LOUISIANA DEPARTMENT OF HEALTH Public Health	**Louisiana Health Alert Message 23-15: CDC recommends the use of a new monoclonal antibody to protect infants and children from Respiratory Syncytial Virus**
Origination Date: August 10, 2023	**Revision Dates (List All Revision Dates):**

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Recommendations

Following a review by their **Advisory Committee on Immunization Practices (ACIP), the Centers for Disease Control and Prevention (CDC)** is recommending the use of a new immunization, nirsevimab, to help protect all infants under 8 months and some older babies from severe illnesses caused by RSV.

Nirsevimab, trade name BeyfortusTM, is a long-acting monoclonal antibody product, which has been shown to reduce the risk of both hospitalizations and healthcare visits for RSV in infants by about 80 percent.

- **CDC recommends one dose of nirsevimab** for all infants younger than 8 months, born during – or entering – their first RSV season (typically fall through spring).
    - Dose: 50 mg for infants <5 kg and 100 mg for infants ≥5kg
- **CDC recommends a second dose in the following RSV season** for children between the ages of 8 and 19 months who are at increased risk of severe RSV disease, such as children who are severely immunocompromised.
    - Dose: 200 mg

Administration of Nirsevimab

Nirsevimab, which was approved last month by the U.S. Food and Drug Administration (FDA), is administered as an injection and provides infants and toddlers with antibodies to protect against severe RSV illness. It provides critical protection during a baby's first RSV season, when they're most at risk for severe illness.

Background

RSV is one of the most common causes of childhood respiratory illness and results in annual outbreaks of respiratory illnesses in all age groups. It is the leading cause of hospitalizations for infants and older babies.

- An estimated 58,000 to 80,000 children under 5 years of age, most of them infants, are hospitalized each year nationwide due to RSV infection.
- Each year, an estimated 100 to 300 children younger than 5 years of age die due to RSV.

Availability of Nirsevimab

According to CDC, nirsevimab is expected to be available this fall for RSV season. There are many factors affecting the implementation rollout of this new medication that are currently being addressed at the national level, before it begins arriving to local hospitals and doctors' offices. Once implementation hurdles are cleared, AstraZeneca and Sanofi have indicated they are prepared to meet public demand and make nirsevimab available to providers.

Expectant parents and parents of infants under the age of 8 months, as well as those with older babies, should talk with their healthcare providers to request this added layer of protection against RSV this season and inquire when they expect have supply on hand.

Clinical Guidance

Timing of nirsevimab administration

Providers should target administration:

- In the first week of life for infants born shortly before and during the season
- Shortly before the start of the RSV season for infants aged <8 months
- Shortly before the start of the RSV season for children aged 8–19 months who are at increased risk of severe RSV disease

While **optimal timing for nirsevimab administration is shortly before the season**, nirsevimab may be given at any time during the RSV season for age-eligible infants and children who have not yet received a dose.

- Based on pre-pandemic patterns, this means nirsevimab could 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 based on local epidemiology.

Nirsevimab should be administered within one week of birth. Administration can be during the birth hospitalization or in the outpatient setting. Infants with prolonged birth hospitalizations due to prematurity or other causes should receive nirsevimab shortly before or promptly after discharge.

In most regions of the United States and other areas with similar climates, RSV season typically starts during the fall and peaks in the winter. Tropical climates may have seasonality that differs from most of the continental United States or is unpredictable. Providers in these jurisdictions should consult state, local or territorial guidance on timing of nirsevimab administration. Within Louisiana, reports of RSV and other viral respiratory disease activity can be found here.

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

Coadministration with routine childhood vaccines

- In accordance with CDC's general best practices for immunizations, simultaneous administration of nirsevimab with age-appropriate vaccines is recommended.
- In clinical trials, when nirsevimab was given concomitantly with routine childhood vaccines, the safety and reactogenicity profile of the coadministered regimen was similar to the childhood vaccines given alone.

- When coadministered, nirsevimab is not expected to interfere with the immune response to vaccines.

Children aged 8–19 months who should receive nirsevimab when entering their second RSV season because of increased risk of severe disease, include:

- 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 with severe 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 weight-for-length <10th percentile, and
- American Indian and Alaska Native children.

Precautions and Contraindications

- Providers administering nirsevimab should follow ACIP's general best guidelines for immunization.
- Nirsevimab should not be administered to persons with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a product component (contraindication).

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'.

Vaccines for Children

ACIP voted to include nirsevimab in the Vaccines for Children program, which provides recommended vaccines and immunizations at no cost to about half of the nation's children. CDC is currently working to make nirsevimab available through the Vaccines for Children program. Healthcare providers will be a key partner in CDC's outreach efforts. Additional clinical guidance and healthcare provider education material will be provided by CDC in the coming months.

More Information

- RSV in Infants and Young Children | CDC
- Information for Providers