RECOMMENDATION ON ENFORTUMAB VEDOTIN IN THE TREATMENT OF ADVANCED UROTHELIAL CARCINOMA

At its meeting of 15 December 2022, the Council for Choices in Health Care in Finland (COHERE Finland) adopted a recommendation on enfortumab vedotin in the treatment of advanced urothelial carcinoma.

According to the recommendation, enfortumab vedotin is included in the national range of services for the treatment of locally advanced or metastatic urothelial carcinoma in adult patients with good performance status who had previously received platinum-containing chemotherapy and treatment with a PD-1 or PD-L1 inhibitor. COHERE Finland requires that the marketing authorisation holder and the buyer agree on a price significantly lower than the public wholesale price.

Enfortumab vedotin is intended for the treatment of locally advanced or metastatic urothelial cancer in adult patients who had previously received platinum-containing chemotherapy and programmed cell death receptor 1 or the programmed cell death ligand 1 inhibitor (PD(L)-1).

The research evidence is based on a phase III randomised open-label EV-301 study in which patients were randomly assigned to receive enfortumab vedotin (n = 301) or chemotherapy (docetaxel, paclitaxel or vinflunine, n = 307). During the follow-up period, the median survival was four months longer in the enfortumab vedotin group (12.9 vs. 8.9 months) and progression-free survival was 1.8 months longer than in the chemotherapy group (5.6 vs. 3.7 months). At 12 months, 53% of those who had received enfortumab vedotin and 39% of those who had received chemotherapy survived, and at 18 months, 29% and 20% respectively. COHERE Finland considers that the treatment can significantly prolong survival. There is uncertainty about the wider applicability of the

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outcomes. The effect was demonstrated in patients with good performance status, and the comparative treatments do not fully correspond to the Finnish treatment practice.

A slightly higher number of severe or life-threatening adverse events were observed in the enfortumab vedotin group. The incidence of severe adverse skin reactions and pruritus was distinctly higher in the enfortumab vedotin group compared to the chemotherapy group.

According to Fimea, the cost-effectiveness ratio of enfortumab vedotin compared to vinflunine is approximately EUR 140,000–165,000/QALY. Vinflunine, which is little used in Finland, was used as the comparator treatment in the cost-effectiveness analysis. For this reason, the true cost-effectiveness ratio of enfortumab vedotin compared to current Finnish treatment cannot be assessed based on existing research data. The per-patient cost of medication and administration of enfortumab vedotin is around EUR 58,000 with a duration of treatment of 5.5 months. The number of eligible patients is estimated to be 27–45 per year.

Urothelial carcinoma is a cancer of the inner lining of the urinary tract. In 2019, the number of new cases of bladder and urinary tract cancer was 1,430 (1,076 among men and 354 among women). In metastatic or locally advanced carcinoma, the median survival period varies between 8–16 months for first-line treatment and 7–11 months for second-line treatment.

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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 Recommendations.

The summary of the recommendation is also available in Finnish and Swedish.

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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