AAP Recommendations for the Prevention of RSV Disease in Infants and Children

February 21, 2024

Article type: Resources

Topics: Infectious Diseases

Nirsevimab was approved by the US Food and Drug Administration (FDA) on July 17, 2023. Nirsevimab is a long-acting monoclonal antibody product intended for use in neonates and infants to protect against (medically attended) respiratory syncytial virus (RSV) disease. Nirsevimab is preferred over palivizumab because of its efficacy, duration, and convenience.

View the AAP's Nirsevimab Administration Visual Guide

Recommended Populations

The American Academy of Pediatrics (AAP) recommends nirsevimab, consistent with the Advisory Committee on Immunization Practices (ACIP),[1,2] for:

- Infants aged <8 months born during or entering their first RSV season whose pregnant parent did not receive RSVpreF vaccine, whose pregnant parent's RSVpreF vaccination status is unknown, or who were born <14 days after the pregnant parent's RSVpreF vaccination.

  Nirsevimab is not needed for most infants aged <8 months whose pregnant parent received RSVpreF vaccine ≥14 days before giving birth. Nirsevimab may be considered for infants born to a vaccinated pregnant parent in rare circumstances when, based on the clinical judgment of the health care provider, the potential incremental benefit of administration is warranted. These situations include, but are not limited to:

  - infants born to pregnant people who might not have mounted an adequate immune response to vaccination (eg, persons with immunocompromising conditions) or who have conditions associated with reduced transplacental antibody transfer (eg, persons living with HIV infection);
  - infants who might have experienced loss of transplacentally acquired antibodies, such as those who have undergone cardiopulmonary bypass or extracorporeal membrane oxygenation;
  - and infants with substantially increased risk for severe RSV disease (eg, hemodynamically significant congenital heart disease or intensive care admission requiring oxygen at hospital discharge).

- Infants and children 8 through 19 months of age who are at increased risk of severe RSV disease and entering their second RSV season, including those recommended by the AAP to receive palivizumab,[3] regardless of RSV vaccination status of the pregnant parent. This includes the following:

- Infants and children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) at any time during the 6-month period before the start of the second RSV season.
- Infants and children who are severely immunocompromised.
- Infants and children with cystic fibrosis who have manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable) or have weight-for-length that is less than the 10th percentile.
- American Indian and Alaska Native children.

Equity and Access Considerations

Equity in access to nirsevimab is of the highest priority to the AAP. If nirsevimab is not available or not feasible to administer, high-risk infants who are recommended to receive palivizumab in the first or second year of life should receive palivizumab, as previously recommended,[3] until nirsevimab becomes available. High-risk infants whose pregnant parent received a recommended RSV vaccine ≥14 days prior to delivery do not require palivizumab, except in the rare circumstances as described above. The following are considerations with regard to palivizumab versus nirsevimab administration for high-risk infants during the same RSV season:

- If nirsevimab is administered, palivizumab should not be administered later that season.
- If palivizumab was administered initially for the season and <5 doses were administered, the infant should receive 1 dose of nirsevimab. No further palivizumab should be administered. There is no minimum interval between the last dose of palivizumab and the dose of nirsevimab. Because protection from palivizumab wanes after 30 days, nirsevimab should be administered no later than 30 days after the last palivizumab dose, when possible.
- If palivizumab was administered in season 1 and the child is eligible for RSV prophylaxis in season 2, the child should receive nirsevimab in season 2, if available. If nirsevimab is not available, palivizumab should be administered as previously recommended.

If nirsevimab supply is limited and the patient is not eligible for palivizumab, nirsevimab should be prioritized to protect infants and children at the highest risk for severe RSV disease using the following principles: first by high-risk conditions, and then by age, prioritizing the youngest infants first.

Administration Considerations

- Clinicians should aim for administration of nirsevimab in the first week of life for infants who are recommended to receive nirsevimab and are born shortly before and during the RSV season based on geography. Nirsevimab can be administered during the birth hospitalization or in the outpatient setting. Infants with prolonged birth hospitalizations because of prematurity or other causes should receive nirsevimab shortly before or promptly after discharge from the hospital.
- Nirsevimab should be administered to other eligible infants and toddlers shortly before or during the RSV season, as soon as nirsevimab is available.
- While the timing of the onset and duration of RSV season may vary, nirsevimab may be administered from October through the end of March in most of the continental United States. The timing of the onset, peak, and decline of RSV activity vary geographically, and providers may adjust timing of administration based on guidance from public health authorities (eg, CDC, health departments) or regional medical centers. Only children who meet high-risk criteria should receive more than one dose of nirsevimab – one dose in their first RSV season and one dose in their second RSV season.
- In accordance with the CDC's general best practices for immunizations, simultaneous administration of nirsevimab with age-appropriate vaccines is recommended. In clinical trials, when nirsevimab was administered concomitantly with routine childhood vaccines, the safety and reactogenicity profile of the concomitantly administered regimen was similar to that of the childhood vaccines administered alone. When concomitantly administered, nirsevimab is not expected to interfere with the immune response to other vaccines.

Additional Information

- Nirsevimab Administration Visual Guide (AAP.org)
- Nirsevimab Frequently Asked Questions (AAP.org)
- Respiratory Syncytial Virus (*Red Book*)
- Palivizumab Prophylaxis in Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection (AAP Technical Report)
- Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection (AAP Policy Statement)
- Nirsevimab Immunization Information Statement (CDC)

References

1. Jones JM, Fleming-Dutra KE, Prill MM, 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(34):920-925
2. Fleming-Dutra KE, Jones JM, Roper LE, et al. Use of the Pfizer Respiratory Syncytial Virus Vaccine During Pregnancy for the Prevention of Respiratory Syncytial Virus–Associated Lower Respiratory Tract Disease in Infants: Recommendations of the Advisory Committee on Immunization Practices—United States, 2023. *MMWR Morb Mortal Wkly Rep*. ePub: 6 October 2023
3. American Academy of Pediatrics. Respiratory syncytial virus. In: Kimberlin DW, Barnett ED, Lynfield R, Sawyer MH, eds. *Red Book: 2021 Report of the Committee on Infectious Diseases*. 32nd ed. American Academy of Pediatrics; 2021:628-636