DID YOU KNOW?

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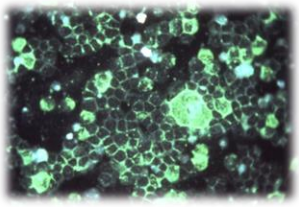
Respiratory Syncytial Virus (RSV) and Vaccination for Older Adults

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.
- 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 2 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)

HOW EFFECTIVE ARE THESE RSV VACCINES?[5]

In clinical trials, vaccination with a single dose of either RSV vaccine demonstrated moderate to high efficacy in preventing symptomatic RSV-associated LRTD among adults aged ≥60 years.

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.

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.

For reference, influenza vaccine efficacy is often found to be ~40-60% annually.[6] 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 first RSV season after vaccination and appears to provide continued protection (2nd season is ongoing; data not finalized)."

HOW SAFE ARE THESE RSV VACCINES?[5]

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

In clinical trials, 6 cases of inflammatory neurologic events were reported post-vaccination (out of 38,177 study participants). Whether RSV vaccination increases the risk for inflammatory neurologic events (e.g., GBS) is currently unknown. Post-marketing surveillance is underway to clarify the existence of potential risks.

In the meantime, 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.

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

WHAT ARE THESE VACCINES' INDICATIONS AND RECOMMENDATIONS FOR USE?[5]

INDICATION

Both RSV vaccines carry the same indication: active immunization for the prevention of LRTD caused by RSV in Individuals ≥60 years of age*.

CDC RECOMMENDATION

Persons aged ≥60 years may receive a single dose of either RSV vaccine, using shared clinical decision-making.

Coadministration of the RSV vaccine with other adult vaccines during the same visit is acceptable, however it may increase the risk of local or systemic reactogenicity. Vaccination should be delayed for those experiencing moderate to severe acute illness with or without fever as a precaution. Until further post marketing surveillance is completed, there is no further guidance available on the necessity of revaccination.

This recommendation to use **shared clinical decision-making** is intended to provide flexibility for providers and patients to consider **patient preferences** and **individual risk factors that increase the patient's risk for severe RSV disease.**

WHO IS AT INCREASED RISK FOR SEVERE RSV 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

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

STORAGE

- Before reconstitution
  - **AREXVY**
    - **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.[7]
    - **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.[7]
  - **ABRYSVO**
    - Store **kit** 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.[8]

- After reconstitution
  - **AREXVY**
    - **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.[7]
  - **ABRYSVO**
    - After reconstitution, **administer immediately or store at room temperature** [15°C to 30°C (59°F to 86°F)] and use within 4 hours. Do **not** store reconstituted vaccine under refrigerated conditions [2°C to 8°C (36°F to 46°F)]. Do not freeze reconstituted vaccine.[8]

**ABRYSVO also carries an indication for the active immunization of pregnant individuals at 32 through 36 weeks gestational age for the prevention of LRTD and severe LRTD caused by RSV in infants from birth through 6 months of age.*

PREPARATION

- **AREXVY** is supplied in 2 vials that must be combined prior to administration.
- Prepare AREXVY by reconstituting the lyophilized antigen component (a sterile white powder) with the accompanying adjuvant suspension component (an opalescent, colorless to pale brownish sterile liquid). Use only the supplied adjuvant suspension component for reconstitution. The reconstituted vaccine should be an opalescent, colorless to pale brownish liquid. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. If either of these conditions exists, the vaccine should not be administered.[7]

Figure 1. Cleanse both vial stoppers. Using a sterile needle and sterile syringe, withdraw the entire contents of the vial containing the adjuvant suspension component (liquid) by slightly tilting the vial. Vial 1 of 2.

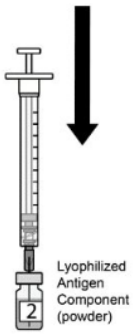


Figure 2. Slowly transfer entire contents of syringe into the lyophilized antigen component vial (powder). Vial 2 of 2.

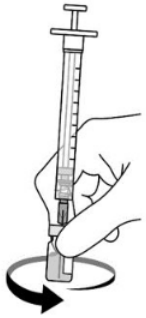


Figure 3. Gently swirl the vial until powder is completely dissolved. **Do not shake vigorously**.

