Communicable Disease Epidemiology and Immunization Section



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Health Advisory – 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 – October 31, 2023

Actions Requested

- Prepare to provide options to protect infants from respiratory syncytial virus (RSV) in the context of a <u>limited supply of nirsevimab</u>, a long-acting monoclonal antibody immunization product recommended for preventing RSV-associated lower respiratory tract disease in infants.
- Follow CDC Interim recommendations for prioritizing available nirsevimab for the 2023–2024 RSV season.
 - Administer a 50mg dose for infants weighing <5 kilograms (<11 pounds). For infants born before October 2023, administer a 50mg dose of nirsevimab now. For infants born in October 2023, and throughout the RSV season, administer a 50mg dose of nirsevimab in the first week of life.
 - o For infants weighing ≥5 kilograms (≥11 pounds), prioritize using a 100mg dose of nirsevimab for infants at highest risk of severe RSV disease:
 - Infants aged <6 months</p>
 - American Indian and Alaska Native infants ages <8 months
 - Infants aged 6 to <8 months with conditions that place them at <u>high risk</u> for severe RSV disease
 - Suspend use of nirsevimab in palivizumab-eligible children aged 8–19 months per <u>AAP recommendations</u>.
 - Continue to offer nirsevimab to American Indian and Alaska Native children aged 8– 19 months who are not palivizumab eligible.
 - Follow <u>AAP recommendations</u> for palivizumab-eligible infants aged <8 months when the appropriate dose of nirsevimab is not available.
 - To preserve supply avoid using two 50mg doses for children weighing >5 kilograms (≥ 11 pounds).
- Encourage pregnant people to receive <u>RSVpreF vaccine (Abrysvo, Pfizer)</u> during 32 weeks' gestation through 36 weeks and 6 days' gestation to prevent RSV-associated lower respiratory tract disease in infants.
 - Only the Pfizer RSVpreF vaccine (Abrysvo) is approved and recommended for use in pregnant people. The GSK RSVpreF3 vaccine (Arexvy) should **not** be used in pregnant people.
 - Refer patients to <u>Abrysvo Find a Vaccine</u> to locate pharmacies and doctor's office that offer RSVpreF vaccine
 - Either RSVpreF vaccination or nirsevimab immunization for infants is recommended to prevent RSV-associated lower respiratory tract disease in infants, but <u>administration of both</u> <u>products</u> is not needed for most infants.

- Continue to recommend and offer coadministration of vaccination against influenza and COVID-19 for all patients 6 months and older who are not up to date.
- Remind patients that layered approaches including vaccination, masking, and improving ventilation remain critical to mitigating risk of COVID-19 and other respiratory viral infections, especially among high-risk individuals.
- Prepare for stress on the healthcare system from increased hospitalizations related to respiratory infections.

Background

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 (1, 2). RSV is the leading cause of hospitalization among U.S. infants (3). The highest incidence of RSV-associated hospitalization occurs in infants aged <3 months and then decreases with increasing age (4). Because of the high incidence of severe RSV disease in the first months of life, RSV prevention products focus on passive immunization of young infants through maternal immunization or immunoprophylaxis with monoclonal antibodies.

For the 2023–2024 RSV season, the manufacturer reports a limited supply of nirsevimab, particularly the 100mg dose prefilled syringes used for infants weighing ≥5 kg. Based on manufacturing capacity and currently available stock, there are not sufficient 100mg dose prefilled syringes of nirsevimab to protect all eligible infants weighing ≥5 kg during the current RSV season. Additionally, supply of the 50mg dose prefilled syringes may be limited during the current RSV season. CDC continues to work with the manufacturer to understand how it may accelerate nirsevimab supply.

Resources

- 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 | CDC
- For Healthcare Professionals: RSV (Respiratory Syncytial Virus) | CDC
- Healthcare Providers: RSV Vaccination for Pregnant People | CDC
- Healthcare Providers: RSV Immunization for Children 19 Months and Younger | CDC
- ACIP and AAP Recommendations for Nirsevimab | Red Book Online | American Academy of Pediatrics
- <u>Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased</u> <u>Risk of Hospitalization for Respiratory Syncytial Virus Infection | Pediatrics | American Academy of</u> <u>Pediatrics</u>

References

- 1. Glezen WP, Taber LH, Frank AL, Kasel JA. <u>Risk of primary infection and reinfection with respiratory</u> <u>syncytial virus.</u> Am J Dis Child 1986; 140(6):543–6.
- 2. Rosas-Salazar C, Chirkova T, Gebretsadik T, et al. <u>Respiratory syncytial virus infection during infancy</u> <u>and asthma during childhood in the USA (INSPIRE): a population-based, prospective birth cohort</u> <u>study.</u> Lancet 2023; 401(10389):1669–80.
- 3. McLaughlin JM, Khan F, Schmitt H-J, et al. <u>Respiratory Syncytial Virus–Associated Hospitalization Rates</u>

among US Infants: A Systematic Review and Meta-Analysis. J Infect Dis. 2022; 225(6):1100-11.

- 4. Hall CB, Weinberg GA, Blumkin AK, et al. <u>Respiratory syncytial virus–associated hospitalizations</u> <u>among children less than 24 months of age.</u> Pediatrics. 2013;132(2):e341-8.
- Jones JM, Fleming-Dutra KE, Prill MM, et al. <u>Use of Nirsevimab for the Prevention of Respiratory</u> <u>Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory</u> <u>Committee on Immunization Practices — United States, 2023.</u> MMWR Morb Mortal Wkly Rep 2023; 72(34):920–5.
- Fleming-Dutra KE, Jones JM, Roper LE, et al. <u>Use of the Pfizer Respiratory Syncytial Virus Vaccine</u> <u>During Pregnancy for the Prevention of Respiratory Syncytial Virus–Associated Lower Respiratory</u> <u>Tract Disease in Infants: Recommendations of the Advisory Committee on Immunization Practices –</u> <u>United States, 2023.</u> MMWR Morb Mortal Wkly Rep 2023; 72(41):1115–22.

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