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## RECOMMENDATION ON COMBINATION THERAPY CONTAINING PEMBROLIZUMAB IN THE FIRST-LINE TREATMENT OF BILIARY TRACT CARCINOMA

At its meeting of 19 December 2024, the Council for Choices in Health Care in Finland (COHERE Finland) adopted a recommendation on combination therapy containing pembrolizumab in the first-line treatment of biliary tract carcinoma.

**Pembrolizumab is not included in the national range of services as the first-line treatment of adults with unresectable or metastatic biliary tract carcinoma. In COHERE Finland's opinion, the addition of pembrolizumab to the gemcitabine and cisplatin combination therapy does not bring any clinically significant additional benefit for patients with unresectable or metastatic biliary tract cancer. The addition of pembrolizumab did not give rise to any new significant safety concerns, but the treatment was associated with a larger number of low-grade immune-mediated adverse events than the comparator. Pembrolizumab will significantly increase the costs of the combination therapy.**

The efficacy and safety of pembrolizumab in the treatment of previously untreated and unresectable or metastatic biliary tract carcinoma has been studied in the phase III KEYNOTE-966 study in which patients received pembrolizumab in combination with gemcitabine and cisplatin. The study control group received a placebo in combination with gemcitabine and cisplatin.

Pembrolizumab-containing combination therapy was only slightly superior to the comparator in terms of overall survival (OS). The median increase in life expectancy was very moderate (1.8 months) with combination therapies containing pembrolizumab. Secondary endpoint results were also highly similar between study groups. The median OS remained similar in the 3-year follow-up analysis. In COHERE Finland's opinion, adding pembrolizumab to the usual chemotherapy combination does not bring any

clinically significant additional benefit for patients with unresectable or metastatic biliary tract carcinoma.

In subgroup analyses, the results in predefined subgroups were largely similar in terms of overall survival. Quality of life results did not exhibit any statistically significant difference between treatment groups.

Nearly all patients who received pembrolizumab experienced at least one adverse event of some degree. In addition, the treatment was associated with more immune-mediated adverse events and infusion-related reactions than the comparator. In COHERE Finland's opinion, the addition of pembrolizumab to the combination therapy of gemcitabine and cisplatin does not raise any new significant safety concerns. The addition of pembrolizumab caused slightly more low-grade immune-mediated adverse events than the comparator.

The medicine and dosage costs of pembrolizumab per patient in a therapy lasting for 7 months were approximately €87,000 at list prices. Due to the uncertainty involved with the number of patients, Fimea decided in its assessment statement to state the annual therapy costs for 30–120 patients. In this case, the annual costs calculated using the list prices of pembrolizumab are €2.6-10.4 million at public list prices.

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 [Valmiit suositukset](#).

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

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](#).