Approved at the meeting of the Council for Choices in Health Care in Finland (COHERE) on 12 December 2019

Cemiplimab (Libtayo) for the treatment of cutaneous advanced squamous cell carcinoma

Cemiplimab does not belong to the national range of public health services for the treatment of locally advanced or metastatic cutaneous squamous cell carcinoma.

The effectiveness of cemiplimab is difficult to assess given the available data, as the research results are exceptionally uncertain. Cemiplimab has not been compared with any other treatment in the studies, and the follow-up period of the studies is still short. Some of the patients treated with cemiplimab did respond to treatment and approximately one in ten of the patients achieved a complete response to treatment. It cannot be concluded whether the achieved response to treatment will ultimately lead to prolonged life expectancy.

In the opinion of the Council of Choices in Health Care in Finland, the effectiveness of cemiplimab has not been adequately demonstrated and its costs are too high in view of the uncertainty associated with the clinical evidence. According to the Finnish Medicines Agency's estimate, the costs of medication and administration calculated at the wholesale price of the medicine are approximately EUR 155,000 per patient, when the average duration of treatment is assumed to be 17.7 months.

Further research data is needed before conclusions can be drawn on the effectiveness of cemiplimab and on the targeting of treatment to those potentially benefiting from it. The European Medicines Agency (EMA) has granted a conditional marketing authorisation for the preparation. According to the terms of the marketing authorisation, the EMA must be provided with further information on the results of long-term monitoring of cemiplimab by October 2022. Due to uncertainty factors, the Finnish Medicines Agency has also not presented an estimate of the cost-effectiveness of cemiplimab.

Cemiplimab is the first medicine to be used to treat cutaneous advanced squamous cell carcinoma. Cemiplimab is a monoclonal antibody belonging to the PD-1 immunotherapy group. It is intended to be used as monotherapy for the treatment of cutaneous metastatic or locally advanced squamous cell carcinoma in adult patients for whom treatment with curative surgery or curative radiation is not suitable. The medicine is administered as an infusion into a vein every three weeks.

About 1,700 new cases of cutaneous squamous cell carcinoma are diagnosed annually in Finland. The majority of patients (approximately 95%) can be treated with surgery and/or radiotherapy. In a small number of patients, the disease progresses either locally or develops metastases. In Finland, approximately 20 to 24 new patients per year would be suited to receiving cemiplimab for advanced squamous cell carcinoma.

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 health care is available on the COHERE Finland website: www.palveluvalikoima.fi.

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