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NEW MEXICO HEALTH ALERT NETWORK (HAN) ALERT

Protecting Infants from RSV during the National Nirsevimab (Beyfortus) Shortage

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For the 2023–2024 RSV season, both CDC and the manufacturer are reporting shortages of Nirsevimab (Beyfortus™), the new long-acting monoclonal antibody to prevent respiratory syncytial virus (RSV) in infants and young children. 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 prefilled syringes may be limited during the current RSV season.

Because supply of nirsevimab (Beyfortus™) is limited and may not be available at the time of birth, providers should discuss RSVpreF vaccine (Abrysvo™, Pfizer) with their pregnant families. In the phase 3 trial, efficacy against medically attended severe RSV-associated LRTI in infants was 69 – 81% when the vaccine is given to pregnant people[1]. Maternal RSVpreF vaccine can be administered to pregnant persons with other recommended vaccines. Although not statistically significant, in the full trial population (vaccine given between 24 – 36 weeks) more preterm births and hypertensive disorders of pregnancy (including preeclampsia) were observed in persons administered the vaccine rather than the placebo, and more infants whose mothers received the vaccine had low birthweight ≤5.5 lbs (≤2,500 g) and neonatal jaundice compared with infants whose mothers received the placebo[2].

Background:
RSV is the leading cause of hospitalization among U.S. infants. The Centers for Disease Control and Prevention (CDC) recommends two new immunizations to prevent severe RSV disease in infants and older babies. Both products protect infants through passive immunization.

1. **Nirsevimab (Beyfortus™)** is a long-acting monoclonal antibody for prevention of RSV-associated lower respiratory tract disease among infants. Nirsevimab is indicated for all infants aged <8 months who are born during or entering their first RSV season (October – end of March in New Mexico) and for infants and children aged 8–19 months who are at increased risk for severe RSV disease and are entering their second RSV season.

[1] Bivalent Prefusion F Vaccine in Pregnancy to Prevent RSV Illness in Infants | NEJM
[2] 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 (cdc.gov)

2. **RSVpreF vaccine (Abrysvo™, Pfizer)** is indicated for pregnant people who are between 32 – 36 weeks gestation from September – January to prevent RSV-associated lower respiratory tract disease (LRTD) in infants.

Recommendations for Healthcare Providers
Given limited supply of Nirsevimab for the 2023–2024 RSV season, CDC recommends the following:

1. Providers should encourage pregnant people to receive RSVpreF vaccine (Abrysvo, Pfizer) between 32 – 36 weeks gestation to prevent RSV-associated LRTD in infants.
2. 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 RSV season, administer a 50mg dose of nirsevimab in the first week of life.
3. For infants weighing ≥5 kg, prioritize using 100mg nirsevimab doses in infants at highest risk of severe RSV disease:
    a. Young infants aged <6 months.
    b. American Indian and Alaska Native infants aged <8 months.
    c. 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.
4. In palivizumab-eligible children aged 8–19 months, suspend using nirsevimab for the 2023–2024 RSV season. These children should receive palivizumab per AAP recommendations.
5. 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.
6. Follow AAP recommendations for palivizumab-eligible infants aged <8 months when the appropriate dose of nirsevimab is not available.
7. Do not use two 50mg doses for infants weighing ≥5 kilograms (≥11 pounds), because 50mg doses should be reserved only for infants weighing <5 kilograms (<11 pounds). Insurers may not cover the cost of two 50mg doses.
8. Either RSVpreF vaccination in pregnancy 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.

RSV Epidemiology
Current reports to the National Respiratory and Enteric Virus Surveillance System (NREVSS), a national laboratory-based surveillance network, indicate RSV transmission has increased to seasonal epidemic levels in the Southern regions of the United States and is expected to continue to increase in the rest of the country within the next 1–2 months.

Additional Information:

- Families should be aware of everyday preventive measures to limit the spread of RSV .
- 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.
- The Pfizer maternal RSVpreF vaccine is the same formulation and dose approved for use in adults aged ≥60 years.
- ACOG support: Maternal Respiratory Syncytial Virus Vaccination | ACOG
- For tracking current and historical RSV activity by state: RSV-NET Interactive Dashboard | CDC
- CDC resource page for providers: Resources to Prepare for Flu, COVID-19, and RSV | CDC and for the public: Protect yourself from COVID-19, Flu, and RSV (cdc.gov)

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