

Health Advisory: Respiratory Syncytial Virus (RSV) Vaccination

November 9, 2023

Situational Update

<u>Respiratory syncytial virus (RSV) detections in California</u> began to rise in October; in prepandemic years this level of activity was not seen until later in the season. RSV detections in <u>wastewater</u> in San Francisco also began rising in October.

RSV can cause outbreaks of upper respiratory illness in all age groups, but infants and older adults with RSV – particularly those with chronic and/or underlying medical conditions – are most likely to develop lower respiratory illness that can be severe and require hospitalization. RSV is the leading cause of hospitalization among infants under the age of 12 months, and a major cause of hospitalization for older adults.

Nirsevimab (Beyfortus; Sanofi-AstraZeneca), the monoclonal antibody product approved for passive immunization of infants and young children up to 19 months of age against RSV, is currently in short supply and most babies for whom it is recommended will be unable to receive a dose this season. Therefore, it is particularly important for providers to ensure their **pregnant patients receive a dose of RSV vaccine** (ABRYSVO; Pfizer) at 32 through 36 weeks' gestation as a <u>safe and effective option to prevent severe RSV illness in infants</u>.

Separately, <u>FDA</u> recently urged providers who administer **Moderna 2023–24 COVID-19 vaccine** to children ages 6 months through 11 years to ensure that the correct (0.25 mL) volume of vaccine is withdrawn from the vial, so that the correct dose is administered to the recipient. The entire contents of the vial should not be withdrawn as the vial itself contains more than 0.25 mL of the vaccine.

Recommendations

Protection of Adults Aged 60 Years and Older

Adults age ≥ 60 years are recommended by CDC to receive one dose of either of the two recently approved RSV vaccines, ABRYSVO (RSVPreF; Pfizer) or AREXVY (RSVPreF3; GlaxoSmithKline) based on a <u>shared clinical decision-making discussion</u> with their healthcare provider that considers the patient's risk for developing severe RSV-associated disease.

 Risk for Severe RSV Disease. Older adults most likely to benefit from RSV vaccination include those with lung disease (e.g., chronic obstructive pulmonary



disease, asthma); cardiovascular disease (e.g., congestive heart failure, coronary artery disease); moderate or severe <u>immune compromise</u> (due to a medical condition or treatment); diabetes mellitus; neurologic or neuromuscular conditions; kidney disorders, liver disorders, and hematologic disorders; elderly persons who are frail or of advanced age; residents of nursing homes and other long-term care facilities; and persons with other underlying conditions or factors that the provider determines might increase the risk for severe RSV-associated lower respiratory disease.

- Timing of Vaccination. RSV vaccines are approved for use as a single dose; there is
 no current indication for re-vaccination. Ideally, RSV vaccine should be administered
 before the onset of the RSV season. Currently, RSV vaccine should be offered to adults
 aged 60 years and up using shared clinical decision-making as early as the vaccine
 supply is available and should continue to offer vaccination to eligible adults who remain
 unvaccinated.
- **Co-Administration.** It is acceptable to co-administer either RSV vaccine with other adult vaccines without regard to timing, including simultaneous vaccination at different anatomic sites on the same day.

Protection of Infants and Children Up to 19 Months of Age

There are two routes available for prevention of RSV during infancy: active immunization of the mother with ABRYSVO RSV vaccine late in pregnancy; and passive immunization of the infant with the long-acting monoclonal antibody product Nirsevimab (Beyfortus; Sanofi-AstraZeneca).

Pregnant individuals are <u>recommended by CDC</u> to receive one dose of Pfizer's ABRYSVO vaccine between 32 and 36 completed weeks of gestation to achieve transplacental transfer of maternal antibodies to protect the newborn infant.

- Efficacy, Safety. Maternal vaccination protects against severe RSV illness during
 infant's first 6 months, the period of highest risk for severe RSV disease. In clinical
 trials, maternal immunization prevented up to 77% of severe RSV disease in infants
 without an increase in serious adverse events or preterm births.
- **Timing of Vaccination.** ABRYSVO should be administered to pregnant persons during September to January to target vaccine to those whose infants will be in their first months of life during the RSV season.
- **Co-Administration.** It is acceptable to co-administer ABRYSVO to pregnant persons with other recommended vaccines (Tdap, flu, and COVID vaccines) without regard to timing, including simultaneous vaccination at different anatomic sites on the same day.

For **infants and children up to 19 months of age**, in August 2023, CDC published <u>initial</u> recommendations for administration of Nirsevimab to all infants aged less than 8 months born during or entering their first RSV season, and to infants and young children aged 8 through 19



months who are at increased risk for severe RSV disease and entering their second RSV season. This <u>CDPH infographic</u> outlines dose and timing recommendations.

However, the <u>supply of Nirsevimab 100-mg doses is insufficient to meet demand</u> at this time, and due to the shortage, the California Vaccines for Children (VFC) program has <u>temporarily</u> <u>limited ordering of Nirsevimab</u> until the supply improves.

Therefore, follow this <u>CDC Health Alert</u> for prioritization recommendations during the shortage (it is unknown when the shortage will resolve):

- Prioritization of Nirsevimab 100-mg doses for highest risk infants weighing over 5 kg
- Continued use of Nirsevimab 50-mg doses among infants weighing 5 kg or less
- Administration of Palivizumab rather than Nirsevimab in Palivizumab-eligible children ages 8 through 19 months

In this context, while Nirsevimab is in short supply, **prenatal care providers should help protect newborns by ensuring that ABRYSVO RSV vaccine is administered this season to all pregnant patients at 32 through 36 weeks' gestation**; administer in-office (preferred) or provide a strong referral to an in-network pharmacy where patients can receive vaccine.

Actions Requested of SF Providers:

- 1. Recommend RSV vaccination with either ABRYSVO or AREXVY using a shared clinical decision-making approach among patients aged 60 years and up, especially for those patients at higher risk of severe RSV disease.
- **2. Strongly recommend and administer** RSV vaccination with ABRYSVO among all pregnant individuals at 32 through 36 weeks' gestation.
- **3. Prioritize** passive immunization with Nirsevimab (while it is in short supply) for the highest risk infants less than 8 months of age, per CDC criteria.
- **4. Ensure that everyone** age 6 months and up receive an age-appropriate dose of the 2023–24 formulations of **influenza** and **COVID-19** vaccines.
 - Administer the correct 0.25-mL dose of Moderna 2023–24 COVID-19 vaccine to recipients ages 6 months through 11 years.

Additional Resources

CDPH RSV Information Page and Immunization Resources

CDC RSV Vaccination Page