SUMMARY OF COHERE FINLAND'S RECOMMENDATION FOR THE USE OF TISLELIZUMAB IN THE TREATMENT OF OESOPHAGEAL SQUAMOUS CELL CARCINOMA AFTER PREVIOUS PLATINUM-BASED CHEMOTHERAPY

The Council for Choices in Health Care in Finland (COHERE Finland) adopted the recommendation at its meeting on 8 May 2025.

Tislelizumab is included in the national range of services for the treatment of unresectable, locally advanced or metastatic oesophageal squamous cell carcinoma in adult patients with good performance status (ECOG 0–1) after previous platinum-based chemotherapy. Patients must have PD-L1 expression ≥ 10%. COHERE Finland also requires that the marketing authorisation holder and the buyer agree on a price significantly lower than the public wholesale price.

In COHERE Finland's view, the clinical efficacy of tislelizumab based on overall survival appears significant, particularly in patients with good performance status and PD-L1 expression ≥ 10%. Treatment-related adverse events are typical of immuno-oncology treatments and are manageable.

Tislelizumab is indicated for the treatment of unresectable, locally advanced or metastatic oesophageal squamous cell carcinoma in adult patients who have previously received platinum-based chemotherapy. Tislelizumab is a humanised IgG4 monoclonal antibody variant against PD-1.

The evidence for the efficacy and safety of tislelizumab in the treatment of oesophageal squamous cell carcinoma is based on a phase III open-label marketing authorisation study comparing tislelizumab treatment with chemotherapy. The study's primary endpoint, the median overall survival (OS), was 8.6 months for patients receiving tislelizumab and 6.3 months for those receiving chemotherapy. However, progression-free survival (PFS) was longer in the chemotherapy group (median 2.1 months) than in the tislelizumab group (median 1.6 months). When considering only those patients with PD-L1 TAP ≥ 10%, the median OS was 10.3 months with tislelizumab, whereas with chemotherapy, it was 6.8 months. In COHERE Finland's view, the clinical efficacy of tislelizumab based on overall survival appears significant, particularly in patients with good performance status and PD-L1 expression ≥ 10%.

No clinically relevant differences in health-related quality of life were observed between tislelizumab and chemotherapy treatments. Based on the marketing authorisation study, it does not appear possible to identify narrower patient subgroups within the authorised indication that would benefit more from tislelizumab treatment than others.

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Almost all the patients receiving tislelizumab in the marketing authorisation study experienced at least one adverse event. Severe, life-threatening or fatal adverse events (grade 3–5) were observed in 18.8% of patients receiving tislelizumab. The most common severe adverse events associated with tislelizumab treatment were pneumonia, dysphagia, oesophageal obstruction and pneumonitis.

In COHERE Finland's opinion, the adverse events associated with tislelizumab treatment are typical of immuno-oncology treatments in terms of both quantity and quality.

The therapeutic and economic value of tislelizumab is considered in this recommendation for patients with good performance status (ECOG 0–1) who are being considered for immuno-oncological treatment. The comparator treatment was nivolumab, which has not been directly compared with tislelizumab in studies. Based on the indirect comparison provided by the marketing authorisation holder, tislelizumab and nivolumab are expected to have similar and comparable effects on treatment outcomes.

The cost-minimisation analysis provided by the marketing authorisation holder considered drug and administration costs, as well as healthcare resource use and costs, treatment-related adverse event costs, and costs of further treatments and terminal care. Based on the cost-minimisation analysis and the anchored indirect comparison, the costs of tislelizumab and nivolumab treatments can be considered to be similar. According to the Finnish Medicines Agency's (Fimea) evaluation team, there is little uncertainty regarding the cost-minimisation analysis conducted by the marketing authorisation holder.

Fimea's clinical expert estimates that up to 20 patients per year could be eligible for tislelizumab treatment. Based on this estimate and Fimea's calculations of drug and administration costs, the annual cost of the use of tislelizumab would be approximately EUR 600,000. However, at list prices, tislelizumab does not result in additional costs compared to nivolumab treatment.

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 COHERE Finland website under Valmiit suositukset.

The summary of the recommendation is also available on the website 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 the about service choices in healthcare is available on the COHERE Finland website.

Sosiaali- ja terveysministeriö

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