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

1. What's New

A. Added additional clarification regarding Abrysvo™ seasonal administration during the final trimester of pregnancy and additional guidance on subsequent vaccination for future pregnancies.

2. Immunization Protocol

A. Administer a 0.5-mL dose, IM, of respiratory syncytial virus (RSV) vaccine to persons ≥ 60 years of age, using shared clinical decision making, as described in Section 5.

B. May be given with all ACIP-recommended adult vaccinations.

3. Vaccine Schedule

RSV Vaccine (ABRYSVO™, AREXVY™) [1,2] Dose and Route – 0.5-mL IM		
Dose	**Acceptable Age Range**	**Minimum Acceptable Spacing**
1	≥60 years	

RSV Vaccine (ABRYSVO™ only) [4] 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 antigen, 25 mcg of MPL and 25 mcg of QS-21	0.5-mL single-dose vial of adjuvant suspension and single-dose vial of lyophilized antigen		

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

5. Recommendations for Use[3,4]

A. Shared clinical decision making for patients 60 years of age and older: until additional evidence becomes available from post-marketing surveillance clarifying the potential risk (e.g. neurologic inflammatory events, atrial fibrillation), RSV vaccination in older adults should be targeted to those who are at highest risk for severe RSV disease. Pharmacists can

engage in shared clinical decision making to discuss RSV vaccination with persons aged 60 years or older who are most likely to benefit. 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
• Lung disease (such as chronic obstructive pulmonary disease and asthma) • Cardiovascular disease (such as congestive heart failure and coronary artery disease) • Moderate or severe immune compromise* • Diabetes mellitus • Neurologic or neuromuscular conditions • Kidney disorders • Liver disorders • Hematologic disorders • Other underlying conditions that a health care provider, including a pharmacist, determines may increase the risk for severe respiratory disease
Other factors
• Frailty† • Advanced age‡ • Residence in a nursing home or other long-term care facility • Other underlying factors that a health care provider, including a pharmacist, determines may increase the risk for severe respiratory disease

*A list of potentially immune compromising conditions is available at:
https://www.cdc.gov/coronavirus/2019-ncov/need-extra-precautions/people-who-are-immunocompromised.html

† 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.

‡ Among adults aged ≥ 60 years, RSV incidence increases with advancing age. Although age may be considered in determining an older adult patient's risk for severe RSV-associated disease, there is no specific age threshold at which RSV vaccination is more strongly recommended within the age group of adults aged 60 years.

B. Pregnancy: Administer 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 LRTI in infants aged < 6 months.

6. 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

7. Warnings and Precautions[1,2,4]

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.

8. Other Considerations[1,2,4]

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 ABREXVY™ 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: RSV vaccines are not approved for individuals <60 years of age. It is unknown if RSV vaccines are excreted in human milk.

C. 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.

9. 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%

10. Storage and Handling

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

Vaccine	Temp	Storage Issues	Notes
ABRYSVO™[1]	Store at 2°– 8°C (36°- 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.

11. References

1. Abrysvo™. [Package insert]. October 2023. https://www.fda.gov/media/168889/download. Accessed 10 October 2023.
2. Arexvy™. [Package insert]. May 2023. https://www.fda.gov/media/167805/download. Accessed 13 August 2023.
3. 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, 2023. MMWR 2023; 72: 793-801. Available at: https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm. Accessed 13 August 2023.
4. 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. Accessed 9 Oct 2023.

12. Appendix

A. Centers for Disease Control and Prevention. Healthcare Providers: RSV Vaccination for Adults 60 Years of Age and Over. Atlanta, GA: U.S. Department of Health and Human Services, Centers for Disease Control and Prevention, 2023. Available from: https://www.cdc.gov/vaccines/vpd/rsv/downloads/provider-job-aid-for-older-adults-508.pdf