

Approved at the meeting of the Council for Choices in Health Care in Finland (COHERE) on 12 December 2019

Axicabtagene ciloleucel (Yescarta) in the treatment of refractory or relapsed diffuse large B-cell lymphoma (DLBCL) and primary mediastinal B-cell lymphoma (PMBCL)

Axicabtagene ciloleucel (Yescarta) is included in Finland's national range of public health services for the treatment of adult patients with good condition (WHO 0-1) and relapsed or refractory diffuse large B-cell lymphoma and primary mediastinal large B-cell lymphoma after two or more lines of systemic therapy, but only if the conditions set out in this recommendation are met.

According to the Council for Choices in Health Care in Finland (COHERE), this is a promising new treatment. For some patients, this treatment can provide sustained long-term response and survival over a longer period. Treatment outcomes with axicabtagene ciloleucel appear to be better than those reported with other previous treatment options. A significant number of patients responded to treatment, and half of the patients were still alive after two years of treatment.

However, the lack of comparator data and the small number of patients treated so far makes assessing the effectiveness of treatment challenging. Treatment is associated with frequent serious adverse reactions for which more follow-up data is required. In addition, information is needed on the efficacy of the treatment as part of standard healthcare service.

Axicabtagene ciloleucel is a CAR T-cell therapy in which the patient's own T cells have been genetically modified to recognise and kill cancer cells. Axicabtagene ciloleucel treatment is demanding and may require intensive care. Treatment is associated with serious and, in some cases, fatal adverse reactions. Treatment can only be provided in treatment centres approved by the manufacturer.

The total costs of treatment are very high, particularly considering the uncertainty associated with clinical evidence available on the effectiveness of the treatment. The public list price for the treatment is EUR 327,000, and its introduction involves additional costs that create a burden on the healthcare system. Based on available information, it is estimated that the incremental cost-effectiveness ratio (ICER) is approximately EUR 69,000. Including the treatment in the service range requires an agreement on a significant discount between the seller and the organiser of services.

Finnish Medicines Agency Fimea estimates that the number of patients with B-cell lymphoma (DLBCL and PMBCL) eligible for CAR T-cell therapy would be around 40 per year.

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 health care is available on the COHERE Finland website: www.palveluvalikoima.fi.

