RECOMMENDATION ON THE USE OF RAVULIZUMAB IN THE TREATMENT OF NEUROMYELITIS OPTICA SPECTRUM DISORDER (NMOSD)

At its meeting of 28 August 2025, the Council for Choices in Health Care in Finland (COHERE Finland) adopted a recommendation on ravulizumab in the treatment of neuromyelitis optica spectrum disorder (NMOSD).

Ravulizumab is not included in the national range of services for treating neuromyelitis optica spectrum disorder (NMOSD) in adult patients who are anti-aquaporin 4 (AQP4) antibody-positive.

In COHERE Finland's opinion, the open-label, single-arm study structure causes uncertainty to the research evidence, although ravulizumab's efficacy on preventing the relapses seems promising. The study lacks evidence for clinically significant effects on patients when compared to the current treatment practice. The research evidence shows that a significant proportion of the patients treated with ravulizumab experienced adverse events. Ravulizumab is a very expensive medicine. The reasoning for the duration of ravulizumab treatment and the criteria for discontinuing treatment have not been adequately defined. No information is available on the cost-effectiveness of this treatment regarding Finland. The standard treatment is rituximab, the costs of which are moderate.

Ravulizumab is indicated for the treatment of adult patients with NMOSD who are anti-AQP4 antibody-positive. The research evidence for the clinical efficacy and safety of ravulizumab for the therapeutic indication specified in the recommendation is based on an open-label, multicentre phase III study which uses an external placebo control, i.e. the study is, in practice, single-armed.

In this study, ravulizumab significantly reduced NMOS seizures. A separate adjudication committee assessed whether the symptoms experienced by the patients fulfilled the criteria for a seizure. No seizures were reported in ravulizumab-treated patients during the follow-up period of the study, but the open-label, single-arm study structure makes it

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difficult to interpret the results. Ravulizumab does not seem to maintain or improve the quality of life compared to the control group. In COHERE Finland's opinion, the evidence for the clinical efficacy of ravulizumab involves uncertainty due to the study setting. Ravulizumab is intended as a long-term treatment. If the treatment fails to bring the desired outcome, it is unclear how to define the criteria for continuing or discontinuing the treatment.

In the marketing authorisation study, 91% of the patients treated with ravulizumab experienced treatment-emergent adverse events of varying grade, while 16% of the patients experienced grade 3 to 4 adverse events and 14% of the patients severe adverse events. Treatment-related adverse events were reported in 45% of the patients treated with ravulizumab. The study reported two cases of meningococcal infection in patients treated with ravulizumab. In COHERE Finland's opinion, a significant proportion of the patients treated with ravulizumab experienced adverse events.

Because of regular dosing, the costs of ravulizumab treatment continuing for years may be considerable high. The annual costs of medication arising from standard treatment are moderate compared to ravulizumab treatment. The annual per-patient cost of medication and administration of ravulizumab would be around EUR 361,000 at tax-free wholesale prices. After the first year of treatment, treating a limited population of patients (1–5 patients) with ravulizumab would cost approximately EUR 0.36–1.81 million per year.

No information is available on the cost-effectiveness of ravulizumab in treating patients with NMOSD when it comes to Finland. Despite its high cost, treatment is used or is recommended to be used in several European countries and Canada. In some of these countries, the HTA authority has set a limited patient population (second-line treatment) or a reduced cost of treatment as a condition for the reimbursement status or introduction of the 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 website of COHERE Finland under Valmiit suositukset.

The summary of the recommendation is also available in Finnish and Swedish on the website.

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 service choices in healthcare is available on the COHERE Finland website.

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