psoriasis who are candidates for systemic treatment and/or phototherapy. Placebo was used as common comparator.

A chronic condition such as moderate to severe plaque psoriasis requires longterm treatment. Studies with a minimum duration of 24 weeks are therefore needed to assess an added benefit. However, the five studies on secukinumab treatment presented by the company only lasted 12 weeks each; and the only study on methotrexate treatment lasted only 16

weeks. Hence the manufacturer dossier provided no suitable data and therefore no hint of an added benefit for this patient group.

No relevant group differences

For adults with plaque psoriasis for whom systemic treatment is not an option or in whom it has been unsuccessful, the manufacturer compared secukinumab with ustekinumab. It presented data of a total of 313 patients after a treatment duration of 24 weeks from an ongoing study for this comparison. However, there were no statistically significant differences between the treatment groups, neither regarding remission nor regarding symptoms and complaints or severe side effects and treatment discontinuations due to adverse events. Regarding the effect of the treatment on quality of life, the manufacturer presented data after a study duration of 16 weeks. These were unsuitable for the assessment because the study duration was too short. Hence no added benefit resulted from the manufacturer dossier for this patient group either.

More information: www.iqwig.de/download/A15-20_S … ertung-35a-SGB-V.pdf

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