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At this time, the CDC states that the RSV vaccine is not an annual vaccine, meaning individuals do not need to get a dose every RSV season. Please work with your provider to maintain an up-to-date record of all vaccinations received.

Respiratory Syncytial Virus (RSV) and Vaccination for Older Adults

WHAT IS RSV?[1,2,3,4]

- **Respiratory Syncytial Virus (RSV)** is a common and contagious pulmonary pathogen that spreads through aerosolization of respiratory droplets or contact with contaminated surfaces.
- RSV produces cold-like symptoms causing significant morbidity and mortality, especially in infants and older adults.

As of spring 2024, approximately 25% of U.S. adults aged 60 years and older were estimated to have received the RSV vaccine.

- Adults who get infected with RSV typically have mild or no symptoms. Disease usually lasts less than 5 days. When disease is symptomatic, symptoms are usually consistent with an upper respiratory tract infection, including **rhinorrhea, pharyngitis, cough, headache, fatigue, and fever**.
- Some adults, however, may have more severe symptoms consistent with a lower respiratory tract disease (LRTD), such as pneumonia.
- The CDC estimates between 60k-160k older adults in the US are hospitalized and 6k-10k of them die due to RSV annually.
- 10-31% of older adults hospitalized with RSV are admitted into the ICU.
- For those admitted into the hospital with RSV, mortality rate is close to 8%.

WHAT RSV VACCINES ARE AVAILABLE?[5]

There are currently 3 FDA approved RSV vaccines available in the United States:

1. AREXVY (respiratory syncytial virus vaccine recombinant, adjuvanted; GSK; NDC: 58160-0848-11)
2. ABRYSVO (respiratory syncytial virus vaccine; Pfizer; NDC: 00069-0344-01)
3. mRESVIA (respiratory syncytial virus vaccine, mRNA; Moderna; NDC: 80777-0345-90)

HOW EFFECTIVE ARE THESE RSV VACCINES?[5,6]

In clinical trials, vaccination with a single dose of any RSV vaccine demonstrated moderate to high efficacy in preventing symptomatic RSV-associated LRTD among adults aged ≥ 60 years. Favorable safety/efficacy data in other patient populations has allowed for additional FDA-labeled indications for select RSV vaccine options (see section on INDICATIONS FOR USE).

AREXVY

The efficacy of 1 dose of the GSK RSV vaccine in preventing symptomatic, laboratory-confirmed RSV-associated LRTD was 82.6% during the first RSV season and 56.1% during the second season. Efficacy of 1 dose over two seasons was 74.5% in preventing RSV-associated LRTD and 77.5% in preventing medically attended RSV-associated LRTD.

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Respiratory Syncytial Virus (RSV) and Vaccination for Older Adults

ABRYSVO

The efficacy of 1 dose of the Pfizer RSV vaccine in preventing symptomatic, laboratory-confirmed RSV-associated LRTD was 88.9% during the first RSV season and 78.6% during the partial second season. Efficacy of 1 dose over two seasons was 84.4% in preventing RSV-associated LRTD and 81.0% in preventing medically attended RSV-associated LRTD.

mRESVIA

The efficacy of 1 dose of the Moderna RSV vaccine in preventing symptomatic, laboratory-confirmed RSV-associated LRTD was 78.7% during the first RSV season and 62.5% during the partial second season.

For reference, influenza vaccine efficacy is often found to be ~40-60% annually.[7] These efficacy statements are abridged for conciseness. Consult the MMWR for more detailed findings.

FOR RESIDENTS

"In older adults with healthy immune systems, one dose of **Arexvy was 83%** effective in preventing lung infections (e.g. pneumonia) due to RSV during the 1st RSV season and still 56% effective in a 2nd season after vaccination.

Abrysvo was 89% effective during the 1st RSV season after vaccination and appears to provide continued protection (2nd season is ongoing; data not finalized).

mRESVIA was 79% effective during the 1st RSV season after vaccination and appears to be 63% effective going into the 2nd RSV season."

HOW SAFE ARE THESE RSV VACCINES?[5,6]

These vaccines were generally well-tolerated with an acceptable safety profile. Side effects after RSV vaccination were usually mild and included pain, redness, and swelling where the shot is given, fatigue, fever, headache, nausea, diarrhea, and muscle or joint pain.

On January 7, 2025, the FDA required Pfizer and GSK to amend their respective package inserts to include a new warning label stating, "The results of a postmarketing observational study suggest an increased risk of Guillain-Barré syndrome (GBS) during the 42 days following vaccination." The warning comes after analysis of Medicare claims data from May 2023 - July 2024 suggested an increased risk of GBS during the 42 days following vaccination, with an estimated 9 excess cases of GBS per million doses of Abrysvo, and an estimated 7 excess cases of GBS per million doses of Arexvy when administered in individuals 65 years of age and older.

