



RECOMMENDATION ON LISOCABTAGENE MARALEUCEL IN THE THIRD-LINE TREATMENT OF LARGE B-CELL LYMPHOMA

At its meeting of 27 March 2025, the Council for Choices in Health Care in Finland (COHERE Finland) adopted a recommendation on lisocabtagene maraleucel in the third-line treatment of large B-cell lymphoma.

Lisocabtagene maraleucel (liso-cel) is included in the national range of services for the third-line treatment of large B-cell lymphoma in patients with good performance status (ECOG 0–1). Treatment can only be given to patients who have not received any prior CAR T-cell therapy.

In COHERE Finland’s opinion, a large proportion of study patients achieved a complete response to liso-cel treatment. The evidence is so far based on phase I/II studies. COHERE Finland requires that the marketing authorisation holder and the buyer agree on a price significantly lower than the public wholesale price. COHERE Finland also requires that they agree, as part of the price negotiations, on the collection and reporting of monitoring data on treatment.

Liso-cel is intended for the treatment of adult patients with relapsed or refractory diffuse large B-cell lymphoma (DLBCL), primary mediastinal large B-cell lymphoma (PMBCL) and follicular lymphoma grade 3B (FL3B) after two or more lines of systemic therapy. The evidence of liso-cel in the therapeutic indication in question is mainly based on phase I and II open-label, single-arm studies. The primary endpoint of this study was the overall response rate (ORR) as determined by an independent review committee. Of the patients with relapsed or refractory B-cell non-Hodgkin lymphoma who participated in the phase I study, nearly three out of four achieved an overall response and approximately half (53%) achieved a complete response. The median duration of complete response was 26 months. The median time to response was one month. The median progression-free survival (PFS) was 6.8 months and the median overall survival (OS) 27.3 months. In the phase II study, 61% of patients achieved an overall response and 33% a complete response. The median duration of response was 3.5 months. In the study, the median PFS was 3.25 months and the median OS 15 months.

When measuring patients' quality of life, the results for general wellbeing improved two months after liso-cel infusion and the results for fatigue nine months after liso-cel infusion. The results for other dimensions remained more or less the same from the baseline up until 18 months. The quality-of-life index declined one month after liso-cel infusion, and it was better than the baseline from six months up until 18 months.

With regard to the overall response rate, the conducted subgroup analyses did not make it possible to identify the patient groups who would benefit from liso-cel treatment more than others.

The results concerning the efficacy and safety of liso-cel treatment were compared, through indirect comparisons, with the results of the CAR T-cell therapies used as comparator treatments. There were no statistically significant differences in efficacy outcomes between liso-cel and axi-cel treatments, whereas liso-cel proved to be more effective than tisa-cel. Patients treated with liso-cel had significantly fewer grade 3 or higher treatment-emergent adverse events (TEAEs) compared to those treated with axi-cel and tisa-cel. Nearly all patients experienced an adverse event of varying grade within 0–90 days following liso-cel infusion and slightly less than half of patients 90 days after infusion. It was assessed that in 74% of patients the adverse event was associated with liso-cel treatment. Acute adverse reactions were those typical of CAR T-cell therapies, which usually last for a few days. However, liso-cel does not differ significantly from other CAR T-cel therapies in respect of the nature of adverse reactions.

The costs of liso-cel and axi-cel are the same (EUR 327,000 at public list prices). This means that replacing one treatment with another would not generate any budget impact. The public list price of tisa-cel is EUR 320,000. With the estimated number of patients (n = 48), the annual medicine costs of liso-cel and axi-cel treatments would be approximately EUR 15.7 million. If all patients were to be treated with tisa-cel, the annual medicine costs would be EUR 15.4 million. Thus, the annual budget impact of liso-cel treatment would be approximately EUR 0.4 million compared to tisa-cel treatment.

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 [English](#) on the website.

The Council for Choices in Health Care in Finland (COHERE Finland) is attached to the Ministry of Social Affairs and Health. Its mission 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](#).