



RECOMMENDATION ON GLOFITAMAB 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 glofitamab in the treatment of relapsed or refractory diffuse large B-cell lymphoma.

Glofitamab 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 achieved a complete response to treatment. So far, the evidence is based on a single-arm phase I/II study. In COHERE Finland's opinion, the number of severe and life-threatening adverse reactions is significant. The efficacy and cost comparison of glofitamab treatment is based on an unanchored indirect comparison, which as a method involves several factors giving rise to uncertainty.

The efficacy and safety of glofitamab was evaluated in an open-label phase I/II study in patients with relapsed or refractory B-cell non-Hodgkin's lymphoma (n=108). In the study, the primary efficacy endpoint was complete response rate as assessed by an independent review committee. Approximately 35% of patients achieved a complete response. With respect to the secondary efficacy endpoints, the overall response rate was approximately 50% among all patients who took part in the study. The median time to a partial or complete response was 42 days. The median duration of overall response was approximately 15 months. The median duration of complete response was not reached. The study did not cover any comparator treatments. Therefore, the efficacy of glofitamab was indirectly compared with bendamustine plus rituximab (BR), Kymriah and Yescarta treatments. Glofitamab was also compared with Pola-BR treatment. The results of these comparisons support the use of glofitamab when compared to BR, Pola-BR and Kymriah

treatments. With Yescarta, the results were better than with glofitamab. All comparisons were indirect comparisons made in a single-arm, non-randomised study. COHERE Finland considers that the conclusions drawn from the comparisons contain a significant amount of uncertainty that cannot be fully assessed.

Nearly all patients who took part in the study experienced a treatment-related adverse event. During glofitamab treatment, 52% of patients died, and nine of these cases were associated with an adverse event. More than half (about 58%) of the patients were reported to have severe, life-threatening adverse events. Less than half (about 49%) of the patients experienced severe adverse events. During treatment, five patients (around 3%) experienced adverse events leading to the discontinuation of treatment. The most common adverse event during glofitamab treatment was cytokine release syndrome. Most of these events were mild and occurred at the start of treatment. Other found side effects were typical of patients who had received several prior treatments. In COHERE Finland's opinion, the number of severe and life-threatening adverse events associated with glofitamab treatment is significant. As such, treatment-related adverse reactions are typical of bispecific antibodies or combinations of antibodies.

The estimated number of eligible patients receiving glofitamab is approximately 15–20 patients per year. The costs of glofitamab treatment per patient would be much higher than those of Pola-BR treatment and chemotherapy combined with rituximab and smaller than those of CAR T-cell therapy. If glofitamab treatment was to fully replace comparator treatments for 24 patients, the overall annual costs arising from glofitamab treatment would be approximately EUR 1.5 million. The annual budget impact would be around EUR 834,000, 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](#).