Respiratory Syncytial Virus (RSV) Vaccine Updates for Adults

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RSV Vaccine	Indications	Dosage and Administration	Indicated in Pregnancy?
RSPpreF Abrysvo™ FDA approved May 2023 recombinant RSV F protein antigen	Adults 75 years of age and older Adults 60-74 at increased risk of severe RSV* **Pregnant individuals at 32-36 weeks gestational age**	0.5 mL Intramuscular once	Yes
		single dose Act-O-Vial kit of lyophilized antigen component and sterile water diluent	
		single dose vial and prefilled syringe kit of lyophilized antigen component, prefilled sterile water diluent syringe, and vial adaptor	
		single dose vial of lyophilized antigen component and vial of sterile water diluent	
RSVPreF3 Arexvy™ FDA approved May 2023 recombinant RSV F protein antigen and $AS01_E$ adjuvant	Adults 60 years of age and older Adults 50-59 years of age who are at increased risk for LRTD caused by RSV*	0.5 mL Intramuscular once	No
		single-dose vial of lyophilized antigen component to be reconstituted with the accompanying vial	
mRNA RSV mResvia™ FDA approved May 2024 mRNA encoding RSV F protein	Adults 60 years of age and older for the prevention of lower respiratory tract disease (LRTD) caused by RSV*	0.5 mL Intramuscular once	No
		pre-filled syringe that contains a frozen suspension that must be thawed prior to administration. Thaw each syringe before use, either in the refrigerator or at room temperature, following manufacturer instructions	

Notes:

- All three RSV vaccines are licensed for the prevention of RSV-associated lower respiratory tract disease (LRTD) in adults 60 age years and older in the United States. RSV vaccine can be administered with any product licensed in this age group. As of March 27, 2025, that includes Arexvy™ and Abrysvo™. There is no preferential recommendation for any licensed product over another for this age group.
- Arexvy™ is also licensed for use in adults aged 50 through 59 years who are increased risk of RSV LRTD; and in April of 2025 ACIP voted to expand recommendation for RSV in this age group.
- Only Abrysvo™ is licensed for use during pregnancy (during 32 through 36 weeks and 6 days' gestation) for the prevention of RSV disease in infants.
- RSV vaccination during pregnancy is only recommended for pregnant people who have not previously received an RSV vaccine and who are at the recommended stage of pregnancy (32 weeks through 36 weeks 6 days' gestation) during the recommended time of year (typically September through January).
- If a pregnant person received an RSV vaccine before the current pregnancy, do not use Abrysvo™ during this pregnancy. Instead, nirsevimab (Beyfortus™) is indicated to protect the infant from RSV after birth.
- At this time, RSV vaccination is recommended as a single dose only. Persons who have already received RSV vaccination are NOT recommended to receive another dose.

Updates to RSV Vaccines:

June 2024: Updated evidence on the balance of RSV vaccination benefits and risks led ACIP to make a definitive routine age-based recommendation for adults aged 75 years and older, accompanied by a risk-based recommendation for those age 60 through 74 years with specific high-risk conditions. Due to the relatively small benefit of vaccination for healthy people younger than age 75 and uncertainty about revaccination, the option for vaccination of people aged 60 through 74 years without risk factors for severe RSV disease was removed.

Updates to CDC Recommendations 2025:

April 2025: ACIP met and voted April 2025 to expand the indication of RSV immunization to include patients aged 50-59 who are at increased risk of severe RSV disease*. This is an expansion from previous recommendation of patients aged 60 and older who are at increased risk of severe RSV disease*.

*CDC will publish Clinical Considerations that describe chronic medical conditions and other risk factors for severe RSV disease for use in this risk-based recommendation.

Current moderate and severe immunocompromising conditions and treatments include:

- Active treatment for solid tumor and hematologic malignancies
- Hematologic malignancies associated with poor responses to COVID-19 vaccines regardless of current treatment status (e.g., chronic lymphocytic leukemia, non-Hodgkin lymphoma, multiple myeloma, acute leukemia)
- Receipt of solid-organ transplant or an islet transplant and taking immunosuppressive therapy
- Receipt of chimeric antigen receptor (CAR)-T-cell therapy or hematopoietic cell transplant (HCT) (within 2 years of transplantation or taking immunosuppressive therapy)

- Moderate or severe primary immunodeficiency (such as common variable immunodeficiency disease, severe combined immunodeficiency, DiGeorge syndrome, or Wiskott-Aldrich syndrome)
- Advanced HIV infection (people with HIV and CD4 cell counts less than 200 per cubic milliliter, history of an AIDS-defining illness without immune reconstitution, or clinical manifestations of symptomatic HIV) or untreated HIV infection
- Active treatment with high-dose corticosteroids (i.e., 20 mg or more of prednisone or equivalent per day when administered for 2 or more weeks), alkylating agents, antimetabolites, transplant-related immunosuppressive drugs, cancer chemotherapeutic agents classified as severely immunosuppressive, tumor necrosis factor (TNF) blockers, and other biologic agents that are immunosuppressive or immunomodulatory (e.g., B-cell-depleting agents)

Factors to consider in assessing the general level of immune competence in a patient include disease severity, duration, clinical stability, complications, comorbidities, and any potentially immune-suppressing treatment.