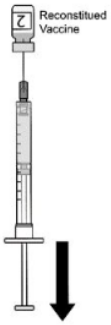
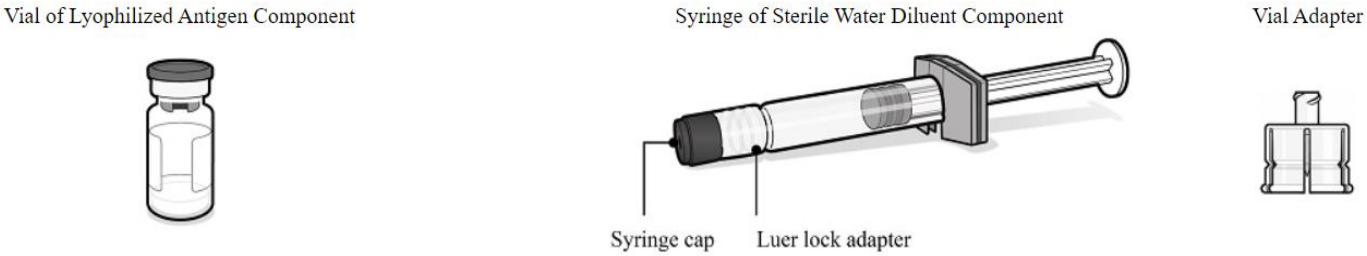


Figure 4. After reconstitution, withdraw 0.5 mL from the vial containing the reconstituted vaccine and administer intramuscularly.

- **ABRYSVO** is supplied in a kit that includes a vial of Lyophilized Antigen Component (a sterile white powder), a prefilled syringe containing Sterile Water Diluent Component and a vial adapter.[8]

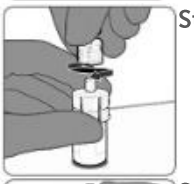


- To form ABRYSVO, reconstitute the Lyophilized Antigen Component with the accompanying Sterile Water Diluent Component as described in the panels below.[8]

Step 1. Preparation of vial and vial adapter
- Remove plastic flip off cap from vial and cleanse the rubber stopper.
- Without removing the vial adapter from its packaging, peel off the top cover.

Step 2. Attachment of vial adapter
- Hold the base of the vial on a flat surface.
- Keep the vial adapter in the packaging and orient it vertically over the center of the vial so that the adapter spike aligns with the center of the vial's rubber stopper.
- Connect the vial adapter to the vial with a straight downward push. The vial adapter will lock into place.
- Do not push vial adapter in at an angle as this may result in leaking during use.
- Remove the vial adapter packaging.

Step 3. Removal of syringe cap
- For all syringe assembly steps, hold the syringe only by the Luer lock adapter located at the tip of the syringe. This will prevent the Luer lock adapter from detaching during use.
- Remove the syringe cap by slowly turning the cap counterclockwise while holding the Luer lock adapter.



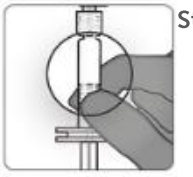
Step 4. Connection of syringe to vial adapter
- Hold the syringe's Luer lock adapter and connect it to the vial adapter by turning clockwise.
- Stop turning when you feel resistance, overtightening the syringe may result in leaking during use.
- Once the syringe is securely attached to the vial adapter, there will be a small space between the top of the vial adapter and the Luer lock adapter of the syringe.

Step 5. Reconstitution of Lyophilized Antigen Component to form ABRYSVO
- Inject the entire contents of the syringe containing the Sterile Water Diluent Component into the vial.
- Do not remove the empty syringe.
- While holding the plunger rod down, gently swirl the vial in a circular motion until the powder is completely dissolved (less than 1 minute).
- Do not shake.

Step 6. Withdrawal of reconstituted vaccine
- Invert the vial completely with the vial adapter and syringe still attached.
- Slowly withdraw the entire contents into the syringe to ensure an approximately 0.5 mL dose of ABRYSVO for administration.
- Do not pull the plunger rod out.

Step 7. Disconnection of syringe
- Hold the Luer lock adapter of the syringe and disconnect the syringe from the vial adapter by turning counterclockwise.

Step 8. Attachment of needle
- Attach a sterile needle suitable for intramuscular injection to the syringe containing ABRYSVO.



Step 9. Visual inspection
- ABRYSVO is a clear and colorless solution.
- Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit. Discard if either condition is present.

ADMINISTRATION

- **AREXVY** is administered as a 0.5mL intramuscular injection only.[7]
- **ABRYSVO** is administered as a 0.5mL intramuscular injection only.[8]

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

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%).[7]
- **ABRYSVO**
  - 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%). 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%).[8]

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 2023

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	GlaxoSmithKline Biologicals SA	58160-0848-11	58160-0723-03	VIAL, 0.5 mL, reconstituted	90679	Respiratory syncytial virus vaccine, preF, recombinant, subunit, adjuvanted, for intramuscuar use
305	Respiratory syncytial virus (RSV), vaccine, bivalent, protein subunit RSV prefusion F, diluent reconstituted, 0.5 mL, preservative free	Abrysvo	Pfizer Laboratories DivPfizer Inc	00069-0344-01 00069-0344-05 00069-0344-10	00069-0207-01	VIAL, 0.5 mL, reconstituted	90678	Respiratory syncytial virus vaccine, preF, subunit, bivalent, for intramuscuar use

HOW ARE RSV VACCINES BILLED?

- RSV vaccines are covered by Medicare Part D, with no patient copay.
- They can be billed to Part D regardless of SNF Part A or long-stay status and they are not subject to consolidated billing.
- 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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