



11 June 2025

STM023:00/2023
VN/33762/2024

SUMMARY OF COHERE FINLAND'S RECOMMENDATION FOR THE USE OF ENFORTUMAB VEDOTIN IN COMBINATION WITH PEMBROLIZUMAB IN THE FIRST-LINE TREATMENT OF UROTHELIAL CARCINOMA

The Council for Choices in Health Care in Finland (COHERE Finland) adopted the recommendation at its meeting on 11 June 2025.

Combination therapy with enfortumab vedotin and pembrolizumab is included in the national range of services for the treatment of unresectable or metastatic urothelial carcinoma in adult patients with good performance status (ECOG 0–1). COHERE Finland requires that the marketing authorisation holder and the buyer agree on a price further significantly lower than the confidential negotiated price, which was given to COHERE. In COHERE Finland's view, the clinical evidence supporting the efficacy and safety of the combination therapy is sufficient. The evidence is based on a phase III randomised study in which the comparator treatment was platinum-based chemotherapy. COHERE Finland considers that the safety of combination therapy with enfortumab vedotin and pembrolizumab is comparable to that of chemotherapy and immuno-oncological treatments in general. There is uncertainty regarding the cost-effectiveness and budget impact of the combination therapy.

Combination therapy with enfortumab vedotin and pembrolizumab (EV+P) is indicated for the first-line treatment of unresectable or metastatic urothelial carcinoma in adult patients who are eligible for platinum-based chemotherapy. The efficacy and safety of EV+P combination therapy have been evaluated in a phase III randomised open-label comparative multicentre study. Platinum-based chemotherapy (cisplatin/carboplatin + gemcitabine) was used as the comparator treatment. The patients enrolled in the study had good performance status (ECOG 0–1). Approximately one in three patients in the comparator group received avelumab as maintenance therapy. The results are available for a period of 17 months.

In the study, the median progression-free survival (PFS) was about six months longer with the EV+P combination therapy than with chemotherapy. The median overall survival (OS) of patients receiving the combination therapy was twice as long as that of the chemotherapy group. In the EV+P group, 67.7% of patients achieved an objective response compared to 44.4% in the chemotherapy group. The median duration of response could not be assessed in the EV+P group, while it was seven months in the chemotherapy group. In COHERE Finland's opinion, the combination therapy is clinically significant, and the evidence is sufficient. The evidence is based on a phase III randomised study in which platinum-based chemotherapy, also used in Finland, served as the comparator.

The median time to pain progression was around four months longer in the EV+P group than in the chemotherapy group. There were no differences in pain progression between the groups



during the first six months. In both treatment groups, changes in the worst pain scores happened after six months, and they were similar.

No significant changes were observed in the EORTC QLQ-C30 and EQ-5D-5L quality of life measures between patients treated with EV+P or chemotherapy during the study. The subgroup analysis results were consistent with those of the overall study population, with no subgroup showing better efficacy than others.

Patients in the chemotherapy group experienced a slightly higher number (79% vs 73%) of treatment-related severe, life-threatening or fatal adverse events (grades 3–5) than the EV+P group. In the EV+P group, 19 (4%) fatal adverse events occurred, four of which were considered related to the treatment arm (1%). The average duration of EV+P combination therapy was more than twice that of chemotherapy, which influenced the incidence of adverse events to some extent. More adverse events of grade 1–5 peripheral sensory neuropathy, maculopapular rash, diarrhoea and hyperglycaemia occurred in patients receiving EV+P combination therapy than in those receiving chemotherapy. In COHERE Finland's view, the safety profile of EV+P combination therapy is similar to that of chemotherapy and immuno-oncological treatments, but the management of peripheral sensory neuropathy, skin reactions and hyperglycaemia requires careful monitoring and treatment.

According to the marketing authorisation holder's estimate, approximately 130 patients per year would be eligible for EV+P combination therapy. The cost of EV+P combination therapy is significantly higher than that of chemotherapy and potential avelumab maintenance therapy. The additional cost per patient is approximately EUR 160,000, considering the drug and administration costs at list prices, as well as the average treatment duration. According to the Finnish Medicines Agency's (Fimea) budget impact calculation, the annual budget impact would be approximately EUR 20.8 million if all 130 eligible patients were to receive EV+P combination therapy instead of chemotherapy. If not all eligible patients received EV+P combination therapy, the budget impact would be smaller. Fimea's estimate suggests that the uncertainties in the budget impact and cost-effectiveness model overlap, stemming from a lack of information about how much enfortumab vedotin and PD-1 inhibitors are already used in first-line treatment. After this, the remaining treatment options are limited to chemotherapy, vinflunine or clinical trials. EV+P combination therapy has yet to be used in Finland, so the most appropriate subsequent treatment for patients who received this combination remains unknown. It is therefore impossible to provide an accurate cost estimate for the entire treatment path, including all potential treatment lines for these patients.

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](#).

The Council for Choices in Health Care in Finland (COHERE Finland) is attached to the Ministry of Social Affairs and Health. Its mission 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](#).

