

RECOMMENDATION ON COMBINATION THERAPY CONTAINING DURVALUMAB IN THE FIRST-LINE TREATMENT OF BILIARY TRACT CANCER

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 durvalumab in the first-line treatment of biliary tract cancer.

Durvalumab is not included in the national range of services as the first-line treatment of adults with unresectable or metastatic biliary tract cancer. In COHERE Finland's opinion, the addition of durvalumab 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 durvalumab 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. Durvalumab will significantly increase the costs of the combination therapy.

The efficacy and safety of durvalumab in the treatment of biliary tract cancer has been studied in a phase III, randomised, double-blind, placebo-controlled, multicentre study (TOPAZ-1), in which adult patients with previously untreated and unresectable or advanced biliary tract cancer received durvalumab in combination with gemcitabine and cisplatin. The study also included a control group that only received gemcitabine and cisplatin.

Durvalumab-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 (1.5 months) with combination therapies containing durvalumab. 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 durvalumab to the usual chemotherapy combination does not bring any clinically significant additional benefit for patients with unresectable or metastatic biliary tract cancer.

Subgroup analyses showed evidence of poorer efficacy of durvalumab combination therapy in patients with tumours located in the gallbladder. Patients' PD-L1 status did not appear to have any impact on the efficacy of treatment. Quality of life results did not exhibit any statistically significant difference between treatment groups.

Nearly all patients who received durvalumab experienced at least one adverse event of some degree. A key concern associated with the treatment are immune-mediated adverse events. These occurred slightly more frequently with the durvalumab combination therapy than with the comparator, but the majority of them were low-grade. Serious adverse events occurred equally in both treatment groups. In COHERE Finland's opinion, the addition of durvalumab to the combination therapy of gemcitabine and cisplatin does not raise any new significant safety concerns. The addition of durvalumab caused slightly more low-grade immune-mediated adverse events than the comparator.

The medicine and dosage costs of durvalumab per patient in a therapy lasting for 7 months were approximately €93,000 at list prices. Due to the uncertainty involved with the number of patients, Fimea calculated the annual therapy costs for 30–120 patients. The annual costs calculated using the list prices of durvalumab are €2.8–11.2 million at public list prices.

General info box in summaries

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](#) 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](#).