

Recommendation for use of a long-acting monoclonal antibody to prevent respiratory syncytial virus infection in infants and young children

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Respiratory syncytial virus (RSV) is a leading cause of acute lower respiratory tract infections (LRTIs) in infants and young children. In April 2024, the Korea Ministry of Food and Drug Safety approved nirsevimab (Beyfortus), a long-acting monoclonal antibody, as a passive immunization to prevent RSV-associated LRTI among infants and young children. Nirsevimab was launched in Korea in February 2025. This report summarizes the recommendations of the Committee on Infectious Diseases of the Korean Pediatric Society regarding the use of nirsevimab. We recommend a single dose of nirsevimab for all neonates born during the RSV season (October to March), as well as all infants younger than 6 months at the start of the RSV season (i.e., those born between April and September of that year). Nirsevimab should be administered shortly after birth (within the first week of life) to neonates born during the RSV season and just before or early in the season (late September to October) to infants entering their first RSV season. Nirsevimab may also be considered for children younger than 2 years of age who are at increased risk of severe RSV disease and entering their second RSV season.

Key words: Respiratory syncytial viruses, Immunization, Monoclonal antibodies, Long-acting monoclonal antibodies

Key message

To prevent respiratory syncytial virus (RSV)-associated lower respiratory tract infections, a single dose of nirsevimab, a long-acting monoclonal antibody, is recom-

mended for all neonates born during the RSV season (October to March) and all infants younger than 6 months old at the start of the RSV season. Nirsevimab should be administered shortly after birth to neonates and just before or early in the season to infants entering their first RSV season.

Introduction

Respiratory syncytial virus (RSV) is a major respiratory pathogen that causes acute lower respiratory tract infections (LRTIs) and hospitalization in infants and young children worldwide.¹⁻³ Since its identification in 1956, efforts to develop effective RSV vaccines have been ongoing.^{4,5} The first pediatric RSV vaccine, the formalin-inactivated vaccine, was developed in the 1960s. However, in RSV-naïve infants, vaccination was associated with more severe illness following natural RSV infection.⁵ In RSV vaccine development, the potential for enhanced respiratory disease is a concern. Young infants may not respond adequately to vaccination because of their immunological immaturity, immune response suppression by maternally derived antibodies, or both.⁶ Therefore, passive immunization against RSV among young infants is a leading strategy. Palivizumab is a humanized murine monoclonal antibody (mAb) targeting an epitope at antigenic site II of the RSV F protein.⁷ Since 1998, palivizumab

has provided effective prevention in young children at a higher risk of severe RSV disease (e.g., those born premature and/or with chronic lung disease of prematurity [CLD] or congenital heart disease [CHD]). However, palivizumab requires a multidose schedule (intramuscular [IM] injection at a maximum of 5 monthly doses during the RSV season). In addition, palivizumab is not widely available in many countries due to its high cost and delivery barriers.⁸⁾

In 2013, the identification of the pre-fusion (pre-F) form of the RSV F protein was a breakthrough in the development of RSV vaccines and drugs.⁹⁾ Stabilization of the pre-F conformation led to the determination of viral epitopes that can elicit highly neutralizing antibodies.¹⁰⁾ More recently, efforts have focused on developing “vaccine-like” RSV mAbs.^{4,5)} Engineering of the Fc domain of immunoglobulin to extend its half-life has led to the development of several long-acting mAbs that can protect infants against RSV-associated LRTI throughout the entire RSV season.^{11,12)}

Nirsevimab (Beyfortus, Sanofi/AstraZeneca, France), a long-acting mAb, is indicated for the prevention of RSV-associated LRTI in neonates and infants born during or entering their first RSV season as well as children up to 24 months of age who remain vulnerable to severe RSV disease through their second RSV season.^{13,14)} Nirsevimab

was first approved in 2022 in Europe and then in 2023 in the United States. The Korea Ministry of Food and Drug Safety approved nirsevimab for use on April 30, 2024; it was then launched in February 2025.⁸⁾ This report summarizes the recommendations for the use of nirsevimab by the Committee on Infectious Diseases of the Korean Pediatric Society (Boxes 1 and 2, Fig. 1). These recommendations may be updated in the future following the introduction of new long-acting RSV mAbs or maternal RSV vaccines in Korea or in accordance with changes in the national immunization program policy.

