



RECOMMENDATION ON EPCORITAMAB IN THE TREATMENT OF RELAPSED OR REFRACTORY DIFFUSE LARGE B-CELL LYMPHOMA

At its meeting of 6 February 2025, the Council for Choices in Health Care in Finland (COHERE Finland) adopted a recommendation on epcoritamab in the treatment of relapsed or refractory diffuse large B-cell lymphoma.

Epcoritamab is not included in the national range of services for treating relapsed or refractory diffuse large B-cell lymphoma.

In COHERE Finland's opinion, the research evidence involves significant uncertainty. According to the available research evidence, less than half of the patients had a complete response to treatment, but the effect of the treatment on the quality of life cannot yet be assessed. So far, the evidence is based on a single-arm phase I/II study. In COHERE Finland's opinion, the number of severe or life-threatening adverse reactions is significant. The efficacy and cost comparison of epcoritamab treatment is based on an unanchored indirect comparison, which as a method involves several factors giving rise to uncertainty.

The evidence for the efficacy and safety of epcoritamab is mainly based on one phase I/II open-label, single-arm study. During the first interim analyses, 54 (38.8%) out of 139 patients with diffuse large B-cell lymphoma (DLBCL) achieved a complete response and 32 (23.0%) out of 139 patients achieved a partial response. The median PFS for patients was 4.4 months in the first two interim analyses. At 3, 6 and 9 months from the start of epcoritamab treatment, the estimated percentage of patients with DLBCL whose disease had not progressed was 44.1%, 39.9% and 37.2% respectively. The estimated percentage of DLBCL patients alive following the start of epcoritamab treatment was 70.6% after 6 months, 63.4% after 9 months, 56.1% after 12 months and 51.6% after 15 months. The median OS for DLBCL patients was 19.4 months in the last interim analysis.

During epcoritamab treatment, nearly all patients experienced at least one adverse event of some degree, and it was assessed that in 83.8% of patients this was associated with epcoritamab treatment. Treatment-related severe adverse events occurred in 36.5% of patients. During the treatment, fatal adverse events occurred in 12 cases (7.2%), one of which, caused by ICANS syndrome, was assessed to be associated with epcoritamab. Progression of the disease during treatment was the most common cause of death during treatment. Adverse reactions are typical of bispecific antibodies.

According to the marketing authorisation holder's estimate, there are about 80–100 DLBCL patients in Finland whose disease progresses after two lines of therapy, and about half of them (40–50 patients) receive third-line therapy. The Finnish Medicines Agency (Fimea) estimated that, based on public information, the median duration of epcoritamab treatment was 6.9 cycles, with the average costs per patient being EUR 122,768 when calculated at public tax-free wholesale prices.

The one-off medicine costs of CAR T-cell therapy was EUR 327,000 for Axi-Cel treatment and EUR 320,000 for Tisa-Cel treatment (wholesale prices for 2023). The cost of six cycles of chemoimmunotherapy was estimated at EUR 8,976.60 when using R-GemOx and at EUR 65,809.19 when using Pola-BR. The duration and price of loncastuximab tesirine were exceptionally based on the information presented in Fimea's assessment report, with the average cost of 4.6 cycles of treatment estimated at EUR 94,500.

Treatments replaced with bispecific treatments involve uncertainty, and epcoritamab may not replace CAR T-cell therapies to the same extent as it replaces chemoimmunotherapy. According to Fimea's estimate, ecoritamab would only replace chemoimmunotherapies for the number of patients estimated by Fimea. Thus, the annual budget impact of epcoritamab treatment would be approximately EUR 171,000–1,253,000 in 2024–2027, calculated at public wholesale prices.

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 [Finnish](#) and [Swedish](#) 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](#).