Secukinumab and ixekizumab in psoriasis: Considerable added benefit for certain patients

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Psoriasis is an incurable chronic disease with a hereditary component, in which the body's immune system attacks parts of the skin. This leads to scaly red patches, which can be very itchy. About two million people in Germany have psoriasis, and 400 000 of them have a moderate to severe form of the disease.

Since 2015, the monoclonal antibody secukinumab (trade name: Cosentyx) has been approved for patients with moderate to severe plaque psoriasis. Since 2016, the monoclonal antibody ixekizumab (trade name: Taltz) has also been approved. The German Institute for Quality and Efficiency in Health Care (IQWiG) now examined in two early benefit assessments whether these drugs offer an added benefit for patients in comparison with the appropriate comparator therapies. For both drugs, there are indications of considerable added benefit for certain patients.

Secukinumab: drug manufacturer submitted new dossier for one patient group

The older of the two drugs had already undergone an early benefit assessment in 2015. At that time, IQWiG had derived indications of a minor and of a non-quantifiable added benefit - but only for patients with no or inadequate response to previous systemic treatments or with contraindication or intolerance to such treatments. There are also those

patients who are candidates for systemic treatment, but who have not yet received such treatment. The manufacturer applied for a new benefit assessment for this group because of new scientific findings.

No negative effects

For this new early benefit assessment, the manufacturer presented data from the study PRIME, in which fumaric acid esters were used in the comparator arm. In comparison with this comparator therapy, secukinumab showed very large positive effects in remissions, which resulted in an indication of an added benefit.

In addition, there was a hint of an added benefit in health-related quality of life and hints and indications of lesser harm in some side effects. There were no negative effects in any outcome. In summary, this resulted in an indication of considerable added benefit of secukinumab in patients who are candidates for systemic treatment.

Ixekizumab: only one of both studies usable

The other drug, ixekizumab, has been approved since 2016, but was not introduced into the market and subjected to an early benefit assessment before now because the manufacturer wanted to wait for new study results for this drug as well. The Federal Joint Committee (G-BA) again distinguished between two patient groups: patients who can receive systemic and/or phototherapy and patients with no or inadequate response to previous systemic treatments.

IQWiG could only analyse the data for the latter patient group because numerous participants who had already had phototherapy, i. e. a systemic treatment, had apparently been included in the study submitted by the manufacturer for patients eligible for systemic treatment. This specific

research question of the benefit assessment can only be answered on the basis of patients who have not received previous systemic treatment, however.

Large positive effects also for this drug

For patients with no or inadequate response to previous systemic treatments, ixekizumab was compared with ustekinumab in the study IXORAS. The study is ongoing; data are available from an interim analysis after 24 weeks. Since there were notably more remissions under ixekizumab than in the comparator arm, there is an indication of a considerable added benefit in the outcome category "morbidity".

There is an indication of a minor added benefit for health-related quality of life. This is accompanied by an indication of greater harm in the outcome "general disorders and administration site conditions", which does not raise doubts about the positive effects, however. In the overall consideration, there is an indication of a considerable added benefit of ixekizumab in comparison with ustekinumab for adults with moderate to severe plaque psoriasis with no or inadequate response to previous systemic treatments.

Symptom analysis inadequate for course of the disease

"Both assessments show that there are notable advances for patients also outside oncology", says the Institute's Deputy Director Stefan Lange in view of the results. "This is good news. We have one suggestion for improvement, however: In both studies, disease-related symptoms were analysed only for fixed time points and only improvements were reported. This is inadequate for the typical course of the disease with its ups and downs. It would be better to present and analyse the burden of

symptoms for each patient over the total study duration. There are simple methods for this purpose. This would also make temporary flare-ups and permanent improvements or deteriorations visible, which are generally of greater importance to the patients than their condition on a single fixed day."

G-BA decides on the extent of added benefit

The dossier assessments are 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 assessments, the G-BA conducts commenting procedures and makes final decisions on the extent of the added benefit.

More information: More English-language information will be available soon (extracts of the dossier assessments as well as easily understandable information on informedhealth.org). If you would like to be informed when these documents are available, please send an e-mail to info@iqwig.de.

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