# Protocol for Respiratory Syncytial Virus Vaccine (ABRYSVO™, AREXVY™, mRESVIA®)

## 1. What's New

A. Updated guidance recommending all adults ages 75 years and older receive a single lifetime dose of a respiratory syncytial virus (RSV) vaccine.

B. Updated guidance recommending adults ages 60-74 years at increased risk of severe RSV, as described in Section 5, are recommended to receive a single lifetime dose of a RSV vaccine. Patients with a risk factor not listed in Section 5 would require a prescription from the patient's provider.

C. The addition of mRESVIA®, a one dose 0.5-mL IM mRNA vaccine, has been approved for the prevention of RSV.

## 2. Immunization Protocol

A. Administer a single lifetime 0.5-mL dose, IM, RSV vaccine to all adults ages 75 years and older.

B. Administer a single lifetime 0.5-mL dose, IM, RSV vaccine to persons ages 60-74 years of age if they are at increased risk of severe RSV disease, as described in Section 5.

C. RSV vaccine be given with all ACIP-recommended adult vaccinations.

## 3. Vaccine Schedule

| RSV Vaccine (ABRYSVO™, AREXVY™, mRESVIA®) [1-3] Dose and Route – 0.5-mL IM | | |
|---|---|---|
| **Dose** | **Acceptable Age Range** | **Minimum Acceptable Spacing** |
| 1 | ≥60 years | |

| RSV Vaccine (ABRYSVO™ only) [5] Dose and Route – 0.5-mL IM | | | |
|---|---|---|---|
| **Dose** | **Acceptable Age Range** | **Indication** | **Minimum Acceptable Spacing** |
| 1 | N/A | Pregnancy | Administer 32 weeks 0 days through 36 weeks and 6 days of pregnancy during or just prior to the start of the RSV season*. |

*Vaccine should be administered to pregnant persons during September–January in most of the continental United States, including Oregon, to target vaccine to pregnant persons whose infants will be in their first months of life during the RSV season. Administer RSV vaccine regardless of previous RSV infection. All other pregnant persons: RSV vaccine not recommended. There is currently no ACIP recommendation for RSV vaccination in subsequent pregnancies. No data are available to inform whether additional doses are needed in later pregnancies.

## 4. Licensed Vaccines

| Product Name | Vaccine Components | Presentation | FDA Approved Age Range | Thimerosal |
|---|---|---|---|---|
| ABRYSVO™[1] | 60 mcg RSV prefusion F A protein and 60 mcg RSV prefusion F B protein | 0.5-mL single-dose diluent in prefilled syringe and vial with lyophilized antigen | ≥60 years | No |
| AREXVY™[2] | 120 mcg of the recombinant RSVPreF3 | 0.5-mL single-dose vial of | | |

| | | | | |
|---|---|---|---|---|
| | antigen, 25 mcg of MPL and 25 mcg of QS-21 | adjuvant suspension and single-dose vial of lyophilized antigen | | |
| mRESVIA®[3] | 50 mcg of nucleoside modified mRNA encoding the RSV F glycoprotein stabilized in the prefusion conformation (pre-F protein). | 0.5-mL single-dose prefilled syringe | | |

MPL: 3-O-desacyl-4'-monophosphoryl lipid A; QS-21: saponin purified from plant extract *Quillaja Saponaria* Molina

**5. Recommendations for Use**[4,5]

A. Adults 75 years and older: all adults are recommended to receive a single lifetime dose of RSV vaccine.

B. Adults 60-74 years of age: adults at an increased risk of severe RSV should receive a single lifetime dose of RSV vaccine. Pharmacists are authorized to administer RSV vaccine if the patient provides information that one of the following risk factors is present:

**Chronic underlying medical conditions**

- Chronic cardiovascular disease (e.g., heart failure, coronary artery disease, or congenital heart disease [excluding isolated hypertension])
- Chronic lung or respiratory disease (e.g., chronic obstructive pulmonary disease, emphysema, asthma, interstitial lung disease, or cystic fibrosis)
- End-stage renal disease or dependence on hemodialysis or other renal replacement therapy
- Diabetes mellitus complicated by chronic kidney disease, neuropathy, retinopathy, or other end-organ damage, or requiring treatment with insulin or sodium-glucose cotransporter-2 (SGLT2) inhibitor
- Neurologic or neuromuscular conditions causing impaired airway clearance or respiratory muscle weakness (e.g., poststroke dysphagia, amyotrophic lateral sclerosis, or muscular dystrophy [excluding history of stroke without impaired airway clearance])
- Chronic liver disease (e.g., cirrhosis)
- Chronic hematologic conditions (e.g., sickle cell disease or thalassemia)
- Severe obesity (body mass index ≥40 kg/m$^2$)
- Moderate or severe immune compromise†
- Residence in a nursing home
- Other chronic medical conditions or risk factors that a health care provider determines would increase the risk for severe disease due to viral respiratory infection (e.g., frailty,§ situations in which health care providers have concern for presence of undiagnosed chronic medical conditions, or residence in a remote or rural community where transportation of patients with severe RSV disease for escalation of medical care is challenging¶)

**Abbreviation:** RSV = respiratory syncytial virus.

- * Patient attestation is sufficient evidence of the presence of a risk factor. Vaccinators should not deny RSV vaccination to a person because of lack of medical documentation.

