Immunization Protocol

Respiratory Syncytial Virus (RSV) Vaccine (Abrysvo™, Arexvy™)	
Last Reviewed	09 Oct 2023
Last Revised	09 Oct 2023
This order expires	31 Oct 2025

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1. What's new

Added indication for Abrysvo seasonal administration during the final trimester of pregnancy between 32–36 weeks' gestation.

2. Oregon immunization protocol

A. Check the ALERT Immunization Information System (IIS) to determine whether the patient needs this vaccine and any other vaccines.

B. Assess risk and benefit to patient of receiving RSV vaccine using shared clinical decision making.

C. Screen clients for contraindications and precautions.

D. Provide a current Vaccine Information Statement (VIS), answering any questions.

E. Counsel patients regarding expected reactogenicity (injection pain, fatigue, muscle pain and headache) before administering vaccine.

F. Record all required data elements in the client's permanent health record.

G. Verify needle length for intramuscular (IM) injection.

H. Reconstitute vaccine with diluent provided with the vaccine.

I. To avoid injury related to vaccine administration, make sure staff who administer vaccines recognize the anatomic landmarks for identifying the deltoid muscle and use proper IM administration technique.

J. May be given with all ACIP-recommended adult vaccinations. See section 8 for additional information.

K. Ask client to remain seated on the premises for 15 minutes after vaccination to decrease the risk of injury should they faint.

L. Appropriate medical treatment used to manage immediate allergic reactions must be immediately available in the event an anaphylactic reaction occurs following administration.

Health Officer Signature Date

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3. Vaccine schedule for RSV Vaccine

Dose and Route: 0.5 mL, IM[1,2,5] (Abrysvo only)			
Dose	**Minimum**	**Indication**	**Notes**

	acceptable age		
1	N/A	Pregnancy	Administer 32–36 weeks 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.

Dose and Route: 0.5 mL, IM[1,2] (Abrysvo and Arexvy)			
Dose	**Preferred age**	**Minimum acceptable age**	**Minimum acceptable spacing**
1	≥60 years	≥60 years	

4. Licensed RSV Vaccines

Trade Name	Presentation	Acceptable Age Range
Abrysvo[1] (bivalent, recombinant, stabilized prefusion F protein [preF])	0.5-mL single-dose diluent in prefilled syringe and vial with lyophilized antigen	≥60 years **or** during 32–36 weeks of pregnancy
Arexvy[2] (adjuvanted, recombinant, stabilized prefusion F protein [preF])	0.5-mL single-dose vial of adjuvant suspension and single-dose vial of lyophilized antigen	≥60 years

5. Recommendations for use:[3]

A. 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.

B. Shared clinical decision-making (SCDM) for patients 60 years of age and older:

- Until additional evidence becomes available from post-marketing surveillance clarifying the potential risks (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.

- Factors associated with increased risk:
  - Frailty
  - Advanced age
  - Residence in a long-term care facility
  - Lung disease
  - Cardiovascular disease
  - Moderate to severe immune compromise
  - Diabetes
  - Neurologic or neuromuscular conditions
  - Kidney disorders
  - Liver disorders
  - Hematologic disorders

6. Contraindications:[1,2,]

History of severe allergic reaction (e.g., anaphylaxis) to any component of the vaccine.

Vaccine	Vaccine Excipient Summary
Abrysvo[1]	0.11 mg tromethamine, 1.04 mg tromethamine hydrochloride, 11.3 mg sucrose, 22.5 mg mannitol, 0.08 mg polysorbate 80, and 1.1 mg sodium chloride per 0.5 mL.
Arexvy[2]	14.7 mg of trehalose, 4.4 mg of sodium chloride, 0.83 mg of potassium dihydrogen phosphate, 0.26 mg of dipotassium phosphate, 0.18 mg of polysorbate 80, 0.15 mg of disodium phosphate anhydrous, 0.5 mg of DOPC, and 0.125 mg of cholesterol.

7. Warnings and precautions:[1,2,5]

A. 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.

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

C. Immunosuppressed people may have a diminished response.

8. Other considerations

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 are currently limited.

Administering RSV vaccine with one or more other vaccines at the same visit might increase local or systemic reactogenicity. When deciding whether to coadminister other vaccines with 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 preferences.

B. **Adverse Events**: Epinephrine hydrochloride solution (1 mg/mL) and other appropriate agents and equipment must be available for immediate use in case of anaphylactic or acute hypersensitivity reaction.

C. **Pregnancy and Breastfeeding**: Abrysvo vaccine is approved for persons during pregnancy at 32–36 weeks' gestation. Arexvy has not been approved for use during pregnancy. It is unknown whether RSV vaccine is excreted in human milk.

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 to the infant.

Nirsevimab immunization 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
Adults ≥60 years

Injection site events (pain at the injection site, redness, swelling)	Up to 61%
Systemic events (fatigue, headache, muscle ache, fever)	Up to 33%
Inflammatory neurologic events[6]	3 events in 20,255 vaccine recipients
Adults who are pregnant	
Preeclampsia	1.8% (95% CI 1.4, 2.3)
Gestational hypertension	1.1% (95% CI 0.8, 1.5)

10. Storage and handling

All clinics and pharmacies enrolled with the Vaccines for Children (VFC) Program must immediately report any storage and handling deviations to the Oregon Immunization Program at 800-980-9431.

Vaccine	Temp	Storage Issues	Notes
Abrysvo[1]	2°C to 8°C (36°F to 46°F)	Store in original carton and protect from light. Do not freeze. Discard if carton has been frozen.	Reconstituted vaccine may be stored at room temperature only,15ºC to 30ºC (59ºF to 86ºF). Use within 4 hours. Do not store reconstituted vaccine in refrigerator.
Arexvy[2]			Reconstituted vaccine may be stored 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. Discard reconstituted vaccine if not used within 4 hours.

