RECOMMENDATION ON EFGARTIGIMOD ALFA FOR TREATING MYASTHENIA GRAVIS

At its meeting of 14 September 2023, the Council for Choices in Health Care in Finland (COHERE Finland) adopted a recommendation on efgartigimod alfa in the treatment of myasthenia gravis.

Efgartigimod alfa is not included in the national range of services for treating generalised myasthenia gravis. Responses to treatment were short-lived, and so far there is only short-term research data available. The clinical relevance of the medicinal product is therefore unclear. More data would be needed on how the product compares with other treatments and on its cost-effectiveness.

Myasthenia gravis is a chronic autoimmune disease which disrupts the transmission of nerve impulses in the neuromuscular junctions. It causes weakness and fatigue in the voluntary muscles. At worst, it can be life threatening. At the end of 2022, there were 1,659 people in Finland who were entitled to special reimbursement for myasthenia gravis medication. 40 to 50 new cases are reported per year. Approximately 85 per cent of patients have generalised myasthenia gravis.

Efgartigimod alfa has been granted a marketing authorisation as an additional treatment to standard of care treatment. It is administered in hospital as intravenous infusion, initially once a week for four weeks, followed by clinical evaluation.

The marketing authorisation for efgartigimod alfa is based on a randomised, double-blind study comparing it with standard treatment. The duration of the study was short, only 26 weeks. The average duration of treatment in both study arms was 152 days and the majority of patients had only the first two cycles of treatment.

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The response rates in patients receiving efgartigimod alfa were higher than in the placebo arm during the first cycles of treatment in AChR positive patients. When assessing the main result variable, a modest but, according to experts, clinically relevant change was achieved. However, the duration of response was short considering the nature of the disease, i.e. only about one in three patients receiving efgartigimod alfa maintained the response for 12 weeks. The greatest uncertainty in the research evidence concerns the number of cycles required and the frequency of dosing.

Mild to moderate adverse reactions were fairly common and were likely to have been caused, in part, by underlying medical conditions.

Efgartigimod alfa is a very expensive treatment; the annual medication and administration costs per patient are EUR 280,000 at public wholesale prices. Since the estimates of the number of patients vary, the overall budgetary impact is also uncertain. The holder of the marketing authorisation for the medicinal product has not presented a cost-effectiveness analysis.

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.

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