SUMMARY OF COHERE FINLAND'S RECOMMENDATION FOR THE USE OF NIRSEVIMAB IN THE PREVENTION OF LOWER RESPIRATORY TRACT INFECTIONS CAUSED BY RESPIRATORY SYNCYTIAL VIRUS (RSV)

The Council for Choices in Health Care in Finland (COHERE Finland) adopted the recommendation at its meeting on 08 May 2025.

Nirsevimab is included in the national range of services for a limited target group during the RSV season 2025–2026. The target group of nirsevimab therapy primarily includes infants under one year of age in 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 nirsevimab in Finland is sufficient, nirsevimab may also be administered to infants under three 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 view, immunisation with nirsevimab should be continued during the RSV season 2025–2026. COHERE Finland continues to recommend limiting the use of nirsevimab. In COHERE Finland's opinion, more information is required about the efficacy of nirsevimab in Finland to justify its broader use.

Nirsevimab is indicated for the prevention of lower respiratory tract diseases caused by RSV in neonates and infants during their first RSV season. In September 2024, the indication was expanded to include children under two years of age who are at risk of severe RSV infection during their second RSV season. The efficacy and safety of nirsevimab have been studied in four studies, which included healthy full-term infants (born from 35 + 0 weeks of gestation onwards) (MELODY); healthy preterm infants (born between 29 + 0 and 34 + 6 weeks of gestation) (Study 3); preterm infants (born at the latest at 34 + 6 weeks of gestation, including those born before 29 + 0 weeks of gestation) with chronic lung disease or congenital heart disease (MEDLEY); and healthy infants under 12 months of age who were born after 29 weeks of gestation before their first RSV season and did not meet the criteria for palivizumab treatment (HARMONIE).

For lower respiratory tract infections caused by RSV, a dose of nirsevimab reduces the risk of illness and hospitalisation during the first 150 days after injection. In the MELODY study, the reduction in the need for hospitalisation in infants receiving nirsevimab was not statistically significant. The results from the Study 3 and MELODY studies indicated a reduced risk of developing very severe lower respiratory

Council for Choices in Health Care in Finland
Meritullinkatu 8, Helsinki
PO Box 33, FI-00023 GOVERNMENT, FINLAND
Telephone +358 295 16001
www.palveluvalikoima.fi
email: palveluvalikoima.stm@gov.fi

tract infections related to RSV infection in those treated with nirsevimab. The subgroup analyses did not show any statistically significant differences in efficacy between the subgroups. In the MEDLEY study, the primary endpoints focused on the safety of nirsevimab, and its efficacy was compared to palivizumab only as a secondary endpoint. One dose of nirsevimab and monthly doses of palivizumab provided similar protection against RSV infection in both preterm infants and infants with lung and heart diseases. The need for hospital care was also similar between the groups.

Adverse events of any grade were observed equally in the nirsevimab and placebo groups. Meanwhile, severe, life-threatening or fatal adverse events were observed slightly more frequently in the placebo group compared to the nirsevimab group. The most common categories of adverse events were infections, skin and subcutaneous tissue reactions, and gastrointestinal symptoms. Among the adverse events of particular interest, hypersensitivity reactions were observed in the same proportion in both the nirsevimab and placebo groups. In the MEDLEY study, adverse events of any grade and severe adverse events were observed equally in the nirsevimab and palivizumab groups. Treatment-related adverse events were observed slightly more frequently in those who received nirsevimab compared to those who received palivizumab.

Nirsevimab was introduced in several European countries and the United States in 2023. Vaccine coverage ranged from 41.3% to 98.6% in these countries. Nirsevimab has significantly reduced the incidence of RSV infections and related complications in infants, including lower respiratory tract infections, bronchiolitis, pneumonia, and hospital or intensive care unit admissions. The efficacy of nirsevimab is particularly emphasised in infants under three months of age, but it is also effective in older children. In addition, no significant safety concerns have been reported regarding the use of nirsevimab. In Finland, nirsevimab was introduced in October and November 2024 in all the wellbeing services counties. The drug has been offered to neonates in maternity hospitals and to infants under three months of age in child health clinics. Children under 12 months and belonging to risk groups have received the drug either in hospitals or child health clinics, depending on the region. The coverage of nirsevimab in the entire target group has been on average 90%.

According to the Finnish Medicines Agency (Fimea), nirsevimab has been sold for approximately EUR 15 million during the RSV season 2024–2025, based on the wholesale price excluding VAT. The public list price for one package has decreased to EUR 355.29. In an earlier analysis provided by the marketing authorisation holder, three different strategies for using nirsevimab were presented, with strategy 2 corresponding to the current implementation of nirsevimab in Finland, i.e. approximately 31,300 infants. According to this estimate, the drug costs for nirsevimab at the new list price would be approximately EUR 11 million.

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 English 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 details of service choices in healthcare are available on the COHERE Finland website.

Sosiaali- ja terveysministeriö

Council for Choices in Health Care in Finland
Meritullinkatu 8, Helsinki
PO Box 33, FI-00023 GOVERNMENT, FINLAND
Telephone +358 295 16001
www.palveluvalikoima.fi
palveluvalikoima.stm@gov.fi