RSV burden and prevention strategy

A systematic analysis of the Global Burden of Disease Study showed that, following *Streptococcus pneumoniae*, RSV was the leading cause of LRTI deaths in children younger than 5 years of age in 2019.¹⁵⁾ A global meta-analysis estimated that RSV caused 33.0 million LRTI episodes in children under 5 years of age in 2019, with one in every 5 (6.6 million) occurring in infants aged 0–6 months.¹⁾ In addition, there have been 3.6 million RSV-associated LRTI hospitalizations globally, approximately 39% of which occurred in infants aged 0–6 months. More

Box 1. Summary of recommended use of nirsevimab

1. Eligible population
(1) All neonates born during the RSV season (October to March)
(2) All infants younger than 6 months old at the start of the RSV season (born between April and September of that year)
(3) Children younger than 2 years of age who are at increased risk of severe RSV disease and entering their second RSV season (Box 2)
2. Timing of administration: Seasonal
(1) Neonates born during the RSV season (October to March): Shortly after birth (within the first week of life)
(2) Other eligible infants/children: Just before or early in the RSV season (late September to October)
3. Administration method: single-dose IM injection
(1) Body weight <5 kg: 50 mg (0.5 mL) IM in the anterolateral thigh
(2) Body weight ≥5 kg: 100 mg (1.0 mL) IM in the anterolateral thigh
(3) For high-risk children entering their second RSV season: 200 mg IM administered as two 100-mg injections given at the same time at different injection sites
4. Coadministration and interchangeability
(1) Nirsevimab can be coadministered with age-appropriate vaccines.
(2) Nirsevimab may be administered to infants and children who are eligible for palivizumab.
(3) Do not administer palivizumab if nirsevimab has already been given in the same season.
(4) Do not administer nirsevimab if palivizumab has already been completed for the current RSV season.

Box 2. Risk conditions eligible for nirsevimab in the second RSV season

Those with bronchopulmonary dysplasia and who required medical support, such as chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen, in the last 6 months
Those with hemodynamically significant CHD who meet one of the following criteria: (1) receiving medication for congestive heart failure management, (2) diagnosed with moderate to severe pulmonary hypertension, and (3) diagnosed with cyanotic heart disease
Those with significant immunosuppression due to primary immunodeficiency, hematopoietic stem cell transplantation, solid organ transplantation, chemotherapy, or immunosuppressive therapy
Those with neuromuscular disorders that impair their ability to clear respiratory secretions
Those with congenital airway anomalies that impair their ability to clear respiratory secretions
Other high-risk groups based on medical judgment: Down syndrome, cystic fibrosis, etc.

