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Summary of a recommendation by COHERE Finland on trastuzumab deruxtecan in the treatment of metastatic HER2-positive breast cancer

The recommendation was approved at a COHERE Finland meeting held by email on 17–23 November 2021.

COHERE Finland recommends that trastuzumab deruxtecan be included in the national range of services for the treatment of unresectable or metastatic HER2-positive breast cancer in adult patients with performance status ECOG 0-1 who have received two or more prior anti-HER2-based regimens. Inclusion in the range of services requires that the marketing authorisation holder and the buyer agree on a price significantly below the wholesale list price. The Council for Choices in Health Care in Finland (COHERE Finland) estimates that the results achieved with the treatment are promising. However, based on the available research data, the assessment of treatment effectiveness involves uncertainties, and serious adverse effects are common.

Trastuzumab deruxtecan is indicated for the treatment of unresectable or metastatic HER2-positive breast cancer in adult patients who have received two or more prior anti-HER2-based regimens. It is administered to the patient as an intravenous infusion once every three weeks until disease progression or unacceptable toxicity.

Evidence of the safety and efficacy of trastuzumab deruxtecan is based on one open-label, phase II, multicenter study (DESTINY-Breast01), in which the primary outcome measure, objective response rate, was 61.4%. The updated results published in a conference paper – median overall survival (OS 29.1 months) and progression-free survival (PFS 19.4 months) – indicate the scale of the expected benefit of the treatment, which the COHERE estimates to be of clinical significance considering the number of prior lines of therapy the

patient group had received. The most significant factor limiting the assessment of the clinical significance of treatment results and the therapeutic value of trastuzumab deruxtecan is the absence of a reference arm in the study. Despite the limitations of available research evidence and reported adverse events, some of them serious, COHERE Finland estimates that trastuzumab deruxtecan is a promising treatment option for patients with metastatic HER2 positive breast cancer who have received two or more prior anti-HER2-based regimens.

According to the scenario analysis of the Finnish Medicines Agency Fimea, patients given trastuzumab deruxtecan would live 0.8–0.9 years longer than patients on existing regimens. The ICER based on this scenario analysis is EUR 147-153,000/QALY. According to COHERE Finland's estimate, the prognosis of patients given trastuzumab deruxtecan could be slightly better than in Fimea's scenario analysis. Based on a budget impact analysis, the number of patients who are eligible for trastuzumab deruxtecan therapy is approximately 74 per year, and including this treatment in the range of services of the Finnish healthcare system would generate additional annual costs of approximately EUR 6.9 million.

Breast cancer is the most common type of cancer among women in Finland. HER2 positive cancer is one of the sub-types of breast cancer in which the growth factor receptor 2 (HER2) is overexpressed. Approximately 12-15% of breast cancers are HER2 positive.

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](#).