



Respiratory Syncytial Virus (RSV) Vaccines Approved for Adults Aged 60 Years and Older and Monoclonal Antibodies for Infants

DATE:	August 30, 2023
TO:	Health Alert Network
FROM:	Debra L. Bogen, M.D., FAAP, Acting Secretary of Health
SUBJECT:	Respiratory Syncytial Virus (RSV) Vaccines Approved for Adults Aged 60 Years and Older and Monoclonal Antibodies for Infants
DISTRIBUTION:	Statewide
LOCATION:	N/A
STREET ADDRESS:	N/A
COUNTY:	N/A
MUNICIPALITY:	N/A
ZIP CODE:	N/A

This transmission is a “Health Advisory” provides important information for a specific incident or situation; may not require immediate action.

HOSPITALS: PLEASE SHARE WITH ALL MEDICAL, PEDIATRIC, NURSING AND LABORATORY STAFF IN YOUR HOSPITAL; **EMS COUNCILS:** PLEASE DISTRIBUTE AS APPROPRIATE; **FQHCs:** PLEASE DISTRIBUTE AS APPROPRIATE **LOCAL HEALTH JURISDICTIONS:** PLEASE DISTRIBUTE AS APPROPRIATE; **PROFESSIONAL ORGANIZATIONS:** PLEASE DISTRIBUTE TO YOUR MEMBERSHIP; **LONG-TERM CARE FACILITIES:** PLEASE SHARE WITH ALL MEDICAL, INFECTION CONTROL, AND NURSING STAFF IN YOUR FACILITY

Summary:

- Respiratory syncytial virus (RSV) is a common cause of childhood illness and the leading reason for infant hospitalizations.
- CDC’s Advisory Committee on Immunization Practices (ACIP) has recommended Nirsevimab (Beyfortus, Sanofi and AstraZeneca), a long-acting monoclonal antibody, for infants aged <8 months entering their first RSV season and for those aged 8–19 months at increased risk for severe RSV infection.
- The FDA has approved Abrysvo, Pfizer’s new RSV vaccine, for pregnant individuals at 32-36 weeks gestational age, to prevent RSV in infants. ACIP plans to discuss and recommend this vaccine in October 2023.
- RSV also causes 60,000-120,000 hospitalizations and 6,000-10,000 deaths annually in adults 65 years and older.
- Two new RSV vaccines, Arexvy (GSK) and Abrysvo (Pfizer), have been approved by the FDA and recommended by ACIP for adults aged 60 years and older.
- RSV vaccines demonstrate moderate to high efficacy in preventing RSV-associated lower respiratory tract disease, aiming to reduce morbidity and mortality in older adults.
- At present, RSV vaccination in older adults should be targeted to those who are at highest risk for severe RSV disease and therefore most likely to benefit from vaccination.
- Several RSV vaccine clinical trials are ongoing, with updates to be shared by the Pennsylvania Department of Health (DOH) upon approval in the U.S.
- If you have additional questions about this health advisory, please contact DOH at 1-877-PA-HEALTH (1-877-724-3258) or your local health department.

Background

Respiratory syncytial virus (RSV) is a highly contagious virus causing acute respiratory infections across all age groups. It is a common cause of childhood illness and the leading reason for infant hospitalizations. Infants and young children typically exhibit mild cold-like symptoms, but some, especially in their first infection, progress to lower respiratory tract conditions such as pneumonia and bronchiolitis leading to emergency visits and hospitalizations. Annual outbreaks affect individuals of all ages, with the U.S. RSV season typically starting in the fall, peaking in winter, and varying in intensity from year to year. Premature infants and those with chronic lung disease or significant congenital heart disease face the highest risk of severe RSV disease. The American Academy of Pediatrics notes that around 1% to 3% of U.S. children under 12 months require hospitalization due to RSV annually.

Other high-risk groups can experience severe outcomes. The virus leads to 60,000-120,000 hospitalizations and 6,000-10,000 deaths annually among adults aged 65 and older. Other underlying factors that might increase the risk of severe RSV-associated respiratory illness include frailty, advanced age, and residence in a long-term care facility. RSV can lead to exacerbation of conditions such as asthma, chronic obstructive pulmonary disorder (COPD), and congestive heart failure.

Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children

In July 2023, the U.S. FDA approved nirsevimab (Beyfortus, Sanofi and AstraZeneca), a long-acting monoclonal antibody, for the prevention of RSV-associated lower respiratory tract infection (LRTI) among infants and children aged <24 months. Nirsevimab is administered as a 1-dose intramuscular injection shortly before or during the RSV season (typically fall through spring).