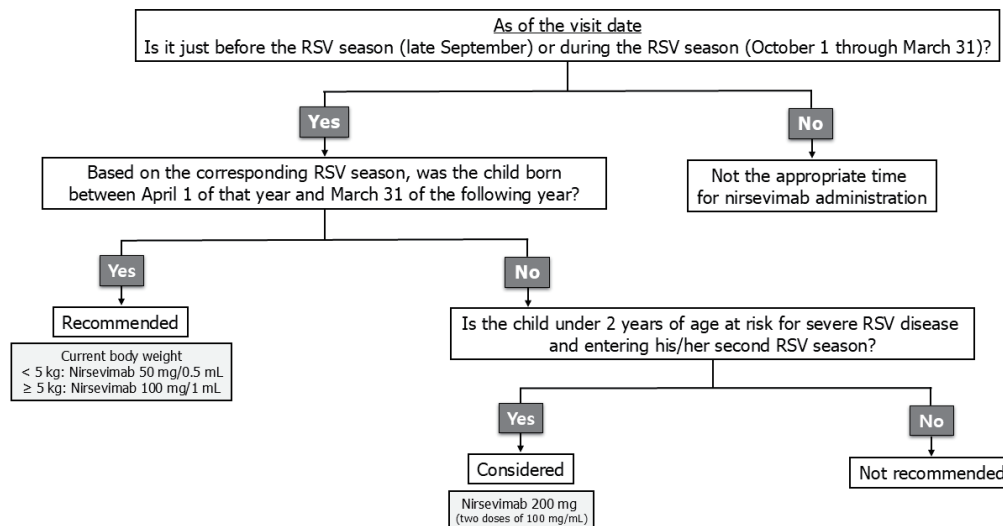


Fig. 1. Flow chart of nirsevimab recommendations. RSV, respiratory syncytial virus.

than 60% of RSV-associated LRTI hospitalizations among infants aged 0–6 months of age occurred within the first 3 months of life.¹⁾ Preterm infants (those born before 37 weeks' gestation) accounted for 25% of all RSV-associated LRTI hospitalizations irrespective of gestational age (GA).¹⁶⁾

According to data from the sentinel surveillance system for respiratory infectious diseases managed by the Korea Disease Control and Prevention Agency, RSV is the most commonly identified virus in infants under 1 year of age who are hospitalized with acute respiratory infections excluding rhinovirus.¹⁷⁾ Han et al.¹⁸⁾ conducted a retrospective cohort study using nationwide claims data from the Korea Health Insurance Review and Assessment Service for infants with RSV infection in the first year of life from January 2017 to April 2022. Among the 31,206 eligible study population, 91.3% were classified as full-term, 5.7% as healthy preterm, and 3.1% as unhealthy preterm (history of at least one dose of palivizumab). More than three-quarters (76.3%) required substantial medical care: 70.6% required hospitalization, 4.3% required intensive care unit (ICU) admission, and 1.4% required mechanical ventilation. RSV-related treatment costs per patient according to the year showed an increasing trend: \$818 (95% confidence interval [CI], \$799–\$923) in 2017, \$1,288 (95% CI, \$1,196–\$1,381) in 2018, \$1,409 (95% CI, \$1,274–\$1,545) in 2019, \$1,908 (95% CI, \$1,611–\$2,204) in 2020, and \$3,338 (95% CI, \$889–\$5,787) in 2021.

In a study analyzing commercial insurance claims data for infants born between April 2016 and February 2020 in the United States (US), term infants without known comorbidities accounted for up to 80% of the medically attended RSV-associated ALRI burden during their first RSV season.¹⁹⁾ The infant mortality rate due to RSV was 6.9 per million live births (95% CI, 6.4–7.5 per million live births) in the US from 1999 to 2018, with the highest rate observed

among infants <29 weeks' GA (103.5 per million live births; 95% CI, 81.8–129.1 per million live births). However, RSV mortality burden was the greatest in full-term infants, with 53.7% of RSV deaths occurring in those born with a GA ≥37 weeks.²⁰⁾ A Canadian study analyzing children hospitalized with RSV-associated acute respiratory tract infections in 2022 and 2023 noted that an age younger than 3 months (adjusted risk ratio [aRR], 2.34; 95% CI, 1.43–3.84), age 3 months to less than 6 months (aRR, 2.79; 95% CI, 1.65–4.70), and prematurity (aRR, 1.40; 95% CI, 1.03–1.89) were associated with severe disease in children younger than 2 years.²¹⁾ An Australian study found that age younger than 6 months and preterm births were associated with a 2.10-fold (95% CI, 1.14–3.79-fold) and 2.35-fold (95% CI, 1.26–4.41-fold) increased risk of ICU hospitalizations, respectively.²²⁾