11. Adverse events reporting

Report adverse events online to the Vaccine Adverse Events Reporting System (VAERS) at https://vaers.hhs.gov/reportevent.html.

VAERS Reporting Table:
https://vaers.hhs.gov/docs/VAERS_Table_of_Reportable_Events_Following_Vaccination.pdf

A. CDC will be monitoring VAERS and the Vaccine Safety Datalink for GBS, ADEM and other inflammatory neurologic events after receipt of RSV vaccine.

B. GSK will be conducting a post-marketing study evaluating risk for GBS, ADEM and atrial fibrillation after receipt of Arexvy.

C. Pfizer will conduct post-marketing studies to evaluate the risk of GBS the risk for atrial fibrillation after receipt of Abrysvo.

12. References

1. Pfizer. Abrysvo package insert, 2023. Available at: www.fda.gov/media/168889/download. Accessed 9 Oct 2023.
2. GlaxoSmithKline. Arexvy package insert, May 2023. Available at www.fda.gov/media/167805/download. Accessed 9 Oct 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/pdfs/mm7229a4-H.pdf.

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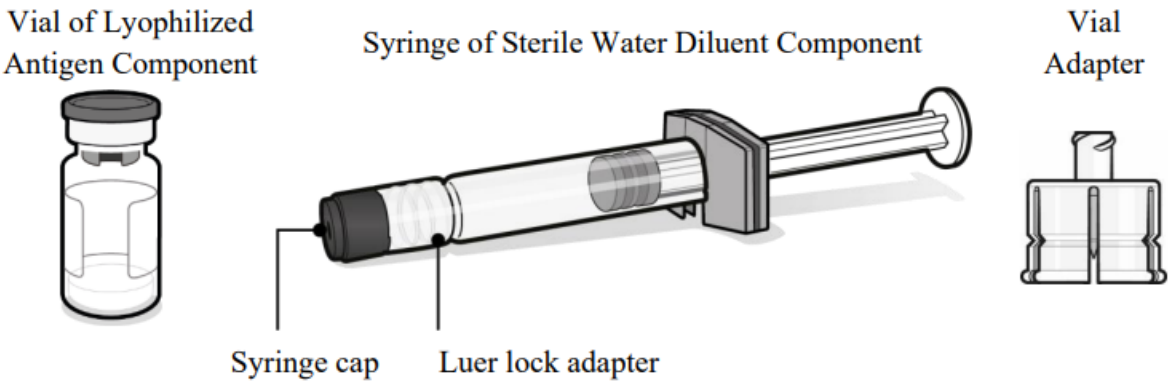
4. Kroger A, Bahta L, Hunter P. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP), updated February 10, 2023. Available at www.cdc.gov/vaccines/hcp/aciprecs/general-recs/downloads/general-recs.pdf. Accessed 9 Oct 2023.
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. Accessed 9 Oct 2023.
6. Melgar M and Britton A. Evidence to recommendations framework, respiratory syncytial virus in adults. ACIP meeting presentation. 21 Jun 2023. Available at: https://www.cdc.gov/mmwr/volumes/72/wr/pdfs/mm7229a4-H.pdf. Accessed 9 Oct 2023.

To request this material in an alternative format (e.g., Braille) or to clarify any part of the above order, contact the Oregon Health Authority Immunization Program at 800-980-9431 and 711 for TTY. For other questions, consult with the vaccine recipient's primary health care provider or a consulting physician.

Electronic copy of this immunization protocol is available at: immunization protocol

13. Appendix A – Abrysvo preparation

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.



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

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 counter-clockwise 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

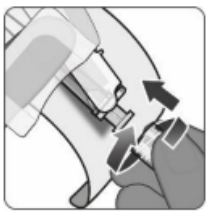
- Inject the entire contents of the syringe containing the Sterile Water Diluent Component into the vial.
- Do not remove the empty syringe.
- While holding the plunger rod down, gently swirl the vial in a circular motion until the powder is completely dissolved (less than 1 minute).
- Do not shake.

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.

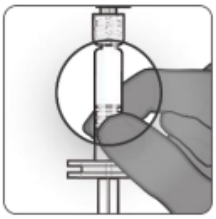
Step 7. Disconnection of syringe

- Hold the Luer lock adapter of the syringe and disconnect the syringe from the vial adapter by turning counter-clockwise.



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.

14. Appendix B – Arexvy preparation

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.

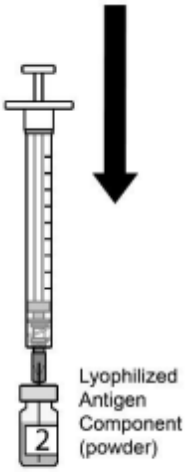


Figure 2. Slowly transfer entire contents of syringe into the lyophilized antigen component vial (powder). Vial 2 of 2.

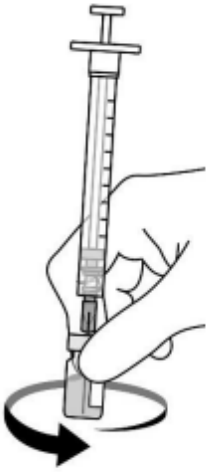


Figure 3. Gently swirl the vial until powder is completely dissolved. **Do not shake vigorously.**

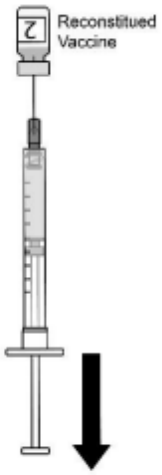


Figure 4. After reconstitution, withdraw 0.5 mL from the vial containing the reconstituted vaccine and administer intramuscularly.