However, despite the addition of the new warning, the FDA continues to adovocate that the benefits of vaccination with Abrysvo and Arexvy continue to outweight the potential risks and recommend all individuals meeting age requirements for vaccination set forth by ACIP strive to get vaccinated.

These safety statements are abridged for conciseness. Consult the MMWR for more detailed findings.

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Respiratory Syncytial Virus (RSV) and Vaccination for Older Adults

WHAT ARE THESE VACCINES' RECOMMENDATIONS FOR USE?[7]

Current CDC guidance states:

- **All adults 75 years of age and older** are recommended to receive a single dose of any of the available RSV vaccines.
- **Older adults 50-74 years of age who are at increased risk* of severe RSV disease** should receive a single dose of an RSV vaccine.
- The RSV vaccine is not *currently* an annual vaccine. Individuals who have already received an RSV vaccine do not need an additional dose.

WHAT ARE THESE VACCINES' RESPECTIVE FDA-LABELED INDICATIONS FOR USE?[6,9,10]

All current RSV vaccine options are approved by the FDA for vaccination of adults 60 years of age and older. Therefore, any of the RSV vaccines are generally appropriate to meet the CDC RSV vaccination recommendations.

Individual RSV vaccines may have additional FDA-labeled indications, as summarized in the following chart:

RSV Vaccine	FDA-Labeled Indication
	Active immunization for the prevention of lower respiratory tract disease (LRTD) caused by RSV in individuals ...
AREXVY	1. **60 years of age and older.** 2. 50 through 59 years of age who are at increased risk for LRTD caused by RSV.
ABRYSVO	1. **60 years of age and older.** 2. Pregnant and at 32 through 36 weeks gestational age, to protect infants from birth through 6 months of age. 3. 18 through 59 years of age who are at increased risk for LRTD caused by RSV. NOTE: As of this publication, use in individuals 49 years and younger is NOT CDC recommended (despite FDA-approval).
mRESVIA	1. **60 years of age and older.** 2. 18 through 59 years of age who are at increased risk for LRTD caused by RSV. NOTE: As of this publication, use in individuals 49 years and younger is NOT CDC recommended (despite FDA-approval).

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Respiratory Syncytial Virus (RSV) and Vaccination for Older Adults

*WHO IS AT INCREASED RISK FOR SEVERE DISEASE?[5]

Chronic medical conditions associated with increased risk:

- Chronic lung disease (Asthma, COPD)
- Chronic cardiovascular disease (CHF, CAD)
- Moderate to severe immunocompromise
- Neurologic or neuromuscular conditions
- Kidney or liver disorders
- Hematologic disorders
- Diabetes mellitus
- Severe obesity

Other associated risk factors

- Frailty
- Advanced age
- **Residence in a long-term care facility**
- Other underlying conditions or factors that a healthcare provider determines might increase risk for severe RSV disease

VACCINE PRODUCT SPECIFICATIONS[6,9,10]

STORAGE

AREXVY

Storage Before Reconstitution

Adjuvant suspension component vials: Store refrigerated between 2°C and 8°C (36°F and 46°F). Store in the original package in order to protect vials from light. Do not freeze. Discard if the adjuvant suspension component has been frozen.

Lyophilized antigen component vials: Store refrigerated between 2°C and 8°C (36°F and 46°F). Store in the original package in order to protect vials from light. Do not freeze. Discard if the antigen component has been frozen.

Storage After Reconstitution

- Administer immediately or store in the refrigerator between 2°C and 8°C (36°F to 46°F) or at room temperature [up to 25°C (77°F)] for up to 4 hours prior to use.
- Protect vials from light.
- Discard reconstituted vaccine if not used within 4 hours.
- Do not freeze. Discard if the vaccine has been frozen.

ABRYSVO

Storage Before Reconstitution

Store refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton. Do not freeze. Discard if the carton has been frozen.

Respiratory Syncytial Virus (RSV) and Vaccination for Older Adults

Storage After Reconstitution

After reconstitution, administer ABRYSVO immediately or store at room temperature [15°C to 30°C (59°F to 86°F)] and use within 4 hours. Do not freeze reconstituted vaccine.

mRESVIA

Frozen Storage

Store frozen between -40°C to -15°C (-40°F to 5°F).

Storage After Thawing

Storage at 2°C to 8°C (36°F to 46°F):

- Pre-filled plastic syringes may be stored refrigerated between 2°C to 8°C (36°F to 46°F) for up to 90 days prior to use.

