

October 10, 2023

Dear Colleague,

This letter provides information about <u>new immunization products</u> that protect against respiratory syncytial virus (RSV) in infants, young children, and older adults. Detailed clinical considerations for the new products are available <u>here</u>.

<u>RSV</u> is the most common cause of hospitalization in infants in the US, with the highest hospitalization rates occurring in the first months of life. Although prematurity and other chronic diseases increase the risk of RSV-associated hospitalization, most hospitalizations are in healthy, term infants.

RSV is also prevalent in adults 60 years of age and older. Approximately 6,000-10,000 deaths from RSV occur in older adults in the US each year. There is an increased risk of severe RSV in those with underlying conditions, including chronic lung diseases such as chronic obstructive pulmonary disease (COPD) and asthma; heart problems such as congestive heart failure and coronary artery disease; kidney problems; liver disorders; blood disorders; neurological disorders; and other endocrine problems, including diabetes. Risk is also elevated for people living in long-term care facilities.

There are two options available for preventing RSV illness in infants: monoclonal antibodies administered to infants directly or vaccine administered to pregnant people. In most instances, only one option is necessary to confer immunity to the infant and there is no preference for one product over the other. Both options are described below.

Monoclonal Antibody Product for Infants and Young Children

In August 2023, the Centers for Disease Control and Prevention (CDC) <u>recommended</u> a new monoclonal antibody product, nirsevimab (Beyfortus™, manufactured by Sanofi and Astra-Zeneca), to protect infants and young children against RSV. Although nirsevimab is not a vaccine, it provides passive immunity.

Nirsevimab is now available to order through the <u>Vaccines for Children (VFC) program</u> for administration to eligible children. It can also be purchased via the commercial sector.

Indications are as follows:

- Infants <8 months of age born during or entering their first RSV reason are recommended to receive one dose of nirsevimab (50 mg for infants <5 kg and 100 mg for infants ≥5 kg).
- Children ages 8-19 months who are at increased risk of severe RSV and entering their second RSV season are recommended to receive one dose of nirsevimab (200 mg).

RSV season in New York City (NYC) is defined as October through the end of March. Providers should target administration in the first week of life for infants born shortly before or during RSV season. Birthing hospitals should plan to administer nirsevimab before infants are discharged from their birth hospitalization.

Providers should ask the birthing parent if they were vaccinated against RSV during their recent pregnancy and also check their electronic medical records and the Citywide Immunization Registry. Most children born to parents vaccinated during pregnancy should not receive nirsevimab; however, it is safe

to administer even if the parent had been vaccinated during pregnancy. Nirsevimab should be administered to the infant if the vaccination status of the birthing parent is unknown.

Administration of nirsevimab shortly before the start of the RSV season is recommended for infants <8 months of age and for children ages 8-19 months who are at increased risk of severe RSV.

Vaccine During Pregnancy

Another new product <u>recommended</u> by CDC for preventing RSV in infants is RSVPreF vaccine (Abrysvo™, manufactured by Pfizer), administered during pregnancy for people 32-36 weeks gestation. Vaccine should be administered between September and January in accordance with RSV seasonality in NYC.

There is no preference for the use of nirsevimab in an infant's first RSV season versus RSVPreF vaccination during pregnancy. When there have been at least 14 days between vaccine administration and birth—thus allowing enough transplacental antibody transfer—there is no recommendation to use both products, except in very limited circumstances, such as when there is concern that the pregnant parent did not mount an adequate immune response (e.g., people living with HIV infection). Healthcare providers of pregnant people should provide information on both options and consider patient preferences when determining whether to vaccinate the pregnant patient or rely on the administration of nirsevimab to the infant after birth.

Vaccines for Older Adults

For adults 60 years of age and older, in July 2023, CDC <u>recommended</u> two RSV vaccines, RSVPreF (Abrysvo[™], manufactured by Pfizer) and RSVPreF3 (Arexvy, manufactured by GSK). People 60 years of age and older may receive a single dose of RSV vaccine, using shared clinical decision-making.

The US Food and Drug Administration (FDA) is requiring post-marketing surveillance for Guillain-Barre Syndrome (GBS) from both manufacturers of the RSV vaccine. Six patients out of the nearly 40,000 patients who received RSVPreF or RSVPreF3 during trials developed inflammatory neurologic events within 42 days of vaccination. At least two of these cases are likely GBS. The risk of GBS increases with age, and it has been shown, as background, that the risk range is from 1.85 per 100,000 population for those in their 60s up to 2.66 per 100,000 population for those in their 80s.

Older adults can access the RSV vaccine at pharmacy locations across NYC, though provider prescriptions may be required at some locations.

For questions regarding the new RSV products, or any other immunizations, call 347-396-2400 or email nycimmunize@health.nyc.gov. Thank you for your continuing efforts to protect NYC residents from vaccine-preventable illnesses.

Sincerely,

Bindy Crouch, MD, MPH Assistant Commissioner

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Bureau of Immunization