Infants and young children with certain comorbidities are at higher risk of severe RSV disease compared to those without comorbidities.^{2,16)} However, most young children hospitalized with RSV-associated ALRI are full-term infants without known risk factors.^{2,3,18,19,21–23)} Therefore, any prevention strategy focused solely on high-risk pediatric populations may prevent only a small proportion of RSV hospitalizations, even if prevention is 100% effective at treating high-risk individuals. In September 2024, given the global burden of RSV disease, the World Health Organization (WHO) Strategic Advisory Group of Experts on Immunization (SAGE) recommended that all countries introduce passive immunization (maternal vaccination and/or administration of long-acting mAb to infants) to prevent severe RSV disease in young infants.²⁴⁾ For countries opting to introduce nirsevimab, SAGE recommends a single dose administered to all infants born during the RSV season, or to those aged ≤12 months entering their first RSV season, when implementing a seasonal approach. As of 2025, only nirsevimab is available for passive immuni-

zation in Korea. RSV vaccine for pregnant women has not been introduced yet.

The key points of the preferred product characteristics for mAbs in infants against severe RSV disease, published by the WHO in 2021, are as follows.²⁵⁾ The primary aim is to protect most infants during their first RSV season, including all infants in the first 6 months of life. The RSV mAb should provide at least 70% efficacy against RSV-confirmed severe disease for 5-month postadministration and protect against both RSV A and B subtypes. A single-dose regimen is highly preferred and can be administered at birth or during any healthcare visit within the first 6 months of life. The preferred route of administration is a single IM or subcutaneous injection of standard dose.

Nirsevimab

Nirsevimab is a recombinant neutralizing human immunoglobulin G1 (IgG1) kappa mAb. Nirsevimab inhibits the essential membrane fusion step in the viral entry process, neutralizing the virus and blocking cell-to-cell fusion.^{13,14)} Nirsevimab is modified by a triple amino acid substitution (M252Y/S254T/T256E [YTE]) in the IgG constant (Fc) region to extend its serum half-life to approximately 71 days.¹³⁾ Based on clinical and pharmacokinetic (PK) data, the minimum duration of protection offered by a single dose of nirsevimab is at least 5 months.²⁶⁾ Nirsevimab binds to a highly conserved epitope in antigenic site Ø on the pre-F conformation of the F protein of RSV subtype A and B strains. The antigenic site Ø is only exposed on pre-F conformation. The antibody targeting site Ø has the most potent neutralizing activity.^{10,27)} A single dose of nirsevimab is associated with approximately 10-fold higher and more sustained levels of neutralizing antibodies through 1-year postdose compared with palivizumab.²⁸⁾

Clinical trials of nirsevimab

Phase IIb²⁹⁾ and Phase III (MELODY)^{30,31)} trials have evaluated the efficacy and safety of nirsevimab to prevent medically attended RSV-associated LRTI (MA RSV LRTI)

in term and preterm infants (GA ≥29 weeks) entering their first RSV season. The MEDLEY (phase II/III) trial evaluated the safety and PK of nirsevimab among infants at higher risk for severe RSV disease who were eligible to receive palivizumab, including extremely preterm infants (GA <29 weeks) and infants with CLD of prematurity or hemodynamically significant CHD.³²⁻³⁴⁾ The MUSIC is an open-label, uncontrolled, single-dose multicenter trial to evaluate safety and PK of nirsevimab in immunocompromised children ≤24 months of age.³⁵⁾ The HARMONIE trial is a phase IIb, open-label, randomized, parallel 2-arm study comparing nirsevimab with standard care (without RSV prophylaxis) for preventing hospitalization due to RSV in infants (GA ≥29 weeks) before or during their first RSV season.³⁶⁾

