

## 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 through 74 years at increased risk of severe RSV, as described in Section 4, are recommended to receive a single lifetime dose of an RSV vaccine. Patients with a risk factor not listed in Section 4 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 through 74 years of age if they are at increased risk of severe RSV disease, as described in Section 4.
- C. RSV vaccine be given with all ACIP-recommended adult vaccinations.

### 3. Vaccine Schedule

RSV Vaccine (ABRYSVO™, AREXVY™, mRESVIA®) <sup>1-3</sup> Dose and Route – 0.5-mL IM		
Dose	Acceptable Age Range	Minimum Acceptable Spacing
1	≥60 years	

RSV Vaccine (ABRYSVO™ only) <sup>5</sup> 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 through 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 is available to inform whether additional doses are needed in subsequent pregnancies.<sup>5</sup>

### 4. Additional Considerations for Use <sup>4</sup>

- A. 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.
- B. For adults 60 through 74 years of age, 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
<ul style="list-style-type: none"> <li>• Chronic cardiovascular disease (e.g., heart failure, coronary artery disease, or congenital heart disease [excluding isolated hypertension])</li> <li>• Chronic lung or respiratory disease (e.g., chronic obstructive pulmonary disease, emphysema, asthma, interstitial lung disease, or cystic fibrosis)</li> </ul>

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

- 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  $\geq 40$  kg/m<sup>2</sup>)
- Moderate or severe immune compromise<sup>†</sup>
- 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,<sup>§</sup> 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<sup>¶</sup>)

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

<sup>†</sup> 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.

<sup>‡</sup> 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. Coadministration with other vaccines: Available data on immunogenicity of coadministration of RSV vaccines and other vaccines is currently limited and 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.
- 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.

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

### **5. Pregnancy and Lactation**

- A. Administer Abrysvo™ to pregnant persons as a one-time dose at 32 weeks and zero days' through 36 weeks and 6 days' gestation using seasonal administration (meaning September through January in most of the continental United States, including Oregon) for prevention of RSV-associated lower respiratory tract infections (LRTI) in infants aged <6 months.<sup>5</sup>
- B. It is unknown if RSV vaccines are excreted in human milk.

### **6. Warnings and Precautions**<sup>1,2,5</sup>

- 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.

### **7. Contraindications**<sup>1,2</sup>

- A. Severe allergic reaction (e.g., anaphylaxis) to a previous dose or to any vaccine component.
- B. See current prescribing information for details about formulation and contents.

### **8. Storage and Handling**

- A. Store medications according to [OAR 855-041-1036](#).
- B. See current prescribing information for additional details about storage and handling.<sup>1,2,3</sup>

### **9. 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]. October 2024.  
<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>