RECOMMENDATION ON BLINATUMOMAB AS CONSOLIDATION THERAPY IN THE TREATMENT OF ADULT PATIENTS WITH ACUTE LYMPHOBLASTIC LEUKAEMIA

At its meeting of 16 June 2026, the Council for Choices in Health Care in Finland (COHERE Finland) adopted a recommendation on blinatumomab.

Blinatumomab is included in the range of healthcare services as consolidation therapy for adult patients diagnosed with Philadelphia chromosome-negative CD19-positive B-cell precursor ALL. COHERE Finland requires that the marketing authorisation holder (MAH) and the buyer agree on a price significantly lower than the public wholesale price.

In COHERE Finland's opinion, adding blinatumomab to consolidation therapy with cytostatic agents can extend life for patients and reduce recurrence risk compared with chemotherapy alone. However, there are still uncertainties in the evidence on clinical efficacy, as the medians for the endpoints – overall survival (OS), relapse-free survival (RFS) – have yet to be reached.

In the context of the therapeutic indication specified in this recommendation, blinatumomab was primarily evaluated in an open-label, randomised study. The study shows that consolidation therapy combining blinatumomab with cytostatic agents demonstrated a statistically significant improvement in efficacy when compared with chemotherapy alone as consolidation therapy. The median OS was not reached in MRD-negative patients in either of the two arms at the time of the primary analysis when the median follow-up period was 4.5 years (HR: 0.44). The five-year Kaplan-Meier survival estimates were 82.4% in the blinatumomab arm and 62.5% in the chemotherapy arm. The median RFS was also not reached in MRD-negative patients in either treatment arm of the E1910 study. The study did not collect data on health-related quality of life. Although the follow-up period of the study was relatively long (4.5 years), neither the median RFS nor the median OS was reached in MRD-negative patients. Results from the final point of analysis are expected in 2030.

No significant new data emerged to add to previously known safety data on blinatumomab. At least one adverse reaction was observed in almost all patients. It is noteworthy that the

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most reported adverse reactions in MRD-negative patients in the blinatumomab arm were observed more frequently in the chemotherapy arm. A decrease in white blood cell count was observed more frequently in the chemotherapy arm during the consolidation phase when compared with the blinatumomab arm. Conversely, cytokine release syndrome was observed in 19 patients in the blinatumomab arm and in none in the chemotherapy arm.

In its cost-effectiveness analysis, MAH compared blinatumomab in combination with chemotherapy with chemotherapy used on its own. The incremental cost-effectiveness ratio (ICER) for blinatumomab treatment at baseline was EUR 43,300 per quality-adjusted life year (QALY). Fimea estimated that the result was of the correct magnitude but involved a degree of uncertainty. In Fimea's scenario analyses, the ICER ranged from EUR 43,400 to EUR 49,400 per QALY. In its budget impact analysis, MAH examined costs over a five-year period, taking into account drug and administration costs, as well as other treatment-related costs. According to MAH, the budget impact per patient would amount to EUR 155,000 over the period of five years. MAH estimates that about 15 patients per year would be eligible for blinatumomab as consolidation therapy, which would amount to 74 patients over five years. This would result in additional annual costs of EUR 2.1 to 2.3 million at public list prices. The cumulative budget impact would be EUR 11.5 million over the five-year period. Fimea estimates some uncertainties relating to the proportion of patients starting the consolidation therapy and the prices of different blinatumomab products. According to Fimea, adding blinatumomab to consolidation therapy administered in line with current treatment practice would increase annual costs per patient up to EUR 375,000 at public list prices. Fimea projects that the budget impact at list prices would amount to EUR 11.5 to 14.7 million over the period of five years.

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