The efficacy of nirsevimab in the phase IIb and MELODY trials is summarized in Table 1. In the HARMONIE trial during the 2022–2023 RSV season, the efficacy of nirsevimab against RSV-associated LRTI hospitalization was 83.2% (95% CI, 67.8–92.0%).³⁶⁾ In the MEDLEY trial, the incidence of MA RSV LRTI through 150-day postdose was 0.6% (4 of 616) in the nirsevimab group and 1.0% (3 of 309) in the palivizumab group.³⁴⁾ There were no cases of MA RSV LRTI through 150 days in the second RSV season.³³⁾ In the MUSIC trial (N=100), there were no cases of MA RSV LRTI through 150-day postdose.³⁵⁾ In a follow-up of children in the MELODY trial through their second RSV season, there was no evidence of antibody-dependent enhancement of infection or disease severity in infants who received nirsevimab.³⁷⁾

Real-world effectiveness of nirsevimab

The benefits of nirsevimab observed in clinical trials are also evident in real-world settings.³⁸⁻⁵⁴⁾ Early clinical data from the 2023–2024 RSV season in Europe^{42,45,49,50,52,53)} and the US^{40,44)} showed 83%–90% effectiveness against RSV-associated LRTI hospitalization.

NIRSE-GAL is a 3-year population-based longitudinal study on the effectiveness of universal nirsevimab prophylaxis against RSV in infants in Galicia, Spain.⁵⁵⁾ For the 2023–2024 RSV season, the immunization campaign in

Table 1. Efficacy of nirsevimab in term and preterm infants through 150-day postdose

Trial	Treatment	MA RSV LRTI		MA RSV LRTI with hospitalization	
		Incidence, % (n)	Efficacy (95% CI)	Incidence, % (n)	Efficacy (95% CI)
Phase II b (preterm infants, GA ≥29 to <35 wk)	Nirsevimab	2.6 (25/969)	70.1 % (52.3-81.2)	0.8 (8/969)	78.4% (51.9-90.3)
	Placebo	9.5 (46/484)		4.1 (20/484)	
MELODY (term and late preterm infants, GA ≥35 wk) (all subjects)	Nirsevimab	1.2 (24/2,009)	76.4% (62.3-85.2)	0.4 (9/2,009)	76.8% (49.4-89.4)
	Placebo	5.4 (54/1,003)		4.1 (20/1,003)	

MA RSV LRTI, medically attended respiratory syncytial virus-associated lower respiratory tract infection; CI, confidence interval; GA, gestational age.

Galicia ran from September 25, 2023, to March 31, 2024. The overall coverage rate of nirsevimab was 92.0% (13,320 of 14,476): 95.3% (7,071 of 7,414) in the seasonal cohort (infants born between September 25, 2023, and March 31, 2024) and 88.5% (6,249 of 7,062) in the catch-up cohort (infants born between April 1 and September 24, 2023). Nirsevimab contributed to a median reduction of RSV-related LRTI hospitalizations in Galicia by 89.2% (interquartile range, 89.1%–91.4%) in the overall cohort and by 95.2% (interquartile range, 94.8%–96.2%) in the seasonal cohort.⁵⁶⁾ In the intention-to-treat analysis, the effectiveness of nirsevimab was 70.7% (95% CI, 42.4%–85.1%) for RSV-related LRTI hospitalization and 80.3% (95% CI, 54.6%–91.5%) for RSV-related LRTI hospitalizations with oxygen support in the catch-up cohort.

A French national population-based study using the French National Health Data System included 82,474 infants born between February 6, 2023, and September 15, 2023.⁵⁷⁾ Each day during the study period (from September 15, 2023, to January 31, 2024), each infant immunized with nirsevimab was matched at a 1:1 ratio to an unimmunized control. The incidence of RSV-LRTI hospitalization was 0.8% (342) in the nirsevimab group versus 2.4% (992) in the unimmunized group. The effectiveness of nirsevimab was 65% (95% CI, 61%–69%) for RSV-LRTI hospitalizations, 74% (95% CI, 56%–85%) for RSV-LRTI ICU admissions, 66% (95% CI, 51%–76%) for RSV-LRTI hospitalizations requiring ventilation support, and 67% (95% CI, 57%–75%) for RSV-LRTI hospitalizations requiring oxygen therapy.

