SUMMARY OF COHERE FINLAND'S RECOMMENDATION FOR THE USE OF CLESROVIMAB IN THE PREVENTION OF LOWER RESPIRATORY TRACT INFECTIONS CAUSED BY RSV

At its meeting of 16 June 2026, the Council for Choices in Health Care in Finland (COHERE Finland) adopted a recommendation for the use of clesrovimab.

Clesrovimab is included in the national range of services for a limited target group during the 2026–2027 RSV season. The target group of clesrovimab therapy primarily includes infants under 12 months of age belonging to risk groups who

- were born before 29 weeks of gestation;
- have a heart condition requiring repair;
- have severe immunodeficiency and/or bronchopulmonary dysplasia (BDP), and have received supportive therapy within the last six months;
- have Down syndrome;
- were born between September and February at 29 to 36 + 6 weeks of gestation; or
- were born at 29 to 36 + 6 weeks of gestation and have children of toddler age in the family.

If the availability of clesrovimab in Finland is sufficient, it may also be administered to infants under three months of age during the 2026–2027 RSV season. The marketing authorisation holder and the buyer must agree on a price significantly lower than the public wholesale price.

In COHERE Finland's view, immunisation with antibodies should be continued during the 2026–2027 RSV season. COHERE Finland recommends limiting the use of clesrovimab in the same way as in the immunisation currently in use. In COHERE Finland's opinion, more information is required about the efficacy of clesrovimab nationally and internationally to justify its broader use.

The clesrovimab recommendation is primarily based on two randomised marketing authorisation studies and the Finnish Medicines Agency's (Fimea) assessment report. The evidence is limited, particularly regarding long-term effects and national use experience. RSV infections cause a significant disease burden, especially in young children, and

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severe forms of the disease may lead to hospitalisation. In Finland, a considerable number of RSV-related hospitalisations occur annually, and the risk is greatest among infants under 12 months of age and in risk groups. Clesrovimab is a long-acting monoclonal antibody administered as a single intramuscular dose during the RSV season. It is intended to be used during the infant's first RSV season.

Compared with a placebo, clesrovimab significantly reduces RSV-related doctor appointments and hospitalisations (with a relative risk reduction of approximately 60–90%). No difference in efficacy compared with palivizumab has been demonstrated. Indirect comparisons with nirsevimab suggest a possible difference in efficacy, but the evidence does not allow reliable conclusions. The safety profile is favourable, with adverse events being mostly mild and similar to those seen with comparator treatments.

According to the marketing authorisation holder's analysis, clesrovimab is dominant compared with nirsevimab, but the results are sensitive particularly to the efficacy assumptions used. According to Fimea's assessment, no reliable difference in efficacy between the two products can be demonstrated, meaning their cost-effectiveness is similar. The total annual cost of clesrovimab immunisation is estimated at around EUR 12.3 million if all infants under six months of age were immunised. The maximum number of patients could correspond to an entire annual birth cohort (approximately 45,000–50,000 children), but the target group is likely to be more limited. The budget impact is associated with significant uncertainty, depending on price, the scope of use, and how the target group is defined.

Further evidence on the efficacy, safety and cost-effectiveness of clesrovimab is required, particularly in the Finnish context. The combined effects of different prevention strategies have yet to be comprehensively evaluated. Continued follow-up and the collection of additional evidence are key conditions for any potential expansion of the treatment's use.

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