RECOMMENDATION ON MOSUNETUZUMAB IN THE TREATMENT OF REFRACTORY OR RELAPSED FOLLICULAR LYMPHOMA

Recommendation adopted at COHERE Finland's meeting on 7 May 2024

Mosunetuzumab is not included in the national range of services in the treatment of refractory or relapsed follicular lymphoma in patients who have previously received at least two systemic therapies. In COHERE Finland's opinion, the research evidence involves significant uncertainty. According to the available research evidence, a significant part of patients obtained a long-term response to the treatment, but the effect of the treatment on survival or quality of life cannot yet be assessed. In addition, treatment-related adverse events of any degree occurred in almost all patients, with severe or life-threatening events occurring in approximately half of the patients. So far, the evidence is based on a single-arm phase II study. The efficacy and cost comparison of mosunetuzumab therapy is based on a matching-adjusted indirect comparison, which as a method involves several factors giving rise to uncertainty.

As monotherapy, mosunetuzumab is indicated for the treatment of refractory or relapsed follicular lymphoma in patients who have previously received at least two systemic therapies.

Follicular lymphoma is a cancer of the lymph tissue. It is the most common of slow-growing lymphomas and the second most common subtype of lymphoma in the United States and Europe. Approximately 300 new cases are diagnosed annually in Finland. Follicular lymphoma often progresses slowly and has a good prognosis. With a relapse of the disease, the prognosis is worse. In patients with relapsed or refractory follicular lymphoma after two or more lines of therapy who have not yet been further treated, the median progression-free survival is 1.0 to 1.1 years and median survival is 4.8 to 8.8 years.

Mosunetuzumab is an antibody that simultaneously binds to both a T cell and a B cell. This leads to T-cell activation and B-cell death. Mosunetuzumab is administered intravenously in

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21-day treatment cycles. Treatment is given for 8 cycles, unless the patient develops unacceptable toxicity, or the patient's disease progresses. In patients who have achieved a complete response, treatment need not be continued after 8 treatment cycles. Patients with partial or stable response are given additional 9 treatment cycles (17 cycles in total).

In the marketing authorisation study, 60% of patients achieved a complete response. In COHERE Finland's opinion, the number of patients with follicular lymphoma in the study is limited, but the proportion of patients who have achieved a complete response to treatment is significant. Based on this, no conclusions can be drawn as to the effect of the treatment on the long-term survival of patients. The median duration of response was approximately three years. In COHERE Finland's opinion, the duration of response in study subjects seems clinically significant, but the result is subject to considerable uncertainty, considering that this is a single-arm study.

In the marketing authorisation study, treatment-related adverse events of any degree occurred in almost all patients, with severe or life-threatening events occurring in approximately half of the patients. In addition, a severe adverse event related to the treatment was reported in one in every three patients. In COHERE Finland's opinion, the number of severe and life-threatening adverse events associated with mosunetuzumab therapy is significant.

It is estimated that there are 12 patients in Finland suitable for receiving mosunetuzumab therapy annually. According to Fimea's estimate, mosunetuzumab therapy would increase the treatment costs of follicular lymphoma over three years, calculated at public wholesale prices, by approximately €360,000–520,000.

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This is a summary of a recommendation adopted by the Council for Choices in Health Care in Finland (COHERE Finland). The actual recommendation and the related background material are available in Finnish on the website of COHERE Finland under Valmiit suositukset.

The summary of the recommendation is also available in Swedish and Finnish on the website.

The Council for Choices in Health Care in Finland (COHERE Finland) works in conjunction with the Ministry of Social Affairs and Health, and its task is to issue recommendations on services that should be included in the range of public health services. Further information about service choices in healthcare is available on the COHERE Finland website.

Ministry of Social Affairs and Health

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