RECOMMENDATION ON NIRSEVIMAB IN THE PREVENTION OF LOWER RESPIRATORY TRACT INFECTION CAUSED BY RESPIRATORY SYNCYTIAL VIRUS (RSV)

Recommendation adopted at COHERE Finland's meeting on 7 May 2024

Nirsevimab is included in Finland's national range of services for a limited target group during the RSV season 2024–2025. The target group of nirsevimab therapy primarily includes neonates and infants, 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 6 months;

- have the Down syndrome;

- were born in September–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 nirsevimab in Finland is sufficient, nirsevimab may also be administered to infants under 3 months of age during the RSV epidemic season between 1 October and 31 March. In both cases, the marketing authorisation holder and the buyer must agree on a price significantly lower than the public wholesale price.

In COHERE Finland's opinion, immunisation with nirsevimab, which has evidence of efficacy similar to that of the currently used comparator, but which is easier to administer, should be introduced during the RSV season of 2024–2025. COHERE Finland recommends limiting the use of nirsevimab. In COHERE Finland's opinion, more information is needed on experiences on its use in Finland in order to justify any wider use of nirsevimab.

Nirsevimab is an antibody indicated for the prevention of lower respiratory tract diseases caused by RSV in neonates and infants during their first RSV season.

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The efficacy and safety of nirsevimab have been studied in four different studies covering very different target groups of children to be immunised.

For lower respiratory tract infection caused by RSV, a dose of nirsevimab reduces the risk of illness and hospitalisation compared to placebo during the first 150 days after injection. The results of marketing authorisation studies suggested a reduced risk of extremely serious lower respiratory tract infection in connection with RSV infection in patients treated with nirsevimab. In subgroup analyses, no statistical significance in efficacy differences was reached in any of the subgroup comparisons.

Based on descriptive results, a single dose of nirsevimab and monthly doses of the comparator palivizumab provided similar levels of protection against RSV infection in both preterm and lung and heart disease patients. The need for hospital care was also similar between the groups.

In marketing authorisation studies, adverse events were observed in equal numbers in those patients who received nirsevimab and in those who received a placebo. Severe adverse reactions were observed slightly more in those who received a placebo compared to those who received nirsevimab. The most common adverse events were infections, skin symptoms and gastrointestinal symptoms. Of the adverse reactions of particular interest, hypersensitivity reactions were observed in 25% of those who received nirsevimab and in 26% of those who received a placebo. Adverse events were observed in equal numbers in those who received nirsevimab and in those who received a placebo.

When the different immunisation strategies of the cost-effectiveness model were analysed, it was estimated that the higher the proportion of children immunised with nirsevimab was, the lower the number of medically attended events. If the additional benefit obtained with nirsevimab is evaluated by patient group, the higher the risk of severe RSV infection in the patient group concerned, the greater the benefit. A study based on register data from Finland and Sweden mapping out the risk factors for RSV infection was utilised in the delimitation of the target group of COHERE Finland’s recommendation.

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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 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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