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RECOMMENDATION ON
**CILTACABTAGENE AUTOLEUCEL IN THE TREATMENT OF ADVANCED MULTIPLE
MYELOMA**

At its meeting of 2 February 2023, the Council for Choices in Health Care in Finland (COHERE Finland) adopted a recommendation on ciltacabtagene autoleucel in the treatment of advanced multiple myeloma.

According to the recommendation, ciltacabtagene autoleucel is included in the national range of services for adult patients with relapsed and refractory multiple myeloma who have good performance status (ECOG score of 0–1) and have received at least three prior treatments, including an immunomodulator, a proteasome inhibitor and a CD38 antibody, and whose disease progressed during the most recent therapy. COHERE Finland requires that the marketing authorisation holder and the buyer agree on a price significantly lower than the public wholesale price. COHERE also requires that the marketing authorisation holder and the national price negotiator agree, as part of the price negotiations, on the collection and reporting of monitoring data on treatment.

Ciltacabtagene autoleucel is a genetically modified CAR T cell therapy for the treatment of relapsed and refractory multiple myeloma in adults who have received at least three prior therapies. The European Commission granted a conditional marketing authorisation in May 2022. During treatment, the patient's own T cells are reprogrammed with a transgene encoding a chimeric antigen receptor (CAR). After modification, the CAR T cells are transplanted back to the patient as a single-dose infusion. The therapy is accompanied by four weeks of follow-up.

The research evidence is based on the phase 1b/2 CARTITUDE-1 study, which did not have a comparison group. Ninety-seven patients received ciltacabtagene autoleucel therapy. Almost all patients in the study who received a ciltacabtagene autoleucel infusion responded to treatment. Most patients had a complete response. At just over two years (28 months) of follow-up, more than two out of three patients survived and more than half were progression-free.

Ciltacabtagene autoleucel has a significantly higher rate of serious adverse events than other treatments in use. Approximately one in five patients experienced a severe cytokine release syndrome typical of CAR T therapies. In a small proportion (6%), the serious adverse event resulted in death.

In COHERE's view, the results achieved with ciltacabtagene autoleucel are promising and also clinically relevant, considering the numerous prior treatments received by the patients. However, efficacy has been demonstrated in younger patients with good performance status, and there is significant uncertainty associated with the research evidence.

Ciltacabtagene autoleucel therapy is extremely expensive. The per-patient cost of medication and administration is EUR 446,000. The additional per-patient cost of treatment is more than EUR 300,000 higher than that of the combination therapy containing pomalidomide. According to scenario analyses carried out by Fimea, the cost-effectiveness of the treatment compared to the reference treatments is EUR 108,000–135,000/QALY.

Myeloma is a cancer of the plasma cells in the blood and bone marrow where malignant plasma cells (myeloma cells) begin to multiply in the bone marrow. With current treatments, it is an incurable disease where any recovery phase is followed by relapse. In 2020, 356 new cases of myeloma were reported in Finland. The average life expectancy for myeloma patients is about 7–8 years. The number of eligible patients is estimated to be 10–15 per year.

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 [Recommendations](#).

The summary of the recommendation is also available in [Swedish](#) and [Finnish](#).

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](#).