



## RECOMMENDATION ON TABELECLEUCEL IN THE TREATMENT OF RELAPSED OR REFRACTORY EPSTEIN-BARR VIRUS POSITIVE POST-TRANSPLANT LYMPHOPROLIFERATIVE DISEASE (EBV+ PTLD)

At its meeting of 19 December 2024, the Council for Choices in Health Care in Finland (COHERE Finland) adopted a recommendation on tabelecleucel in the treatment of relapsed or refractory Epstein-Barr virus positive post-transplant lymphoproliferative disease EBV+ PTLD).

**Tablecleucel is not included in the national range of services in the treatment of relapsed or refractory Epstein-Barr virus positive post-transplant lymphoproliferative disease (EBV+ PTLD) after at least one prior line of treatment. In COHERE Finland's opinion, the evidence on the efficacy of the treatment is insufficient and involves significant uncertainty. In COHERE Finland's opinion, the treatment is not cost-effective.**

Research evidence on the efficacy and safety of tabelecleucel is mainly based on the Phase III single-arm ALLELE study. A total of 43 patients who had previously received an allogeneic stem cell transplant (HCT) or solid organ transplant (SOT) were included in the study. Due to the small number of patients, the results of subgroup analyses are mostly descriptive.

With respect to the primary outcome measure of the ALLELE study, the objective overall response (ORR), the results were similar for the HCT and SOT cohorts; approximately 50% of patients achieved an objective overall response. In the HCT cohort, 43% of patients achieved a complete response, and in the SOT cohort, less than 30% of patients. Twelve-month overall survival (OS) was 70% in the HCT cohort and 56% in the SOT cohort. The estimated median OS was not assessable for the HCT cohort but was 16.4

months for the SOT cohort and 18.4 months for the whole study population. In COHERE Finland's opinion, a significant proportion of patients achieved response to the treatment, and the probability of survival appears to be higher than in patients in the retrospectively collected control arm. The short follow-up period creates uncertainty in the assessment of the significance of the results.

In addition to the ALLELE study, patients from other studies were also included in the safety assessment, so some of the patients could also have other diseases related to the Epstein-Barr virus. Treatment-emergent adverse events occurred in nearly all patients in the extended patient population (96.1%) and treatment-related adverse events in approximately 40% of patients. The main identified risks of the tabellecleucel therapy are related to tumour flare reaction and reverse rejection.

The medicine cost of one treatment cycle for a patient would amount to €225,000 at list prices. If the duration of treatment were 2 to 8 cycles, the medicine and dosing costs of the treatment would amount to approximately €451,000–1,805,000 in Finland. In the HTA assessment report published by the French authorities, the average treatment duration used in the modelling was 2.52 cycles, based on which the medicine and dosage costs per patient in Finland would amount to approximately €569,000. Due to the uncertainty of the treatment duration, the total costs per patient and, consequently, the assessment of the budget impact involve significant uncertainty. In COHERE Finland's opinion, this is an extremely expensive treatment, the clinical evidence of which involves significant uncertainty, and which is not cost-effective.

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) 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](#).