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SUMMARY OF COHERE FINLAND'S RECOMMENDATION ON LUTETIUM (^{177}Lu) VIPIVOTIDE TETRAXETAN FOR THE TREATMENT OF METASTATIC, CASTRATION-RESISTANT AND PSMA-POSITIVE PROSTATE CANCER

At its meeting of 1 February 2024, the Council for Choices in Health Care in Finland (COHERE Finland) adopted a recommendation on lutetium (^{177}Lu) vipivotide tetraxetan for the treatment of metastatic, castration-resistant and PSMA-positive prostate cancer.

According to the recommendation, lutetium (^{177}Lu) vipivotide tetraxetan is included in the national range of services for the treatment of metastatic, castration-resistant and PSMA-positive prostate cancer in patients previously treated with androgen receptor (AR) pathway inhibition and taxane-based chemotherapy.

In the view of COHERE Finland, the effect of the treatment on progression-free survival and overall survival is clinically significant. It is an expensive treatment, which also entails indirect costs for healthcare. COHERE Finland requires that the marketing authorisation holder and the buyer agree on a price significantly lower than the public wholesale price. In addition, the administration of treatment requires compliance with the requirements of the Radiation Act.

Prostate cancer is the most common cancer among men in the Western world. In 2020, approximately 5,000 new cases of prostate cancer were diagnosed in Finland. The five-year relative survival rate for patients with prostate cancer is 94%. Prostate cancer is called castration resistant when it progresses during castration therapy. Medical or surgical castration is the main form of treatment for advanced prostate cancer. The median survival of patients with metastatic, castration-resistant prostate cancer is approximately 22 to 31 months.

It is recommended to administer the assessed treatment every six weeks for a total of up to six times, or fewer times in case of disease progression or unacceptable toxicity. The product binds to cancer cells expressing the antigen PSMA, whereby the radiation from lutetium (^{177}Lu) causes damage to the DNA of the cells, which can lead to cell death.

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The research evidence supporting the granting of the marketing authorisation compared lutetium (^{177}Lu) vipivotide tetraxetan in combination with current therapy with the current therapy alone. With lutetium (^{177}Lu) vipivotide tetraxetan in combination with current therapy, the overall survival was four months longer and progression-free survival more than five months longer. In the view of COHERE Finland, the effect of the treatment is clinically significant, although it does not change the basic nature of the disease as a fatal disease.

Almost all study patients experienced some degree of adverse event, and almost the same number of adverse events were observed in both arms of the study. However, more severe, life-threatening or fatal adverse events (Grade ≥ 3) were observed in patients treated with lutetium (^{177}Lu) vipivotide tetraxetan.

According to the Finnish Medicines Agency, the incremental cost-effectiveness ratio of lutetium (^{177}Lu) vipivotide tetraxetan treatment is EUR 240,000 per QALY compared to current treatment and EUR 228,000 per QALY compared to cabazitaxel. Based on a scenario analysis by the Finnish Medicines Agency, the annual budget impact for 154 patients would be approximately EUR 13 million, calculated at the public wholesale price.

The administration of treatment requires compliance with the requirements of the Radiation Act. The nuclear medicine practise requires a safety licence issued by the Radiation and Nuclear Safety Authority. Treatments may only be administered by healthcare professionals authorised to handle radiopharmaceuticals in a hospital.

This is a summary of a recommendation adopted by the Council for Choices in Health Care in Finland (COHERE Finland). The full 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) 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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