Dupilumab for neurodermatitis: Indication of an added benefit in adults

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Dupilumab (trade name: Dupixent) has been approved since September 2017 for the treatment of adult patients with moderate to severe neurodermatitis (atopic dermatitis) who are candidates for systemic treatment. Typical symptoms of this chronic, non-contagious skin disease include rash and severe itching, which occur in flare-ups and might entail massive impairment of the quality of life.

In an early benefit assessment, the German Institute for Quality and Efficiency in Health Care (IQWiG) examined whether the new drug offers these patients an advantage over conventional treatments. According to the findings, the dossier contains informative data on the treatment goals that are essential for the patients, the so-called outcomes. They demonstrate clear advantages in symptom alleviation and particularly regarding the quality of life.

First neurodermatitis drug undergoing the AMNOG procedure

In most cases, neurodermatitis is treated topically with anti-inflammatory, cortisone-containing ointments. Patients with severe diseases might also undergo treatment with UV light or a so-called systemic therapy. The drug dupilumab is supposed to reduce the inflammation of the skin by inhibiting a proinflammatory mediator. Dupilumab is injected under the skin and is the first neurodermatitis drug undergoing the benefit assessment according to the Act on the

Reform of the Market for Medicinal Products (AMNOG).

In accordance with the specifications of the Federal Joint Committee (G-BA), dupilumab was to be compared with the therapy that has been standard to date (appropriate comparator therapy).

Drug manufacturer presented one relevant study

The manufacturer presented one usable randomized controlled trial in which patients were observed over a sufficiently long period (52 weeks). All participants received glucocorticoid ointments as so-called background therapy. In two study arms they were additionally administered two different dosages of dupilumab, the patients in the third study arm (control group) received a placebo.

Quality of life well documented

As the CHRONOS data show, the treatment results are in favour of dupilumab for numerous aspects of treatment (patient-relevant outcomes). This applies to itching and sleep loss on the one hand, and to health-related quality of life on the other. For the latter, the improvement is shown for the symptom-related outcomes. And this is also where the difference compared with the control group turns out to be most clear (indication of a major added benefit).

Dupilumab also has a disadvantage regarding side effects: Eye disorders occurred more often than in the control group in the study. According to the scientists, however, this issue does not challenge the advantages of the other outcomes.

Accurate assessment of the extent of the advantage is impossible

However, an accurate assessment of the total extent of this advantage, i.e. across all outcomes, is impossible. For the design of the CHRONOS study has one shortcoming: To prevent further occurrence of the symptoms, patients also received drugs when they were free of symptoms (proactive therapeutic strategy).

While dupilumab was continuously injected within the CHRONOS study, the background therapy was stopped in the placebo arm. Consequently, these patients might have been "undertreated". As it is unclear how this might have influenced the differences in the treatment results, IQWiG rates the - basically undisputed - added benefit as "non-quantifiable". It can therefore be minor, considerable or major.

G-BA decides on the extent of added benefit

The 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/en/projects-resul … book-sgb-v.8671.html

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