

# LAC DPH Health Advisory: Prevent Severe RSV in Infants with Maternal or Infant Immunization October 6, 2023



This message is intended for all family practice, pediatric, and obstetric providers.

Please distribute as appropriate.

# **Key Messages**

- There are now two immunization methods available to prevent severe respiratory syncytial virus (RSV) disease in infants: maternal RSV vaccination and infant immunization with RSV monoclonal antibody.
- The <u>CDC</u> and <u>American College of Obstetricians and Gynecologists</u> (ACOG) recommend maternal RSV vaccination to protect infants from severe RSV disease. Pregnant people who are 32 through 36 weeks pregnant during September through January should get a single dose of Pfizer's bivalent RSVpreF vaccine (Abrysvo).
- Either maternal or infant RSV immunization is recommended. Most infants will not need both. Providers should counsel families on both immunization options.
- It is vital that all maternal RSV vaccines administered are entered into the <u>California Immunization Registry</u> (CAIR). Pediatric providers will require this information to assess the eligibility of infants for RSV immunization.

## **Situation**

RSV activity is increasing <u>nationally</u>. In LA County, <u>sentinel laboratory surveillance</u> shows a small increase in the percent of weekly specimens positive for RSV. In California, RSV is most common between October and March.

This communication provides information on the recently recommended maternal RSV vaccine to prevent severe RSV in their newborns as well as updated considerations for administering the long-acting RSV monoclonal antibody nirsevimab in the context of maternal vaccine availability. For details on immunizing older adults for RSV see the September 6, 2023, LAHAN, <a href="Immunize Infants and Older Adults to">Immunize Infants and Older Adults to</a> Protect them from Severe RSV.

#### **Immunizations to Prevent Severe RSV in Infants**

Either maternal vaccination or infant immunization with nirsevimab is recommended to prevent RSV lower respiratory tract infection during infancy. Both products are not necessary for most patients, and providers should offer counseling to families regarding both options.

### Maternal vaccination

On August 21, 2023, the <u>FDA</u> approved the new Pfizer RSV vaccine Abrysvo for use in pregnant persons to protect newborns and infants against severe RSV disease in the first 6 months after birth. Abrysvo is approved for use at 32 through 36 weeks gestational age of pregnancy. Note: Abrysvo was FDA approved this May for the prevention of RSV-associated lower respiratory tract disease in individuals 60 years of age and older.

On September 22<sup>nd</sup>, 2023, the <u>CDC</u> recommended the RSV vaccine for pregnant persons during 32 through 36 weeks of gestation, using seasonal administration, to prevent RSV lower respiratory tract infection in infants. In most of the continental United States, it is recommended that pregnant people receive the RSV vaccine from September through January.

## Vaccine efficacy and safety

Clinical trial <u>data</u> show that receipt of the RSV vaccine in pregnancy reduced the risk of RSV hospitalization for infants by 57% and having a RSV-related healthcare visit by 51% within 6 months after birth. Furthermore, the maternal RSV vaccine reduced the risk of severe disease from RSV by 82% within 3 months and by 69% within 6 months after birth. Severe disease was defined as RSV infection that resulted in tachypnea, hypoxemia, use of a high-flow nasal cannula or mechanical ventilation, admission to an intensive care unit, or unresponsiveness.

The most common side effects reported in the clinical trials were pain at injection site, headache, muscle pain and nausea.

In the <u>clinical trials</u> that included pregnant persons who received the RSV vaccine from 24 to 36 weeks of pregnancy, there was an imbalance of preterm births (5.7% in vaccine group, 4.7% in placebo). Available data are insufficient to establish or exclude a causal relationship between receipt of RSV vaccine and preterm birth. To reduce the potential risk of preterm birth when administering maternal RSV vaccine, FDA approved the vaccine for use during weeks 32 through 36 of pregnancy.

See <u>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</u> for a detailed discussion of vaccine efficacy and safety.

For healthcare provider guidance, see CDC RSV Vaccination for Pregnant People.

