

SUMMARY OF COHERE FINLAND'S RECOMMENDATION ON DIFELIKEFALIN FOR THE TREATMENT OF PRURITUS ASSOCIATED WITH CHRONIC KIDNEY DISEASE IN PATIENTS UNDERGOING HAEMODIALYSIS

At its meeting of 19 December 2023, the Council for Choices in Health Care in Finland (COHERE Finland) adopted a recommendation on difelikefalin for the treatment of pruritus associated with chronic kidney disease in patients undergoing haemodialysis.

According to the recommendation, the drug difelikefalin, under the conditions specified in the recommendation, is included in the national service range only for the treatment of severe or very severe (e.g. WI-NRS score 7–10) pruritus associated with chronic kidney disease in adult haemodialysis patients and only when other treatments do not sufficiently relieve the symptom. COHERE Finland also requires that the marketing authorisation holder and the buyer agree on a price lower than the wholesale price.

The drug difelikefalin is administered by intravenous injection at the end of the haemodialysis session. Difelikefalin binds to receptors that are involved in the control of pruritus and inflammation and activates them, reducing the inflammation that leads to pruritus and the signals that lead to the sensation of pruritus itself. Pruritus associated with chronic kidney disease can significantly worsen the patient's quality of life, and existing symptomatic treatments are not sufficient for everyone.

The marketing authorisation was granted based on evidence from two studies in which patients received the addition of either difelikefalin or a placebo to their usual care. Approximately half of the patients treated with difelikefalin and more than a third of the patients treated with placebo and standard of care reported a significant reduction in pruritus on the WI-NRS. The results were based on a short 12-week double-blind comparative study followed by an open-label 52-week study.

In the view of COHERE Finland, the difference in the proportion of patients receiving relief (51.1% vs 35.2%) can be considered modest. More than a third of the placebo group also experienced a clinically significant reduction in their pruritus symptoms. The quality of life related to pruritus improved in a greater proportion of difelikefalin-treated patients than in placebo-treated patients.

Adverse reactions such as diarrhoea, dizziness, nausea and hyperkalaemia (increased blood potassium) were observed slightly more frequently in patients treated with difelikefalin. However, the incidence of serious adverse events was similar in both treatment groups. The observed adverse events are typical in dialysis patients.

COHERE Finland considers that the treatment should be targeted at haemodialysis patients suffering from severe or very severe pruritus who do not receive help from current treatment. In this case, the number of patients per year would be at most 160–170. When considering the initiation of treatment with difelikefalin, an assessment of the symptoms of pruritus should be made to confirm the severity of the patient's symptoms. The effectiveness of the treatment should be monitored regularly, and treatment should be discontinued if the symptoms do not improve sufficiently.

The cost per patient of the difelikefalin medication is €123 per week for most patients at the tax-free wholesale price. The budgetary impact depends in particular on the number of patients treated and the duration of treatment. When targeting patients with severe or very severe pruritus who do not receive adequate support from other treatments, the total annual budget impact can be estimated at less than EUR 1 million. COHERE Finland also requires that the marketing authorisation holder and the buyer agree on a price lower than the public wholesale price.

This is a summary of a recommendation adopted by the Council for Choices in Health Care in Finland (COHERE Finland). The full 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 [Swedish](#) and [English](#).

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](#).