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October 24, 2023

CDC Issues Interim Recommendations Due to Limited Availability of Nirsevimab in the United States

On October 23, 2023, the U.S. Centers for Disease Control and Prevention issued [interim recommendations](#) to protect infants from respiratory syncytial virus (RSV) during the 2023–2024 respiratory virus season.¹ These interim recommendations are due to limited availability of the long-acting monoclonal antibody, nirsevimab, an immunization product recommended for the prevention of RSV-associated lower respiratory tract disease in infants.

Background:¹

RSV is a common cause of respiratory infection in U.S. infants, most of whom are infected with RSV during their first year of life. RSV is the leading cause of hospitalization among U.S. infants. The highest incidence of RSV-associated hospitalization occurs in infants aged <3 months and then decreases with increasing age. Because of the high incidence of severe RSV disease in the first months of life, RSV prevention products focus on passive immunization of infants through maternal immunization or immunoprophylaxis with monoclonal antibodies.

Recommendations for Healthcare Providers:^{1, 2}

In settings with limited nirsevimab availability during the 2023–2024 RSV season

- For infants weighing <5 kg, ACIP recommendations are unchanged. For infants born before October 2023, administer a 50mg dose of nirsevimab now. For infants born during October 2023 and throughout the RSV season, administer a 50mg dose of nirsevimab in the first week of life.
- For infants weighing ≥5 kg, prioritize using 100mg nirsevimab doses in infants at highest risk of severe RSV disease:
 1. Young infants aged <6 months.
 2. **American Indian and Alaska Native infants aged <8 months.**
 3. Infants aged 6 to <8 months with conditions that place them at high risk of severe RSV disease: premature birth at <29 weeks' gestation, chronic lung disease of prematurity, hemodynamically significant congenital heart disease, severe immunocompromise, severe cystic fibrosis (either manifestations of severe lung disease or weight-for-length less than 10th percentile), neuromuscular disease or congenital pulmonary abnormalities that impair the ability to clear secretions.
- **Continue offering nirsevimab to American Indian and Alaska Native children aged 8–19 months who are not palivizumab-eligible and who live in remote regions**, where transporting children with severe RSV for escalation of medical care may be challenging, or in communities with known high rates of severe RSV among older infants and toddlers.
- Follow [AAP Recommendations](#) for palivizumab-eligible infants aged <8 months when the appropriate dose of nirsevimab is not available.
- Avoid using two 50mg doses for infants weighing ≥5 kilograms (≥11 pounds), because 50mg doses should be reserved only for infants weighing <5 kilograms (<11 pounds), for example those born during the season who will be at increased risk for severe RSV illness because of their young age.
- Providers should encourage pregnant people to receive RSVpreF vaccine (Abrysvo, Pfizer) during 32 weeks' gestation through 36 weeks and 6 days' gestation to prevent RSV-associated lower respiratory tract disease in infants.
- Either RSVpreF vaccination or nirsevimab immunization for infants is recommended to prevent RSV-associated lower respiratory tract disease in infants, but [administration of both products](#) is not needed for most infants.

Availability: (For questions regarding availability, please contact CAPT Weston Thompson, NSSC)

All formulations of nirsevimab are currently available to order in McKesson Connect. It is recommended that sites assess local needs and regularly check the pharmaceutical prime vendor for updated inventory.

Clinician Resources:^{2, 3}

- AAP: [Nirsevimab Frequently Asked Questions](#)
- FDA: [Nirsevimab Prescribing Information](#)
- MMWR: [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](#)

References:

1. U.S. Centers for Disease Control and Prevention. [Limited Availability of Nirsevimab in the United States- Interim CDC Recommendations to Protect Infants From Respiratory Syncytial Virus \(RSV\) during the 2023-2024 Respiratory Virus Season](#). Published online October 23, 2023.
2. American Academy of Pediatrics. [ACIP and AAP Recommendations for Nirsevimab](#). Published August 15, 2023.
3. U.S. Food and Drug Administration. [Nirsevimab Prescribing Information](#). July 2023.
4. CDC Advisory Committee in Immunization Practices. [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](#), Published August 25, 2023.