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SUMMARY OF COHERE FINLAND'S RECOMMENDATION ON NIVOLUMAB IN COMBINATION WITH RELATLIMAB FOR THE FIRST-LINE TREATMENT OF ADVANCED CUTANEOUS MELANOMA

At its meeting of 19 December 2023, the Council for Choices in Health Care in Finland (COHERE Finland) adopted a recommendation on nivolumab in combination with relatlimab for the first-line treatment of advanced cutaneous melanoma.

Nivolumab in combination with relatlimab is included in the national range of services for the first-line treatment of advanced cutaneous melanoma in adults and adolescents aged 12 years and older with tumour cell PD-L1 expression < 1%.

In the opinion of COHERE Finland, targeting the treatment at patients specified in the marketing authorisation is justified. COHERE Finland requires that the marketing authorisation holder and the buyer agree on a price lower than the public wholesale price.

Nivolumab and relatlimab are antibodies, nivolumab binding to T-cell PD-1 receptors and relatlimab to the LAG-3 receptor. The simultaneous blocking of both receptors increases the activity of T cells so that the body's own defense mechanism can destroy cancer cells. Nivolumab in a fixed-dose combination with relatlimab is indicated for the first-line treatment of advanced, unresectable or metastatic melanoma in adults and adolescents aged 12 years and older with tumour cell PD-L1 expression < 1%.

The results on the effects of nivolumab in combination with relatlimab for the first-line treatment of advanced cutaneous melanoma are mainly based on a phase 2/3 study. Nivolumab in combination with relatlimab resulted in a 22% reduction in the risk of disease progression or death in the overall study population compared to nivolumab monotherapy. In the patient population (PD-L1 expression less than 1%) limited as per the marketing authorisation, the risk was reduced by a further 32%. Median overall survival was not reached in the nivolumab in combination with relatlimab arm in the overall study population or in PD-L1 < 1% of patients. In the view of COHERE Finland, the results in the population limited as per the marketing authorisation are clinically significant.



Severe or life-threatening adverse events (Grade 3–4), serious adverse events and adverse events leading to treatment discontinuation were observed slightly more frequently in patients who received nivolumab in combination with relatlimab compared to patients who received nivolumab monotherapy. Adverse events leading to treatment discontinuation were clearly more frequently observed in the nivolumab in combination with relatlimab group than in the nivolumab monotherapy group. In contrast, no consistent differences were observed between treatment arms in the incidence of immune-related adverse events or in the duration of required immunosuppressive therapy.

According to the marketing authorisation holder, the cost per patient is approximately EUR 150,000 for nivolumab in combination with relatlimab and approximately EUR 73,000 for nivolumab monotherapy. According to Fimea, the cost of medication and administration of nivolumab in combination with relatlimab is approximately EUR 80,500 per patient. The marketing authorisation holder estimates that there could be approximately 8–10 patients in Finland each year who are eligible for treatment of advanced cutaneous melanoma with nivolumab in combination with relatlimab. For this number of patients, the annual cost of treatment with nivolumab in combination with relatlimab will be approximately EUR 640,000 to EUR 810,000.

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](#).