# Pediatric immunization with nirsevimab

On August 3, 2023, the CDC recommended the use of nirsevimab, a long-acting monoclonal antibody product, for the prevention of RSV in infants and some young children. It is administered as an intramuscular injection (IM). Nirsevimab has been shown to reduce the risk of both hospitalizations and health care visits for RSV in

infants by about 80%. This protection is expected to last at least 150 days, the length of an average RSV season. For more information on the use of nirsevimab, see <u>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.</u>

For considerations for the use of palivizumab versus nirsevimab for high-risk infants this 2023-2024 RSV season see ACIP and AAP Recommendations for the Use of the Monoclonal Antibody Nirsevimab for the Prevention of RSV Disease.

Note: Access to nirsevimab may be challenging this season but is expected to improve throughout this RSV season. Providers can order nirsevimab directly through the manufacturer for privately insured patients. Ordering through <a href="Vaccines for Children Program">Vaccines for Children Program</a> is expected to be available in mid-October.

### For more information on nirsevimab see:

- RSV Immunization for Infants and Young Children (CDC)
- FAQs-RSV Immunization for Children 19 Months and Younger (CDC)
- FAQs-Nirsevimab (AAP)
- Nirsevimab Guide to Prevent Severe RSV in Infants and Toddlers (CDPH)

# **Actions requested of providers**

- Educate all pregnant persons that they now have two ways to protect their baby from getting very sick with RSV this season—a dose of RSV vaccine in pregnancy or an RSV immunization given directly to their infant shortly after birth. Discussion of these two options should include the following considerations:
  - Patient preference for receiving a vaccine during pregnancy vs immunizing their infant shortly after birth.
  - Their infant having reliable and immediate access to a pediatric provider who is administering nirsevimab. While maternal vaccine provides protection immediately after birth, nirsevimab offers protection one week after administration.
    - See ACOG counseling guide for clinicians.
- Offer the RSV vaccine to all pregnant persons at weeks 32-36 weeks'
  gestation now through January. Please report all administered doses to CAIR
  so pediatric providers are aware when they are assessing a newborn's need for
  nirsevimab.
- Co-administer the maternal RSV vaccine with other recommended vaccines for pregnant persons, such as Tdap, COVID-19, and influenza vaccines. It is critically important that pregnant patients receive all recommended vaccines.
- Administer nirsevimab to all infants younger than 8 months of age if:
  - o The birth mother did not receive RSV vaccine during pregnancy.
  - o The birth mother's RSV vaccination status is unknown.
  - The infant was born within 14 days of maternal RSV vaccination. Note: this means that nirsevimab is recommended for all infants born at <34 weeks' gestation.

- Consider administering nirsevimab to infants younger than 8 months of age, in addition to maternal RSV vaccination, in very rare situations when the potential incremental benefit of administration is warranted. These situations include, but are not limited to the following:
  - Infants who were born to mothers who may not have mounted an adequate immune response to vaccination (e.g., persons with immunocompromising conditions) or who have conditions associated with reduced transplacental antibody transfer (e.g., persons living with HIV infection).
  - Infants who might have experienced loss of maternal antibodies (e.g., received cardiopulmonary bypass).
  - Infants at substantially increased risk for severe RSV disease (e.g., those with hemodynamically significant congenital heart disease, or intensive care admission requiring oxygen at hospital discharge).
- Administer nirsevimab to children 8 through 19 months of age who are at increased risk for severe RSV disease and entering their second RSV season. This includes the following:
  - Children with chronic lung disease of prematurity who require medical support during the 6 months before the start of the second RSV season.
  - o Children with severe immunocompromise.
  - Children with cystic fibrosis who have manifestations of severe lung disease or weight for length <10th percentile.</li>
  - American Indian and Alaska Native children.
- Report adverse events to <u>Vaccine Adverse Events Reporting System (VAERS)</u> if it may be related to maternal vaccination or nirsevimab co-administered with other vaccines. Report possible adverse events to nirsevimab administered alone to FDA MedWatch.
- Report all RSV-related deaths in children under aged 5 years to Los Angeles County Department of Public Health.

### **Additional Information**

- RSV for Healthcare Providers (CDC)
- RSV (LAC DPH)
- Vaccine information for general public (LAC DPH)

This communication was sent by Dr. Nava Yeganeh, Medical Director of Vaccine Preventable Disease Prevention, Los Angeles County Department of Public Health

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