**Other factors**

- Frailty†
- Residence in a nursing home or other long-term care facility‡
- Other underlying conditions that a medical health care provider, with an authorized prescription, determines may increase the risk for severe respiratory disease.

† Frailty is a multidimensional geriatric syndrome and reflects a state of increased vulnerability to adverse health outcomes. Although there is no consensus definition, one frequently used tool is the Fried frailty phenotype in which frailty is defined as a clinical syndrome with three or more of the following symptoms present: unintentional weight loss (10 pounds or 4.5 kilograms in the past year), self-reported exhaustion, weakness (grip strength), slow walking speed, and low physical activity.

‡Retirement communities and independent living communities for seniors are not considered long-term care facilities. Adults ages 60-74 living in these facilities may still be recommended to receive RSV vaccination if they have certain medical conditions listed above.

C. The RSV vaccine is not currently an annual vaccine, meaning people do not need to get a dose every RSV season. Eligible adults can get an RSV vaccine at any time, but the best time to get vaccinated is in late summer and early fall before RSV usually starts to spread in communities.

D. **Pregnancy:** Administer Abrysvo™ at 32–36 weeks' gestation during every pregnancy using seasonal administration (September–January in most of the continental United States, including Oregon) for prevention of RSV-associated lower respiratory tract infection in infants aged < 6 months.

## E. Contraindications[1,2]

**A.** Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.

| Vaccine | Contains |
|---|---|
| ABRYSVO™[1] | Tromethamine, tromethamine hydrochloride, sucrose, mannitol, polysorbate 80, sodium chloride, host cell protein and DNA |
| AREXVY™[2] | Trehalose, sodium chloride, potassium dihydrogen phosphate, dipotassium phosphate, polysorbate 80, disodium phosphate anhydrous, dioleoyl phosphatidylcholine (DOPC), host cell protein and DNA |
| mRESVIA®[3] | Lipid content of 1.02 mg (SM-102 (heptadecan-9-yl 8-((2-hydroxyethyl) (6-oxo-6-(undecyloxy) hexyl) amino) octanoate), polyethylene glycol 2000 dimyristoyl glycerol [PEG2000-DMG], cholesterol, and 1,2-distearoyl-sn-glycero3-phosphocholine [DSPC]), 0.25 mg tromethamine, 1.2 mg tromethamine hydrochloride, 0.021 mg acetic acid, 0.10 mg sodium acetate trihydrate, 44 mg sucrose, and water for injection |

## F. Warnings and Precautions[1,2,5]

A. Individuals with acute, moderate, or severe illness with or without fever should delay immunization until symptoms have improved.

B. Individuals with an immunocompromising condition may experience a diminished immune response to the vaccine.

C. Potential risk of preterm birth. To avoid the potential risk of preterm birth (defined as birth before 37 weeks' gestation), administer Abrysvo™ as indicated only to pregnant individuals at 32 through 36 weeks' gestational age.

## G. Other Considerations[1,2,5]

A. Coadministration with other vaccines: Coadministration of RSV vaccines with other adult vaccines during the same visit is acceptable. Available data on immunogenicity of coadministration of RSV vaccines and other vaccines is currently limited. Coadministration of RSV and influenza vaccines met noninferiority criteria for immunogenicity except for a lower antibody response to the influenza A Darwin H3N2 strain when AREXVY™ was administered with an adjuvanted quadrivalent inactivated influenza vaccine. The clinical significance of this is unknown.

Administering RSV vaccines with one or more other adult vaccines during the same visit may increase local or systemic reactogenicity. When determining whether to coadminister other vaccines with the RSV vaccine, providers should consider whether the patient is up to date with currently recommended vaccines, the feasibility of the patient returning for additional vaccine doses, risk for acquiring vaccine-preventable disease, vaccine reactogenicity profiles, and patient preference.

B. Pregnancy and Breastfeeding: Abrysvo™ is the only RSV vaccine indicated for pregnant individuals. To avoid the potential risk of preterm birth (defined as birth before 37 weeks' gestation), administer Abrysvo™ as indicated only to pregnant individuals at 32 through 36 weeks' gestational age.It is unknown if RSV vaccines are excreted in human milk.
C. In June 2024, FDA licensed AREXVY™ for use in people ages 50–59 who are at increased risk of RSV lower respiratory tract disease. ACIP did not hold a vote to recommend AREXVY for people ages 50–59. At this time, ACIP concluded more information is needed to determine the best policy option for the use of RSV vaccines in people ages 50–59. CDC will continue to monitor the effectiveness and safety of these vaccines in people ages 60 and older and is committed to re-evaluating potential RSV vaccine recommendations for people ages 50–59 when additional information becomes available.[2]
D. Nirsevimab administration: Providers who care for pregnant persons should discuss the relative advantages and disadvantages of maternal RSV vaccination and nirsevimab and consider patient preferences when determining whether to vaccinate the pregnant person or to rely on administration of nirsevimab for prevention of RSV in the infant. Nirsevimab administration is recommended for infants aged < 8 months who are born during or are entering their first RSV season and whose mother did not receive a RSV vaccination or vaccination status is unknown; but administration of both products is not needed for most infants.

