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ACIP and AAP Recommendations for Nirsevimab

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ACIP and AAP Recommendations for the Use of the Monoclonal Antibody Nirsevimab for the Prevention of RSV Disease

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 newborns and infants to protect against (medically attended) respiratory syncytial virus (RSV) disease. Nirsevimab is recommended for:

- All infants younger than 8 months born during or entering their first RSV season, including those recommended by the American Academy of Pediatrics (AAP) to receive palivizumab;
- Infants and children aged 8 through 19 months who are at increased risk of severe RSV disease and entering their second RSV season, including those recommended by the AAP to receive palivizumab.

Per the FDA label, children who have received nirsevimab should not receive palivizumab for the same RSV season.

On August 3, 2023, the Advisory Committee on Immunization Practices (ACIP) of the Centers for Disease Control and Prevention (CDC) voted unanimously in favor of recommending use of nirsevimab as indicated in its FDA package insert.[1] The ACIP also voted unanimously for inclusion of nirsevimab in the Vaccines for Children (VFC) program. Equity in access to nirsevimab is of the highest priority to the AAP. As with any new product, nirsevimab may not be readily available in all clinical settings, including birthing hospitals and primary care settings, particularly in the first season of implementation of this recommendation. 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[2] should receive palivizumab, as previously recommended, until nirsevimab becomes available.

Some considerations for the 2023–2024 RSV season with regard to palivizumab versus nirsevimab administration for high-risk infants during the same RSV season

1. If nirsevimab is administered, palivizumab should not be administered later that season.
2. 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.
3. 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.

Timing of nirsevimab

- Providers should aim for nirsevimab administration in the first week of life for infants born shortly before and during the RSV season based on geography. Administration can occur 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.
- Nirsevimab should be administered shortly before the start of the RSV season for infants younger than 8 months.
- Nirsevimab should be administered shortly before the start of the RSV season for infants and children 8 through 19 months of age who are at increased risk of severe RSV disease.
- Nirsevimab may be given to age-eligible infants and children who have not yet received a dose at any time during the season.
- 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. Healthy newborns born at the end of RSV season who received nirsevimab around the time of delivery (first RSV season) should not receive a second dose entering their second season even if they are <8 months of age; conversely, healthy infants born at the end of their first RSV season who did NOT receive nirsevimab and are <8 months of age entering their second RSV season may receive one dose of nirsevimab.
- On the basis of pre-pandemic RSV infection patterns, nirsevimab may be administered in most of the continental United States from October through the end of March. Because timing of the onset, peak, and decline of RSV activity may vary, providers can adjust administration schedules on the basis of local RSV activity in the community.

Tropical climates and Alaska

- Tropical climates may have RSV circulation patterns that differ from most of the continental United States or are unpredictable. Locations with tropical climates include southern Florida, Hawaii, Guam, Puerto Rico, US Virgin Islands, and US-Affiliated Pacific Islands.
- In Alaska, RSV circulation patterns are less predictable, and the duration of RSV season is often longer than the national average.
- Providers in these jurisdictions should consult state, local, or territorial guidance on timing of nirsevimab administration.

Children 8 through 19 months of age who are recommended to receive nirsevimab when entering their second RSV season because of increased risk of severe disease

- Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season.
- Children who are severely immunocompromised.
- 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 <10th percentile.
- American Indian and Alaska Native children (note that this is a new group for whom second-season prophylaxis is recommended in contrast to the current palivizumab recommendations).

Coadministration with routine childhood vaccines

- 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 the childhood vaccines administered alone.
- When concomitantly administered, nirsevimab is not expected to interfere with the immune response to other vaccines.

Additional Information

- 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)
- Respiratory Syncytial Virus (Red Book)
- Nirsevimab Frequently Asked Questions (AAP.org)

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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. 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