Storage at 8°C to 25°C (46°F to 77°F):

- Pre-filled plastic syringes may be stored between 8°C to 25°C (46°F to 77°F) for a total of 24 hours after removal from refrigerated conditions. Discard the pre-filled syringe if not used within this time. Syringes should not be returned to the refrigerator after being thawed at room temperature.
- Total storage at 8°C to 25°C (46°F to 77°F) must not exceed 24 hours.
- Do not refreeze once thawed. Do not shake.

Transportation of Thawed Pre-Filled Plastic Syringes

Thawed pre-filled syringes can be transported at 2°C to 8°C (36°F to 46°F) using shipping containers which have been qualified to maintain 2°C to 8°C (36°F to 46°F). Once thawed and transported at 2°C to 8°C (36°C to 46°F), pre-filled plastic syringes should not be refrozen and should be stored at 2°C to 8°C (36°F to 46°F) until use.

PREPARATION

Refer to each product's respective package insert for product-specific preparation instructions. Abrysvo is now available in Act-O-Vials®, which is a "dual-component vial system that allows reconstitution of sterile, injectable medications by pressening on the plastic cap." For instructions on how to use, please visit AOVdemo.com.

ADMINISTRATION

- AREXVY is administered as a 0.5mL intramuscular injection only.[10]
- ABRYSVO is administered as a 0.5mL intramuscular injection only.[10]
- mRESVIA is administered as a 0.5mL intramuscular injection only.[6]

Consult the ACIP Vaccine Administration General Best Practice Guidelines for Immunization for guidance on administering IM injections.

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Respiratory Syncytial Virus (RSV) and Vaccination for Older Adults

ADVERSE EFFECTS

AREXVY

The most commonly reported solicited local adverse reaction (≥10%) was injection site pain (60.9%). The most commonly reported solicited systemic adverse reactions (≥10%) were fatigue (33.6%), myalgia (28.9%), headache (27.2%), and arthralgia (18.1%).[9]

ABRYSVO

The most commonly reported solicited local and systemic adverse reactions in individuals 60 years of age and older (≥10%) were fatigue (15.5%), headache (12.8%), pain at the injection site (10.5%), and muscle pain (10.1%).[10] The most commonly reported solicited local and systemic adverse reactions in pregnant individuals (≥10%) were pain at the injection site (40.6%), headache (31.0%), muscle pain (26.5%), and nausea (20.0%).

mRESVIA

The most commonly reported solicited local and systemic adverse reactions (≥10%) were injection site pain (55.9%), fatigue (30.8%), headache (26.7%), myalgia (25.6%), arthralgia (21.7%), underarm swelling or tenderness (15.2%) and chills (11.6%).[6]

HOW ARE RSV VACCINES CODED FOR AND DOCUMENTED IN EHRs?

RSV Vaccines may be identified by sale proprietary (brand) name, generic name, description, and/or NDC.

Respiratory Syncytial Virus (RSV) Vaccine Codes Fall 2025

CVX Code	CVX Description	Sale Proprietary Name	Sale Labeler	Unit of Sale NDC11	Unit of Use NDC11	Presentation	CPT Code	CPT Description
303	Respiratory syncytial virus (RSV), vaccine, recombinant, protein subunit RSV prefusion F, adjuvant reconstituted, 0.5 mL, preservative free	Arexvy	GlaxoSmith-Kline Biologicals SA	58160-0848-11	58160-0723-03	VIAL, 0.5 mL, reconstituted	90679	Respiratory syncytial virus vaccine, preF, recombinant, subunit, adjuvanted, for intramuscular use
305	Respiratory syncytial virus (RSV), vaccine, bivalent, protein subunit RSV prefusion F, diluent reconstituted, 0.5 mL, preservative free	Abrysvo	Pfizer Laboratories Div Pfizer Inc	Needle Free Reconstiution KIt: 00069-0344-01 00069-0344-05 00069-0344-10 Act-O-Vial®: 00069-2465-01 00069-2465-10	00069-0207-01 00069-2465-19	VIAL, 0.5 mL, reconstituted VIAL, 0.5 mL, SINGLE-DOSE	90678	Respiratory syncytial virus vaccine, preF, subunit, bivalent, for intramuscular use
326	Respiratory syncytial virus (RSV), mRNA, injectable preservative free	mRESVIA	Moderna US, Inc.	80777-0345-90 80777-0345-96 80777-0345-61 80777-0345-62 80777-0345-63	80777-0345-01	Syringe, 0.5mL	90683	Respiratory syncytial virus vaccine, mRNA lipid nanoparticles, for intramuscular use

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Respiratory Syncytial Virus (RSV) and Vaccination for Older Adults

HOW ARE RSV VACCINES BILLED?

- RSV vaccines are covered by Medicare Part D, with no patient copay.
- RSV vaccines have been covered by commercial plans for eligible recipients (i.e., those who meet the FDA-approved indication and CDC recommendations) but may carry copay liabilities on the part of the patient.

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