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LETTER TO THE EDITOR

Recommendations of the Spanish Society of Neonatology for the prevention of severe respiratory syncytial virus infections with nirsevimab, for the 2024–2025 season

Recomendaciones de la Sociedad Española de Neonatología para la profilaxis frente a las infecciones graves por virus respiratorio sincitial con nirsevimab, para la estación 2024-2025

Dear Editor:

Respiratory syncytial virus (RSV) is one of the leading causes of severe respiratory disease and hospital admission in healthy infants without known risk factors. Monoclonal antibody prophylaxis has been available for more than 20 years, but due to their high cost and short half-life, they have only been used in at-risk neonates and infants. Recently, monoclonal antibodies with higher potency, longer half-life and lower cost have become available, allowing their universal use not only in high-risk groups but also in healthy neonates and infants. Nirsevimab, a new long-acting monoclonal antibody, has exhibited a high efficacy and a good safety profile in clinical trials,[1–3] and its use was approved in the European Union on November 3, 2022. On May 9, 2023, the Ministry of Health of Spain approved the recommendations for the use of nirsevimab during the 2023–24 epidemic season in infants at high risk of severe RSV disease, and on July 12, 2023 approved its routine use in infants aged less than 6 months (born between April 1, 2023 and March 31, 2024) at the beginning or during the RSV season. In September of 2023, the Sociedad Española de Neonatología (SENeo, Spanish Society of Neonatology) published its recommendations.[4]

To assess the effectiveness of this approach, a Joint Vaccination Register was established for the COVID-19 vaccination strategy and a working group formed in the framework of the Vaccination Strategy, Registration and Evaluation Committee to evaluate the RSV vaccination/immunisation programme in the paediatric and adult populations, taking into account currently available and soon to be authorised vaccines and monoclonal antibodies for the prevention of medically attended RSV. The excellent outcomes observed in this evaluation, with a mean immunisation coverage of over 90% in infants born during the season and 87% in infants born before season onset, with an effec-

Table 1 Indications for immunoprophylaxis against severe RSV infection, 2024–2025 season.

Group of healthy infants born at or after 35 weeks' gestation:
Routine administration of a single dose to all infants aged less than 6 months at the start of the season (defined as October 1, 2024 to March 31, 2025). This includes all infants born during the season and those born between April 1, 2024 and September 30, 2024.
Groups at risk of severe RSV disease:
In this group, the use of nirsevimab is recommended instead of palivizumab.
[1]One dose before age 12 months at the start of the season. In this group, the use of nirsevimab is recommended as a substitute for palivizumab.
[a]Infants born preterm before 35 weeks (including those with gestational age < 29 weeks).
[2]One dose per year until age 24 months (2 seasons), given before season onset.
[a]Patients with bronchopulmonary dysplasia (BPD). Especially those with grade 2 and 3 moderate/severe BPD, giving priority to those who have required treatment for their underlying disease in the 6 months preceding season onset.
b Patients with other underlying diseases that carry a high risk of severe bronchiolitis due to RSV: severe immunosuppression, inborn errors of metabolism, neuromuscular diseases, severe pulmonary malformations, genetic syndromes with clinically significant respiratory manifestations, Down syndrome, cystic fibrosis.

RSV, respiratory syncytial virus.

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Table 2 Additional considerations to take into account for immunoprophylaxis with nirsevimab.

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[•]Nirsevimab should be administered:
[◯]In the group of *healthy infants born at or after 35 weeks' gestation during the RSV season*, as early as possible before discharge from the maternity ward, and those born in the 6 months before the start of the season as soon as possible after season onset.
◯ In the group of *preterm infants born before 35 weeks' gestation and patients with grade 2–3 BPD* discharged from hospital, as soon as possible if discharge takes place during the RSV season or, otherwise, at least 2–3 weeks before season onset.

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[•]To *infants hospitalised in neonatal units*, during the RSV season, preferably *as soon as the clinical condition of the patient allows it after birth, and always at least 4–6 days before hospital discharge or, if discharge happens earlier, as soon as possible*. There are no safety data for its administration to infants weighing less than 1000 g, so in this group it is prudent to wait until the infant achieves a weight of more than 1000 g before prophylaxis is administered.

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[•]Establishment of a follow-up register is recommended, especially in risk groups, to evaluate the effectiveness of nirsevimab under real-world conditions.