ACIP systematically reviewed available evidence regarding the efficacy and safety of nirsevimab, using the Grading of Recommendations, Assessment, Development, and Evaluations (GRADE) framework. Evidence regarding potential use of nirsevimab was presented to ACIP at meetings during June 2022–August 2023. Among infants <8 months of age, pooled efficacy in preventing medically attended RSV-associated LRTI was 79%; efficacy in preventing hospitalization was 81%, and efficacy in preventing ICU admission was 90%. On August 3, 2023, ACIP recommended nirsevimab for infants aged <8 months who are born during or entering their first RSV season and for infants and children aged 8–19 months who are at increased risk for severe RSV disease and are entering their second RSV season.

Before licensure of nirsevimab, the only FDA-approved product to prevent severe RSV disease among infants and young children was palivizumab, another monoclonal antibody. However, the American Academy of Pediatrics (AAP) recommends palivizumab only for children with certain underlying medical conditions (comprising <5% of all infants), and its use is further limited by high cost and the requirement for monthly dosing.

Vaccinations for persons 60 years of age and older

Two new vaccines against RSV were recently approved by the U.S. Food and Drug Administration (FDA) for prevention of RSV lower respiratory tract disease in adults aged 60 years and older. At present, ACIP recommends that adults aged 60 and older may receive a

single dose of an RSV vaccine, after shared clinical decision-making with their provider. RSV vaccines have demonstrated moderate to high efficacy in preventing RSV-associated lower respiratory tract disease and have the potential to prevent substantial morbidity and mortality among older adults.

Although both vaccines had acceptable safety profiles, there were six cases of rare neurologic events that could have occurred due to chance or may have been associated with RSV vaccination. Until additional evidence becomes available from post-marketing surveillance, RSV vaccination in older adults should be targeted to those who are at highest risk for severe RSV disease and therefore most likely to benefit from vaccination. The recommendation for shared clinical decision-making is intended to allow flexibility for providers and patients to consider individual risk for RSV disease, while taking into account patient preferences.

RSV vaccine is recommended as a single dose. Studies are ongoing to determine whether (and if so, when) revaccination may be needed. Vaccine information:

- Arexvy (GSK): Single dose, 0.5 mL IM, must be reconstituted.
- Abrysvo (Pfizer): Single dose, 0.5 mL IM, must be reconstituted (prefilled syringe w/diluent & vial adapter)

The vaccine can be co-administered with other recommended vaccines for adults, including influenza vaccine, during the same visit. However, there is limited data on immunogenicity and reactogenicity with co-administration, and no data on co-administration with COVID-19 vaccine. For this reason, many experts are being cautious in this regard. Decisions to co-administer should be based on factors such as the likelihood of the patient returning for additional vaccines, risk for acquiring vaccine-preventable disease, patient preference, whether the patient is up to date with currently recommended vaccines, and vaccine reactogenicity profiles.

Vaccines in the pipeline

On August 21, 2023, U.S. FDA approved Abrysvo, Pfizer's RSV vaccine, to prevent RSV in infants through active immunization of pregnant individuals at 32-36 weeks of gestational age. Abrysvo is administered as a single dose intramuscular injection. This vaccine has not been recommended by ACIP yet and will be discussed in a meeting scheduled in October 2023. Many clinical trials are ongoing and DOH will share updates regarding those products when they are approved for use in the U.S.

For additional questions, please call your local health department or DOH at 1-877-PA HEALTH.

For more information:

- [Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023](#)
- [FDA Approves First Respiratory Syncytial Virus \(RSV\) Vaccine](#)
- [FDA Approves New Drug to Prevent RSV in Babies and Toddlers](#)
- [Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children](#)
- [FDA Approves First Vaccine for Pregnant Individuals to Prevent RSV in Infants](#)

Individuals interested in receiving PA-HANs are encouraged to register at [HAN Notification Registration \(mir3.com\)](https://www.mir3.com)

Categories of Health Alert messages:

Health Alert: conveys the highest level of importance; warrants immediate action or attention.

Health Advisory: provides important information for a specific incident or situation; may not require immediate action.

Health Update: provides updated information regarding an incident or situation; unlikely to require immediate action.

This information is current as of August 30, 2023 but may be modified in the future. We will continue to post updated information regarding the most common questions about this subject.