A test-negative case-control study using data from the Yale New Haven Health System, the largest health system in Connecticut in the US, analyzed 3,090 infants who were eligible for nirsevimab and tested for RSV using polymerase chain reaction between October 1, 2023, and May 9, 2024.⁵⁸⁾ Nirsevimab uptake was 10.7%. The adjusted effectiveness was 68.4% (95% CI, 50.3%–80.8%) against medically attended RSV infections, 80.5% (95% CI, 52.0%–93.5%) against RSV-associated hospitalizations, and 84.6% (95% CI, 58.7%–95.6%) for preventing severe RSV infections.

In April 2024, Western Australia launched the nation's first state-wide nirsevimab program for all infants and high-risk children entering their second RSV season. A test-negative case-control study was conducted in children hospitalized with RSV-associated infections in Western Australia between April and October 2024.⁵⁹⁾ Of the 284 enrolled children, nirsevimab coverage was 22.8% in the RSV cases and 60.0% in the controls. The overall adjusted effectiveness of nirsevimab against RSV-associated hospitalization was 88.2% (95% CI, 73.5%–94.7%).

A recent meta-analysis study on the real-world effectiveness of nirsevimab showed that it was associated with a lower odds of RSV-related hospitalization (odds ratio [OR],

0.17; 95% CI, 0.12–0.23), ICU admission (OR, 0.19; 95% CI, 0.12–0.29), and LRTI incidence (OR, 0.25; 95% CI, 0.19–0.33) in infants aged 0–12 months.⁶⁰⁾

Safety of nirsevimab

The most frequent adverse reaction in clinical trials was rash (0.7%; vs. 0.3% for placebo), which occurred within 14 days of dosing. Most cases were mild to moderate in severity. Pyrexia and injection-site reactions were reported at rates of 0.5% (vs. 0.6% for placebo) and 0.3% (0% for placebo), respectively, within 7 days of nirsevimab administration. The injection-site reactions were nonserious.¹⁴⁾ In the MEDLEY trial, the safety profile of nirsevimab was comparable to that of the palivizumab comparator and consistent with the safety profile of nirsevimab in term and preterm infants with a GA $\geq$ 29 weeks.^{33,34)} Anaphylaxis has also been observed with human IgG1 mAbs. Hypersensitivity reactions have been reported following nirsevimab administration since approval. However, its frequency of occurrence remains unknown.¹⁴⁾ Nirsevimab is contraindicated in individuals with a history of severe hypersensitivity reactions, including anaphylaxis, to other human IgG1 mAbs.

Recommendations for use of nirsevimab

We recommend a single dose of nirsevimab for all neonates and infants born during or entering their first RSV season. Nirsevimab is recommended to all neonates born during the RSV season (from October 1 to March 31) and all infants younger than 6 months of age at the start of the RSV season (born between April 1 and September 30 of that year). Nirsevimab may be considered for children younger than 2 years of age who are at an increased risk of severe RSV disease and entering their second RSV season (Box 2).

Although the timing of the onset, peak, and decline of RSV activity may vary from year to year, the RSV season in Korea typically runs from October to March of the following year, with peak activity usually occurring in November and January.⁶¹⁾ Nirsevimab administration should be timed to maximize protection during the peak RSV season.²⁴⁾ Infants born just before or during the RSV season should receive nirsevimab shortly after birth, within the first week of life. For infants born outside of the RSV season or children in their second RSV season, the optimal timing for nirsevimab administration is just before or early in the RSV season, typically from late September to October. However, nirsevimab may be given at

any time during the RSV season to eligible infants who have not yet received the dose.