**H. Side Effects and Adverse Reactions**

| **Adverse Event** | **Frequency** |
|---|---|
| ABRYSVO™[1] | |
| Fatigue | 15.5% |
| Headache | 12.8% |
| Injection site pain | 10.5% |
| Myalgia | 10.1% |
| Adults who are pregnant | |
| Preeclampsia | 1.8% (95% CI 1.4, 2.3) |
| Gestational hypertension | 1.1% (95% CI 0.8, 1.5) |
| AREXVY™[2] | |
| Injection site pain | 60.9% |
| Fatigue | 33.6% |
| Myalgia | 28.9% |
| Headache | 27.2% |
| Arthralgia | 18.1% |
| mRESVIA®[3] | |

| | |
|---|---|
| Injection site pain | 55.9% |
| Fatigue | 30.8% |
| Headache | 26.7% |
| Myalgia | 25.6% |
| Arthralgia | 21.7% |
| Axillary (underarm) swelling or tenderness | 15.2% |
| Chills | 11.6% |

I. **Storage and Handling**

A. Store medications according to OAR 855-041-1036.

| Vaccine | Temp | Storage Issues | Notes |
|---|---|---|---|
| ABRYSVO™[1] | Store at 2° to 8°C (36° to 46°F) | Store in original carton and protect from light. Do not freeze. Discard if carton has been frozen. | Reconstituted vaccine may **only** be stored at room temperature, 15°– 30°C (59°-86°F). Discard reconstituted vaccine if not used within 4 hours. |
| AREXVY™[2] | | | Reconstituted vaccine may be stored in the refrigerator between 2°– 8°C (36°- 46°F) or at room temperature up to 25°C (77°F). Discard reconstituted vaccine if not used within 4 hours. |
| mRESVIA®[3] | Store at -40°C to -15°C (-40°F to 5°F) until manufacturer expiration date | Minimize exposure to room light and avoid exposure to direct sunlight and ultraviolet light.<br><br>mRESVIA® is a white to off-white suspension that may contain visible white or translucent product-related particles. **Do not shake.** Do not administer if the vaccine is discolored or contains other particulate matter. | After thawing do not refreeze. |
| | Store at 2° to 8°C (36° to 46°F) for up to 30 days | | |
| | Store at 8° to 25°C (46° to 77°F) for a total of 24 hours | | Syringes **should not** be returned to the refrigerator after standing at room temperature. |

| **mRESVIA® Thawing Conditions and Times[3]** | | |
|---|---|---|
| **Configuration** | **Thaw in Refrigerator** | **Thaw at Room Temperature** |
| Carton of one pre-filled syringe in single blister pack | Thaw between 2°C to 8°C (36°F to 46°F) for 60 minutes.<br><br>Let each pre-filled syringe stand at room temperature for between 10 and 20 minutes before administering the vaccine. | Thaw between 15°C to 25°C (59°F to 77°F) for 45 minutes.<br><br>If mRESVIA® is thawed at room temperature, the vaccine is ready to be administered. |
| Carton of 10 pre-filled syringes in blister packs | Thaw between 2°C to 8°C (36°F to 46°F) for 155 minutes.<br><br>Let each pre-filled syringe stand at room temperature for between 10 and 20 minutes before administering the vaccine. | Thaw between 15°C to 25°C (59°F to 77°F) for 140 minutes.<br><br>If mRESVIA® is thawed at room temperature, the vaccine is ready to be administered. |

## J. References

1. Abrysvo™. [Package insert]. October 2023. https://www.fda.gov/media/168889/download.

2. Arexvy™. [Package insert]. June 2024 https://www.fda.gov/media/167805/download?attachment

3. mRESVIA®. [Package insert]. https://www.fda.gov/media/179005/download?attachment

4. Melgar M, Britton A, Roper LE, et. al. Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices – United States, 2024. Weekly / August 15, 2024 / 73(32);696-702 Available at: https://www.cdc.gov/mmwr/volumes/73/wr/mm7332e1.htm

5. Fleming-Dutra KE, Jones JM, Roper LE, et al. Use of the Pfizer respiratory syncytial virus vaccine during pregnancy for the prevention of respiratory syncytial virus-associated lower respiratory tract disease in infants: recommendations of the Advisory Committee on Immunization Practices— United States, 2023. MMWR ePub: 9 October 2023. Available at http://dx.doi.org/10.15585/mmwr.mm7241e1