

LAC DPH Health Advisory: Immunize Infants and Older Adults to Protect them from Severe RSV September 6, 2023



This message is intended for all pediatricians, general internal medicine providers, geriatricians, and obstetricians. Please distribute as appropriate.

Key Messages

- Respiratory syncytial virus (RSV) is a significant cause of hospitalizations and death in infants and older adults. These high-risk populations can now be immunized to reduce their risk of severe RSV.
- The <u>CDC</u> recommends that adults ages 60 years and older may receive a single dose of RSV vaccine, using shared clinical decision-making.
- The <u>CDC</u> and the <u>American Academy of Pediatrics</u> (AAP) recommend a single dose of the monoclonal antibody product nirsevimab for all infants under 8 months of age born during or entering their first RSV season. In addition, nirsevimab is recommended for infants and children 8-19 months of age who are at increased risk for severe RSV disease and entering their second RSV season.
- Healthcare providers are required to enter all vaccines administered to the <u>California Immunization Registry</u> (CAIR) per <u>Assembly Bill 1797</u>. If your organization provides vaccinations but is not currently reporting to CAIR, please contact <u>CAIRhelpdesk@cdph.ca.gov</u>.

Situation

RSV causes substantial morbidity and mortality in infants and older adults. In the United States, it is estimated that RSV is associated with 60,000-160,000 hospitalizations and 6,000-10,000 deaths among adults ages 65 and older each year.

RSV is the most common cause of hospitalization in infants in the U.S. with the highest rates in the first months of life. Prematurity and chronic diseases increase the risk of RSV-associated hospitalization, but nearly 80% of hospitalizations occur in healthy, term infants. In children under 5 years of age, RSV is associated with 60,000-80,000 hospitalizations and 100-300 deaths each year in the U.S.

In the 2022-23 season, California experienced an early and especially <u>severe RSV</u> <u>season</u> with unusually high numbers of hospitalizations and deaths due to RSV in infants and older adults. While <u>RSV activity</u> is still low in Los Angeles County, the CDC is <u>reporting</u> increases in RSV activity across some parts of the southeast United States. This suggests a continued shift toward seasonal RSV trends observed prior to the COVID-19 pandemic. Historically, such regional increases have predicted the beginning of RSV season nationally, with increased RSV activity spreading north and west over the following weeks.

Fortunately, effective immunizations are now available to help protect adults 60 years of age and older and young children from severe RSV. Note: An RSV vaccine for pregnant individuals to prevent RSV in their newborns and infants has been approved by the FDA. CDC/ACIP recommendations regarding use will be available this fall.

In anticipation of the onset of the 2023-2024 RSV season, CDC and LAC DPH encourage clinicians to prepare to implement these new RSV prevention options.

This communication provides immunization details and recommendations for older adults and for pediatric populations.

Adults 60 Years of Age and Older

In May 2023, the FDA approved two vaccine products, <u>GSK's Arexvy</u> and <u>Pfizer's</u> <u>Abrysvo</u>, to prevent RSV-associated lower respiratory tract disease in adults 60 years of age and older. In June 2023, the <u>CDC</u> recommended that adults age of 60 years and older may receive a single dose of RSV vaccine using <u>shared clinical decision-making</u>. There is no preferential recommendation of one vaccine over the other.

In clinical trials, both vaccine products demonstrated strong efficacy, with a single dose being more than 80% effective in preventing RSV-associated lower respiratory tract disease among adults ≥60 years during the first season post administration. These vaccines were well-tolerated and their most common side effects were comparable to those seen with other vaccines, resulting in an acceptable safety profile. In the clinical trials there were six reported cases of inflammatory neurologic events out of more than 38,000 vaccinated individuals. Additionally, there was a slight imbalance in the occurrence of arial fibrillation events among vaccine recipients compared to placebo recipients. The ACIP states that until there is further post marketing data, that RSV vaccination should be targeted to adults at highest risk for severe RSV disease who are most likely to benefit from vaccination. See the <u>Use of Respiratory Syncytial Virus</u> Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023 for a detailed discussion.

