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# RECOMMENDATION ON TREMELIMUMAB AND DURVALUMAB IN THE TREATMENT OF HEPATOCELLULAR CARCINOMA

Recommendation adopted at COHERE Finland's meeting on 7 May 2024

**Tremelimumab-durvalumab combination therapy is not included in the national range of services for the first-line treatment of adults with advanced or unresectable hepatocellular carcinoma. Durvalumab monotherapy is included in the national range of services for the first-line treatment of adults with advanced or unresectable hepatocellular carcinoma. Inclusion in the range of services requires that the marketing authorisation holder and the buyer agree on a price significantly lower than the public wholesale price. In COHERE Finland's opinion, the research evidence involves uncertainty due to the open-label study setting. The addition of tremelimumab to durvalumab therapy will not, in COHERE Finland's opinion, bring any significant additional benefits in the treatment of hepatocellular carcinoma. The incidence of serious adverse events, adverse reactions leading to discontinuation of treatment and immune-mediated adverse events was higher with combination therapy than with durvalumab monotherapy in the treatment of advanced hepatocellular carcinoma.**

The combination of tremelimumab and durvalumab and durvalumab as monotherapy are indicated for the first-line treatment of advanced or unresectable hepatocellular carcinoma in adults.

Hepatocellular carcinoma is a rare cancer in Finland. In 2014–2020, a total of 450–600 hepatocellular carcinomas per year were diagnosed in Finland, and 400–500 people per year died of liver cancers. Due to minor early-stage symptoms, hepatocellular carcinoma is often only diagnosed when the disease is advanced and the prognosis is poor. According to the statistics of the Finnish Cancer Registry, the age-standardised relative survival rate for liver cancers in Finland is 40% after one year, 17% after three years, and 11% after five years of diagnosis.

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Tremelimumab and durvalumab are both antibodies that inhibit proteins that suppress the immune function in cancer (either PD-L1 or CTLA-4). Both antibodies and their combination enhance the activation and function of T-cells that inhibit tumour growth at different stages of the immune response.

In the marketing authorisation study, the median overall survival of tremelimumab-durvalumab combination therapy was 2.7 months and of durvalumab monotherapy 2.8 months longer than that of the comparator therapy. According to preliminary follow-up, a higher proportion of patients who received combination therapy or durvalumab monotherapy were alive at four years compared to the comparator therapy. A complete response was achieved by 3% of the patients who received combination therapy and 1.5% of the patients who received durvalumab monotherapy. There were no significant differences in the objective response rate, partial response and progression-free survival between the two therapies.

In the marketing authorisation study, approximately one in every two patients treated with tremelimumab-durvalumab combination therapy or comparator therapy experienced a grade 3 to 4 adverse event. Of patients treated with durvalumab, 37% experienced a grade 3 to 4 adverse event. Durvalumab monotherapy had the least adverse effects associated with treatment discontinuation.

It is estimated that there are 10–12 patients in Finland suitable for receiving tremelimumab-durvalumab combination therapy annually. Compared to the comparator therapies, the total costs per patient of the combination therapy are approximately €86,000–120,000 higher. The total costs of a durvalumab monotherapy treatment cycle are approximately €106,000. According to Fimea, the estimate involves uncertainty due to the number of patients and the comparator therapies and their duration.



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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 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.

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