

Summary 1(2)

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SUMMARY OF A RECOMMENDATION BY COHERE FINLAND ON THE USE OF BELANTAMAB MAFODOTIN IN THE TREATMENT OF RELAPSED MULTIPLE MYELOMA

The Council for Choices in Health Care in Finland (COHERE Finland) approved the recommendation at its meeting on 5 May 2021.

According to the recommendation, belantamab mafodotin is not included in the range of public services for the treatment of relapsed multiple myeloma resistant to prior treatments. It has not been possible to sufficiently demonstrate the effectiveness of belantamab mafodotin, the risks of side effects are great and the costs high when considering the uncertainty related to clinical evidence.

Belantamab mafodotin is intended for patients with advanced multiple myeloma who have already received at least four prior treatments. Belantamab mafodotin consists of a monoclonal antibody that has been combined with a cytotoxic substance (maleimidocaproyl monomethyl auristatin F). Belantamab mafodotin is administered as an intravenous infusion at intervals of three weeks.

The efficacy and safety of belantamab mafodotin has been examined in one phase II DREAMM-2 study comparing two different doses of belantamab mafodotin. According to the study, approximately one third of the patients benefitted from the therapy. The median duration of the response achieved was 11 months, which can be considered a clinically significant result for these patients. The median progression-free survival was less than 3 months and in 71% of the patients, the disease had progressed or the patient had died during follow-up. According to the results, it appears that a significant proportion of those who participated in the study did not benefit from belantamab mafodotin for a longer period of time. There is no research data comparing the effects of belantamab mafodotin with other treatment options or placebo and it is not known whether any survival time benefits would be achieved with belantamab mafodotin compared with the other treatment options.



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The therapy involves a high risk of side effects. Adverse events related to the cornea

(keratopathy) are the most frequently reported adverse events (71%). In the majority of

patients with adverse events related to the cornea, epithelial damage was reversible.

The costs of the treatment per patient are EUR 63,000–80,000 a year. Every year, there

would be 10–20 patients suitable for the therapy.

Multiple myeloma is a cancer of the blood, in which malignant plasma cells begin to

proliferate in the bone marrow. With current treatments, myeloma is an incurable disease

in which a possible remission phase is followed by a relapse of the disease. In 2018, 359

new cases of myeloma were diagnosed and 263 deaths from myeloma were reported.

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.

The summary of the recommendation is also available in <u>Swedish</u> and <u>Finnish</u> 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