Actions Requested of Providers – Adult RSV Immunization

• Discuss the RSV vaccine with patients ages 60 years and older. Consider risk factors for severe RSV-associated disease including frailty and advanced age, residence at skilled nursing facilities or other long term care facilities, and chronic medical conditions such as lung diseases (e.g., chronic obstructive pulmonary disease, asthma), cardiovascular diseases (e.g., congestive heart failure, coronary artery disease), moderate or severe immunocompromise, and diabetes.

The CDC has released several RSV vaccination provider resources including a summary <u>webpage</u> and job aid on shared clinical decision making.

- Offer RSV vaccination now and throughout the RSV season. Ideally, vaccination would occur before RSV season onset but this is harder to predict as there has been increased season variability during the COVID-19 pandemic.
- **Consider coadministration of the RSV vaccine with other vaccines**. CDC states that the coadministration of RSV vaccines with other adult vaccines, including influenza is acceptable but may increase local or systemic reactogenicity. If vaccines are not administered the same day, there is no required interval between RSV and other vaccines.
- Report administration of RSV vaccines to CAIR.
- Report any adverse event after RSV vaccination to the <u>Vaccine Adverse</u> <u>Event Reporting System (VAERS)</u>.

Pediatric Populations

Nirsevimab is a long-acting monoclonal antibody product that was <u>FDA approved</u> in July 2023 to prevent RSV-associated lower respiratory tract infections in infants and some young children. It is administered as an intramuscular injection (IM). In a pooled analysis of the clinical trials, nirsevimab had an efficacy of 80.6% (95% CI 62.3%-90.1%) for preventing hospitalizations due to RSV-associated lower respiratory tract infections and was well tolerated without any serious adverse events. This protection is expected to last at least 150 days, the length of an average RSV season. Nirsevimab is included in the <u>Vaccines for Children Program</u> (VFC) and is anticipated to be available for procurement this fall.

Per the <u>FDA label</u>, children who have received nirsevimab should not receive palivizumab (Synagis) for the same RSV season.

See <u>Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease</u> <u>Among Infants and Young Children: Recommendations of the Advisory Committee on</u> <u>Immunization Practices — United States, 2023</u> and <u>ACIP and AAP Recommendations</u> <u>for Nirsevimab</u> and for more detailed information.

Actions Requested of Providers – Pediatric RSV Immunization

- **Procure nirsevimab now** in preparation for the start of the RSV season.
- Sign up for LAC DPH <u>Influenza Watch</u> to learn when RSV activity is increasing locally email <u>influenza@ph.lacounty.gov</u>.
- Administer nirsevimab per ACIP recommendations once the season has begun:
 - A single dose of nirsevimab to all infants younger than 8 months entering or born during their first RSV season (Dose: 50 mg for infants <5kg, and 100 mg for infants <u>></u>5kg). Target administration within one week of birth. The ideal approach is to administer nirsevimab at the birth hospital at the same time as a dose of Hepatitis B vaccine.

- A single dose of nirsevimab to infants and children 8-19 months of age who are at increased risk for severe RSV disease and entering their second RSV season (Dose 200 mg). This includes children with chronic lung disease of prematurity who require medical support during the 6 months before the start of the second RSV season, children with severe immunocompromise, children with cystic fibrosis who have manifestations of severe lung disease or weight for length <10th percentile, and American Indian and Alaska Native children.
- Coadminister nirsevimab with other age-appropriate vaccines if they are due. Simultaneous administration of nirsevimab with other routine childhood vaccines is recommended by both the CDC and AAP. Nirsevimab is not expected to interfere with the immune response to other vaccines. In clinical trials, when nirsevimab was coadministered with routine childhood vaccines, the safety and reactogenicity profile of the coadministered regimen was similar to the childhood vaccines administered alone.
- Report administration of nirsevimab to the CAIR.
- Report adverse events to <u>FDA MedWatch</u> if nirsevimab is administered alone. If adverse events occur when nirsevimab is co-administered with vaccines please report to <u>VAERS</u>.
- <u>Report</u> all RSV-related deaths in children under aged 5 years to Los Angeles County Department of Public Health.

Additional Information

- <u>Nirsevimab FAQs (AAP)</u>
- RSV for healthcare providers (CDC): older adults | general | FAQs adults
- Shared clinical decision making for older adults (CDC) job aid
- <u>RSV</u> (LAC DPH)

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