For additional information about the degree of immune suppression associated with different medical conditions and treatments, refer to the CDC General Best Practice Guidelines for Immunizations section on altered immunocompetence (www.cdc.gov/vaccines/hcp/imz-best-practices/altered-immunocompetence.html).

Co-administration:

Any of the three available RSV vaccines may be administered at the same time as other recommended vaccines, in accordance with CDC's general best practice guidelines for immunization. This is especially important when there is concern that the patient will not return or if the patient's immediate risk is high (such as when seasonal influenza, RSV, and COVID-19 are circulating).

Coadministration might increase short-term side effects (greater reactogenicity), such as fever, soreness, body aches, or headache, especially when administering more than one vaccine containing a non-aluminum adjuvant designed to enhance the immune response.

When confident that a patient will return, it is an option to separate the administration of vaccines that are less time-sensitive (e.g., shingles vaccine) to reduce the likelihood of uncomfortable side effects. There is no specific minimum interval between non-live vaccines, so separation by a few days is acceptable.

Contraindications and Precautions:

Do not administer RSV vaccine to patients with history of severe allergic reaction (e.g., anaphylaxis) to previous dose or vaccine component.

Guillain-Barré Syndrome. The results of a post-marketing observational study suggest an increased risk of Guillain-Barré syndrome during the 42 days following vaccination with Abrysvo™ and Arexvy™. Vaccine safety monitoring systems will continue to monitor for GBS caused by any RSV vaccine, including mResvia. Based on the available data, ACIP and CDC continue to conclude that the benefits of RSV vaccination, in terms of preventable hospitalizations and deaths, outweigh the potential risk for GBS, among adults ages 75 years and older and among adults ages 60-74 years at increased risk of severe RSV

disease. CDC and FDA will continue to monitor RSV vaccine safety and will share data as they become available. As new data become available, CDC may update RSV vaccine recommendations.

Potential risk of preterm birth. To avoid the potential risk of preterm birth with use of Abrysvo™ before 32 weeks of gestation, administer Abrysvo™ as indicated in pregnant individuals at 32 through 36 weeks gestational age.

Use of Arexvy™ and mResvia™ is not recommended in pregnancy due to lack of safety data.

Adverse Reactions:

The most commonly reported adverse reactions were injection-site pain, fatigue, headache, myalgia, arthralgia, axillary swelling or tenderness, and chills.

Storage:

Abrysvo™ should be stored refrigerated in the original carton prior to reconstitution. Do not freeze. Discard if the carton has been frozen. After reconstitution, Abrysvo™ should be immediately administered or stored at room temperature and used within 4 hours. Do not freeze reconstituted vaccine.

Arexvy™ should be stored in the refrigerator or at room temperature for up to 4 hours prior to use. Discard reconstituted vaccine if not used within 4 hours. Do not freeze. Discard if the vaccine has been frozen.

mResvia™ is supplied as a pre-filled syringe that contains a frozen suspension to be stored frozen and thawed prior to administration. Thaw each syringe before use, either in the refrigerator or at room temperature following manufacturer instructions.

Efficacy:

Currently, RSV vaccination is recommended as a single dose only. Persons who have already received RSV vaccination are NOT recommended to receive another dose. Additional data are needed for all three RSV vaccines to determine how long protection lasts.

Availability and Cost:

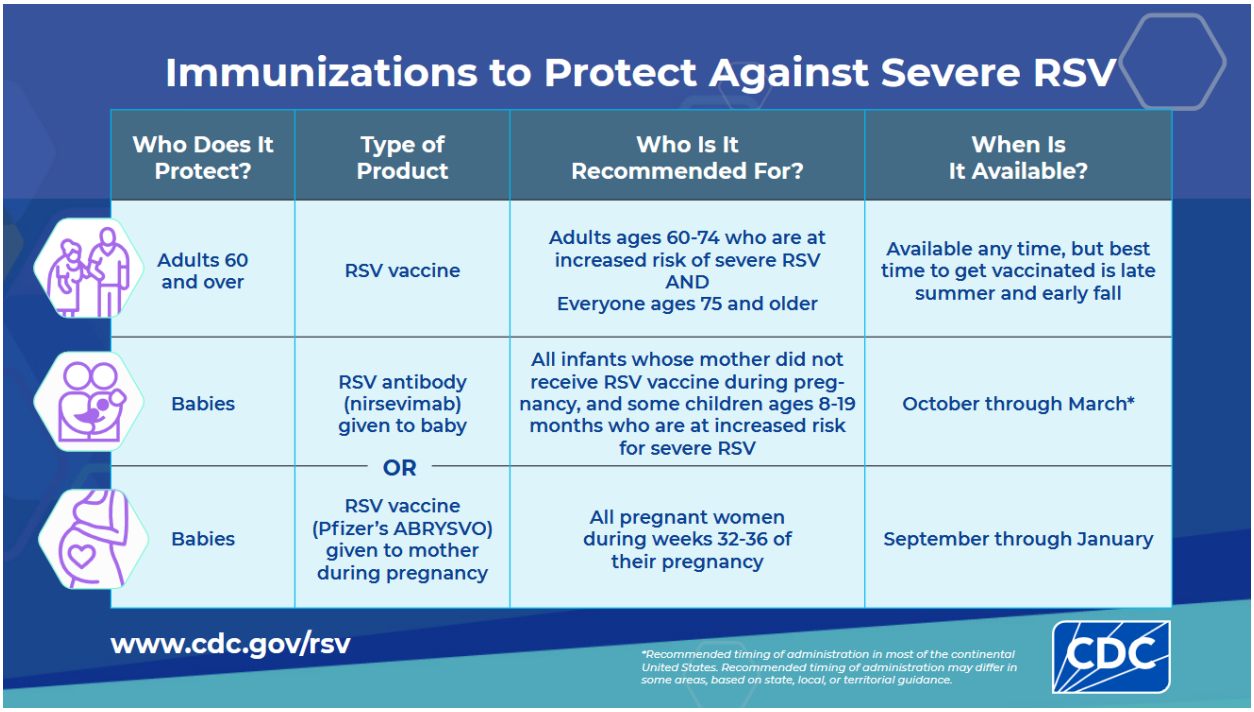
RSV vaccine is available at many ambulatory care clinics, retail pharmacies, community health clinics, health departments, and other community locations.

Private health plans are required to cover new vaccine recommendations in the next plan year. Check with insurance provider for details on formulary and patient out of pocket cost.

Medicare Part D plans make all adult vaccines recommended by ACIP (except those covered by Part B) available at no cost, including RSV vaccine. Even if a particular drug plan's formulary does not list all Part D vaccines, it must provide access when a physician prescribes a Part D vaccine.

There are different assistance programs that can assist with vaccine cost for those who are not able to afford them.

RVS Background and patient information:



RSV is a common respiratory virus that usually causes mild, cold-like symptoms including cough, runny nose, sore throat, headache, fatigue, and fever. These symptoms make it difficult to distinguish RSV from other respiratory viruses such as influenza or COVID-19.

- RSV typically spreads in the continental United States (US) during the Fall and Winter months (October-March) with peaks in December and January.
- Though most recover in a few days, RSV can cause serious lower respiratory tract infection (LRTI) such as bronchiolitis or pneumonia.

Infants and older adults are more likely to develop severe RSV and need hospitalization.

- RSV is the most common cause of hospitalization in US infants.
- There is no specific treatment for RSV illness, only supportive symptomatic care. In severe cases, patients may require additional oxygen, intravenous fluids, or mechanical ventilation.

CDC recommends immunizations to protect infants, some young children, and older adults.

Like common cold and influenza, RSV is spread by airborne respiratory droplets. Common examples of transmission include:

- RSV-infected person coughs or sneezes near others
- virus droplets from a cough or sneeze are transferred to another's' eyes, nose, or mouth
- direct contact with the virus, such as kissing the face of a child with RSV
- touching a surface that has the virus on it, like a doorknob, and then touching one's face before washing hands

Anyone can get RSV, but typically most people get RSV for the first time as an infant or toddler. Most children will get RSV before their second birthday and repeat infections can occur throughout life.

People infected with RSV are often contagious for 3 to 8 days and may become contagious even a day or two before signs of illness. Some infants and adults with weakened immune systems can continue to spread the virus for 4 weeks or longer, even after symptoms has ceased.

Children are often exposed to and infected with RSV outside the home, such as in school or childcare centers. They can then transmit the virus to other members of the family.

The virus can survive for many hours on hard surfaces, such as tables, doorknobs, and crib rails.

How to prevent spread of RSV and other respiratory viruses:

Cover coughs and sneezes to reduce the spread of germs and protect others. Handwashing with soap removes germs from hands, making viruses less likely to become infectious to the respiratory system when touching eyes, nose, or mouth. When soap and water are not available, a hand sanitizer with at least 60 percent alcohol can help kill the virus. Household cleaners that contain soap or detergent can help remove germs and dirt on surface.

- Always cover your mouth and nose with a tissue when you cough or sneeze
- Immediately dispose of used tissues in the trash.
- Cough or sneeze into your elbow, not your hands if you are unable to use a tissue.
- Follow proper handwashing technique with soap and water.
- Teach and observe children proper handwashing technique.
- Clean frequently touched surfaces, such as countertops, handrails, and doorknobs.

Helpful Resource for Clinical Questions
Immunize.org Ask the Experts: https://www.immunize.org/ask-experts/topic/rsv/

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