RECOMMENDATION ON RAVULIZUMAB IN THE TREATMENT OF GENERALISED MYASTHENIA GRAVIS (gMG)

At its meeting of 25 September 2025, the Council for Choices in Health Care in Finland (COHERE Finland) adopted a recommendation on ravulizumab in the treatment of generalised myasthenia gravis (gMG).

Ravulizumab is not included in the national range of services for treating generalised myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AChR) antibody-positive. In COHERE Finland's opinion, the therapeutic value of ravulizumab in the treatment of Finnish patients is limited compared to current standard treatments. Based on the available research data, the clinically significant benefit as an add-on to conventional therapy is low, and the evidence is subject to considerable uncertainty due to the study design. The efficacy of ravulizumab in treating severe or treatment-resistant disease remains unproven. The data generated by the metrics used in the study also introduce uncertainty in evaluating therapeutic value. Ravulizumab is an expensive drug, with annual treatment costs at public list prices being extremely high. There is no information available on its cost-effectiveness from the Finnish perspective.

Ravulizumab is indicated for the treatment of adult patients with generalised myasthenia gravis (gMG) who are anti-acetylcholine receptor (AChR) antibody-positive. The clinical efficacy and safety of ravulizumab for the therapeutic indication specified in the recommendation were assessed in a randomised, double-blind and placebo-controlled phase III study. During the randomised-controlled period of the study, treatment with ravulizumab improved patients' abilities to perform daily activities when assessed using the patient-reported MG-ADL scale. Ravulizumab also reduced disease severity on the physician-assessed QMG scale. A similar outcome was observed in patients who switched from placebo to ravulizumab during an open-label extension period. However, the outcomes did not meet the thresholds for minimal clinical significance defined in research literature. A larger proportion of patients treated with ravulizumab achieved a significant response on the scales used when compared to placebo.

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In COHERE Finland's opinion, the evidence for the clinical efficacy of ravulizumab involves uncertainty when it comes to the suitability of the indicators used in the study for clinical use. The doses of standard treatment used in the study have not been published. The use of rituximab was not permitted in the study. Ravulizumab is administered as an add-on to other therapy. Therefore, comparative evidence against commonly used immunosuppressive adjunct therapies in Finland is lacking.
The subgroup analyses did not identify any groups that would have benefited either more or less from ravulizumab. The Nordic treatment guideline recommends targeting new therapies to difficult-to-treat cases of myasthenia gravis. At the beginning of the marketing authorization study, there were few patients with severe myasthenia gravis. The benefit of treatment for patients with severe disease remains unclear, and there is insufficient evidence of ravulizumab's efficacy in treating severe or treatment-resistant disease.
Patients who received ravulizumab during the randomised-controlled period experienced more grade 3 or 4 adverse events and severe adverse events than patients receiving the comparator therapy. Two of the patients treated with ravulizumab died during the randomised-controlled period and two patients during the extension period.

The annual per-patient cost of medication and administration of ravulizumab is around EUR 379,000 for the first year and around EUR 361,000 for the following years as tax-free wholesale prices. The treatment is intended as a continuous treatment, which means that if it continues for years, the costs may be considerably high. The annual costs of medication of standard therapies are moderate compared to ravulizumab. No information is available on the cost-effectiveness of ravulizumab regarding Finland.

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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