Infants with prolonged birth hospitalizations related to prematurity or other conditions should receive nirsevimab shortly before or immediately after discharge. There is no evidence to support the use of nirsevimab to prevent hospital-acquired RSV infection; thus, nirsevimab is not recommended for this indication.

Dose and administration method

Only a single dose of nirsevimab is recommended for an RSV season. Nirsevimab is available in 2 forms of prefilled syringe: 50 mg per 0.5 mL and 100 mg per 1 mL.¹⁴⁾ For infants during their first RSV season, a single dose of 50 mg is recommended for those weighing <5 kg, and a single dose of 100 mg is recommended for those weighing ≥5 kg. A single dose of 200 mg, administered as two 100-mg injections, is recommended for children receiving nirsevimab in their second RSV season. Nirsevimab is administered via IM injection, preferably in the anterolateral aspect of the thigh. If 2 injections are required, they should be administered at different injection sites. As with other IM injections, nirsevimab should be administered with caution to individuals with thrombocytopenia, with any coagulation disorder, or who are on anticoagulation therapy.

Dosing in infants with a body weight from 1.0 kg to <1.6 kg is based on extrapolation and clinical data are unavailable.¹⁴⁾ Exposure in infants weighing <1 kg is anticipated to yield higher exposure than those weighing more. Limited data are available for extremely preterm infants (GA<29 weeks) aged <8 weeks. No clinical data available for infants with a postmenstrual age (GA at birth plus chronological age) of <32 weeks.

Coadministration with routine childhood vaccines

As nirsevimab is a mAb, it is not expected to interfere with an individual's active immune response to co-administered vaccines. However, there is limited experience with the coadministration of nirsevimab and vaccines. In clinical trials, when nirsevimab was administered along with routine childhood vaccines, the safety and reactogenicity profiles were comparable to those observed when childhood vaccines were administered alone.¹⁴⁾ In accordance with the general best practices for immunization, the simultaneous administration of nirsevimab with age-appropriate vaccines is recommended.⁶²⁾ After nirsevimab administration, live vaccines such as MMR (measles, mumps, and rubella), varicella, and live attenuated Japanese

encephalitis should be administered as scheduled without a specific interval between nirsevimab and the live vaccine.

Use of nirsevimab in infants and children eligible for palivizumab

Nirsevimab may be administered to infants and children who meet the indications for palivizumab in Korea. Palivizumab should not be administered to infants who received nirsevimab during the same season. If palivizumab was administered in the first RSV season and the child is eligible for RSV prophylaxis in their second RSV season, nirsevimab may be administered in the second season, if available. There are currently no data regarding switching from palivizumab to nirsevimab after initiating RSV prophylaxis with palivizumab. According to the American Academy of Pediatrics, infants who initially received palivizumab during the RSV season but received fewer than 5 doses should receive a single dose of nirsevimab as soon as it becomes available regardless of the interval since the last palivizumab dose.^{62,63)}

In Korea, palivizumab is currently reimbursed by the National Health Insurance System for eligible high-risk infants and children.⁶⁴⁾ In contrast, nirsevimab must be paid for out of pocket by caregivers, as it is not yet publicly funded. The lack of economic support for nirsevimab poses a significant barrier to its access, particularly for socioeconomically disadvantaged populations. In several other countries, nirsevimab has already been incorporated into national or regional immunization programs and administered as part of routine RSV prevention strategies.⁶⁵⁾ We strongly advocate for the inclusion of nirsevimab in national immunization programs, with coverage to all infants entering their first RSV season, as well as to high-risk children entering their second RSV season.

Conclusion

To prevent RSV-associated LRTI, a single dose of nirsevimab is recommended for all neonates born during the RSV season (October to March) and all infants younger than 6 months of age at the start of the RSV season. Nirsevimab should be administered shortly after birth to neonates and just before or early in the season to infants entering their first RSV season.

Footnotes

Conflicts of interest: No potential conflict of interest rele-

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