

## **SUMMARY OF A RECOMMENDATION BY COHERE FINLAND ON LUSPATERCEPT IN THE TREATMENT OF RED-BLOOD-CELL TRANSFUSION-DEPENDENT ANAEMIA ASSOCIATED WITH MYELODYSPLASTIC SYNDROME**

Recommendation approved at the meeting of the Council for Choices in Health Care in Finland (COHERE) on 24 March 2021

According to the recommendation of the Council for Choices in Health Care in Finland (COHERE Finland), luspatercept is not included in the national range of services for the treatment of red-blood-cell transfusion-dependent anaemia associated with myelodysplastic syndrome (MDS). The efficacy of luspatercept treatment is slight and the cost of treatment is high relative to the therapeutic value and the evidence-based uncertainty.

Luspatercept is a new drug for the treatment of very low, low and intermediate-risk anaemia associated with MDS. The objectives of treatment are to reduce the number of red-blood-cell transfusions required in symptomatic anaemia and to improve patients' health-related quality of life. Luspatercept also has marketing authorisation for the treatment of anaemia caused by beta thalassaemia.

The research data are based on the double-blind, phase III MEDALIST study in which patients were randomised to receive luspatercept (n = 153) or placebo (n = 76). Luspatercept or placebo was administered subcutaneously every three weeks. Treatment was continued up to 48 weeks if the patient had benefited from treatment during the first 24 weeks. Luspatercept was found to have a slight effect in the treatment of anaemia associated with at most intermediate-risk MDS. A little over one third (38%) of patients receiving luspatercept reached at least eight weeks of independence from red-blood-cell transfusions during the first 24 weeks of treatment, compared to 13% in the placebo group. Treatment had no effect on the health-related quality of life. The study did not determine the effect of luspatercept on the need for iron chelation treatment, which is needed to reduce the accumulation of iron in the body.

Based on a cost–benefit analysis by the marketing authorisation holder, adding luspatercept to the present treatment would result in additional costs of about EUR 130,000 per patient per year compared to the present treatment practice. An estimated 20–25 patients meet the indication for treatment with luspatercept.

Myelodysplastic syndrome (MDS) is a group of malignant blood diseases in which the production of blood-forming cells in the bone marrow is disturbed. In about one third of patients, MDS progresses to acute myeloid leukaemia. The number of new cases of the disease per year is about 2–3 per 100,000. In 2018, 121 new cases were detected.

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 [recommendations](#) page of the website of COHERE Finland.

The summary of the recommendation is also available on the website 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 health care is available on the [COHERE Finland website](#).