Presentation and dose:
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[•]For infants with weights of less than 5 kg:
[◯]Beyfortus 50 mg (single dose): preloaded syringe with purple plunger rod for intramuscular delivery. It contains 50 mg of nirsevimab in 0.5 mL (100 mg/mL).

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[•]For infants with weights of 5 kg or greater.
[◯]Beyfortus 100 mg (single dose): preloaded syringe with light blue plunger rod for intramuscular delivery. It contains 100 mg of nirsevimab in 1 mL (100 mg/mL).

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[•]Infants requiring prophylaxis for a second season:
[◯]Beyfortus 100 mg in those with a body weight of less than 10 kg or 200 mg (2 doses of 100 mg administered at different sites) in those with a weight of 10 kg or greater.[7,8]

BPD, bronchopulmonary dysplasia.

tiveness against RSV-related hospitalisations of around 80% and an excellent safety profile, motivated the issuing of new recommendations for prophylaxis against RSV infection for the 2024–2025 season in Spain by the Interterritorial Council of the Ministry of Health, which were approved by the Public Health Commission on March 14, 2024 and the Vaccination Strategy, Registration and Evaluation Committee on February 29, 2024 and reviewed by the Working Group on Paediatric RSV of the Vaccination Strategy, Registration and Evaluation Committee, essentially leaving unchanged the previous recommendations issued for the 2023-2024 season.[5]

In light of the excellent results of the universal prophylaxis campaign in the 2023–2024 season, the SENeo recommends maintaining the same universal prophylaxis schedule with monoclonal antibodies for the 2024–2025 season, including a modification in the dosage of nirsevimab for patients who require its administration for a second season,[6] as can be seen in Tables 1 and 2.

Declaration of competing interest

MSL has received fees for consulting and scientific meetings from Sanofi and AstraZeneca. All other authors have no conflicts of interest to declare.

References

1. Nirsevimab Study GroupGriffin MP, Yuan Y, Takas T, Domachowske JB, Madhi SA, Manzoni P, et al. Single-dose nirsevimab for prevention of RSV in preterm infants. N Engl J Med. 2020;383:415–25.
2. MELODY Study GroupMuller WJ, Madhi SA, Seoane Nuñez B, Baca Cots M, Bosheva M, Dagan R, et al. Nirsevimab for prevention of RSV in term and late-preterm infants. N Engl J Med. 2023;388:1533–4.
3. HARMONIE Study GroupDrysdale SB, Cathie K, Flamein F, Knuf M, Collins AM, Hill HC, et al. Nirsevimab for prevention of hospitalizations due to RSV in infants. N Engl J Med. 2023;389:2425–35.
4. Sánchez Luna M, Fernández Colomer B, Couce Pico ML. Recomendaciones de la Sociedad Española de Neonatología para la profilaxis frente a las infecciones graves por virus respiratorio sincitial con nirsevimab, para la estación 2023.2024. An Pediatr. 2023;99:264–5.
5. Ministerio de Sanidad. Recomendaciones de utilización de nirsevimab para la temporada 2024-2025 en España. Available from: https://www.sanidad.gob.es/areas/promocionPrevencion/vacunaciones/comoTrabajamos/docs/NirsevimabActualizacion.pdf.
6. Jones JM, Fleming-Dutra KE, Prill MM, Roper LE, Brooks O, Sánchez PJ, et al. Use of nirsevimab for the prevention of respiratory syncytial virus disease among infants and young children: recommendations of the advisory committee on immunization practices - United States, 2023. MMWR Morb Mortal Wkly Rep. 2023;72:920–5.
7. Public Health Agency of Canada (PHAC). Statement on the prevention of respiratory syncytial virus (RSV) disease in infants: An Advisory Committee Statement (ACS) National Advisory Committee on Immunization (NACI); 2024 [Accessed 19 September 2024]. Available from: https://www.canada.ca/content/dam/phacaspc/documents/services/publications/vaccines-immunization/national-advisory-committee-immunization-statement-prevention-respiratory-syncytial-virus-disease-infants/naci-statement2024-05-17.pdf
8. Domachowske J, Hamrén UW, Banu I, Baronio R, Basavaraju B, Koen A, et al. Safety and pharmacokinetics of nirsevimab in immunocompromised children. Pediatrics. 2024;154(4):e2024066508, http://dx.doi.org/10.1542/peds.2024-066508.

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