

15th of December 2021

STM051:00/2020
VN/20455/2021

SUMMARY OF A RECOMMENDATION BY COHERE FINLAND ON TECARTUS IN THE TREATMENT OF MANTLE-CELL LYMPHOMA

Recommendation approved at the meeting of the Council for Choices in Health Care in Finland (COHERE Finland) on 15 December 2021

According to the recommendation, brexucaptogene autoleusel (Tecartus®) is included in the national range of services provided to adults with relapsed or refractory mantle-cell lymphoma who are in good general health (WHO 0 – 1) and who have received at least two previous lines of treatment including Bruton's tyrosine kinase (BTK) inhibitor therapy. Inclusion in the range of services requires that the market authorisation holder and the buyer agree on a price that is significantly lower than the public wholesale price.

Tecartus, which falls under CAR T-cell therapies, is intended for adult patients with relapsed or refractory mantle-cell lymphoma that has been treated using at least two previous lines of treatment including treatment with a Bruton's tyrosine kinase inhibitor. Currently (December 2021), ibrutinib is the only Bruton's tyrosine kinase inhibitor on sale in Finland, and it has restricted eligibility for special rate of reimbursement in the treatment of relapsed or refractory mantle-cell lymphoma when at least three treatments have previously been given to the patient. Tecartus therapy is therefore not possible in clinical practice until after ibrutinib and in later lines of treatment.

The evidence of the effectiveness of Tecartus therapy is based on one single-arm phase 2 multicentre study (ZUMA-2) and indirect comparison. In the ZUMA-2 study, the overall survival and the duration of the response indicate that in some of the patients, the response is long, possibly even permanent. Slightly over one half of patients with a response seem to maintain the response for at least 2 years. However, because of the short monitoring period, it is difficult to draw conclusions regarding the final duration of the response. Tecartus

therapy has not been studied in a randomised design, which reduces the estimated reliability of the findings of the study. When compared to current treatment (allogeneic stem cell transplantation and different rituximab combination therapies), it is difficult to estimate the difference between the impacts of the treatments. Based on indirect comparisons, the impact of Tecartus therapy on the final results of the treatment seems to be better than with the current treatments, however.

Tecartus therapy is associated with a large number of different degrees of adverse reactions related to CAR T-cell therapies. The possibility of adverse reactions related to and emerging soon after the infusion require close monitoring, and the patient is required to stay near the centre providing the therapy for several weeks.

The overall costs of Tecartus therapy are more than EUR 500,000 per patient. According to the basic analysis conducted by the market authorisation holder, the incremental cost-effectiveness ratio (ICER) was EUR 76,000 per QALY. If the cost-effectiveness analysis is carried out without an assumption of recovery, ICER is EUR 90,000–210,000 per QALY, depending on the modelling method. The market authorisation holder estimates that between 2 and 4 patients per year could receive Tecartus therapy in Finland. In that case, the additional costs resulting from the treatment would be EUR 0.9–1.9 million per year.

Mantle-cell lymphoma is a rare B cell lymphoma, or cancer of lymphoid tissue. When diagnosed, mantle-cell lymphoma has often spread widely in the body. There is no known cure for the disease, but disease-free periods, or remissions, lasting several years are possible. Mantle-cell lymphoma develops at an average age of 68 and three out of four of those developing the disease are men. In 2019, 110 new cases were diagnosed in Finland.

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 [Recommendations](#).

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](#).