LOUISIANA DEPARTMENT OF HEALTH Public Health	**Louisiana Health Alert Message 23-19: Limited Availability of Nirsevimab in the United States—Interim CDC Recommendations to Protect Infants from RSV during the 2023–2024 Respiratory Virus Season**
Origination Date: October 25, 2023	**Revision Dates (List All Revision Dates):**

Louisiana Health Alert Message 23- Limited Availability of Nirsevimab in the United States—Interim CDC Recommendations to Protect Infants from RSV during the 2023–2024 Respiratory Virus Season

Background

In July 2023, the Food and Drug Administration (FDA) approved nirsevimab (Beyfortus™, Sanofi and AstraZeneca). On August 3, 2023, CDC's Advisory Committee on Immunization Practices (ACIP) recommended nirsevimab for all infants aged <8 months who are born during or entering their first RSV season 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.

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.

Limited Supply/Availability

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.

Nirsevimab and the Vaccines for Children Program

Nirsevimab is available for inclusion in the Louisiana Vaccines for Children (VFC) Program. However, ordering is currently restricted due to robust demand and limited inventory at the manufacturer. CDC has informed the Louisiana Immunization Program that capped allocations will be put in place to ensure equitable distribution nationwide. The Louisiana VFC Program will alert providers when allocations have been replenished and providers can resume placing VFC orders. Facilities/providers may also receive less inventory than ordered, due to quantity restrictions during this time of limited nirsevimab supply.

Interim CDC Recommendations for Providers

1. For infants weighing <5 kg, CDC 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.
2. For infants weighing ≥5 kg, prioritize using 100mg nirsevimab doses in infants at highest risk of severe RSV disease:
   - Young infants aged <6 months.
   - American Indian and Alaska Native infants aged <8 months.
   - 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.

   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.

   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. Furthermore, providers should be aware that some insurers may not cover the cost of two 50mg doses for an individual infant.

   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. 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.

   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.

Recommendations for the Public

1. Families should be aware of everyday preventive measures to limit the spread of RSV and other respiratory illnesses, including washing hands, covering coughs and sneezes, cleaning frequently touched surfaces, and staying home when sick.
2. Expectant parents should talk with their healthcare provider about receiving the RSV vaccine (Abrysvo, Pfizer) during pregnancy to protect their infant from severe RSV. CDC

recommends that all infants are protected against RSV through either vaccination of the mother with RSV vaccine during pregnancy or giving the infant nirsevimab after birth.
3. Parents should talk with their healthcare provider about whether nirsevimab is available for their infant.

Reporting Adverse Reactions

- Report suspect adverse reactions following the administration of nirsevimab without coadministration with any vaccine to MedWatch. Reports can be submitted to MedWatch online at www.fda.gov/medwatch or by phone at 1-800-FDA-1088.
- Report suspect adverse reactions following co-administration of nirsevimab with any vaccine to the Vaccine Adverse Event Reporting System (VAERS).
  - Please specify that the patient received nirsevimab on the VAERS form, specifically, in Section 9: 'Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination.

Additional Information for Healthcare Providers:

- 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
- Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection | Pediatrics | American Academy of Pediatrics
- Beyfortus Coding and Billing Sheet

Additional Information for the Public:

- Symptoms and Care of RSV (Respiratory Syncytial Virus) | CDC
- Preventing RSV (Respiratory Syncytial Virus) | CDC
- RSV Vaccination: What Parents Should Know | CDC
- RSV Vaccination for Pregnant People | CDC
- Frequently Asked Questions About RSV Vaccine for Children 19 Months and Younger | CDC
- Protect yourself from COVID-19, Flu, and RSV | CDC
- RSV National Trends – NREVSS | CDC
- RSV (Respiratory Syncytial Virus) Preventive Antibody Immunization Information Statement | CDC