Interim Immunization Protocol

Respiratory Syncytial Virus (RSV) Vaccine (Abrysvo™, Arexvy™, mResvia®)	
Last Reviewed	11 August 2025
Last Revised	11 August 2025
This order expires	31 August 2027

Table of contents

1. What's new

A single dose of RSV vaccine is recommended for certain adults, 50 through 59 years of age, at high-risk of severe RSV disease.[6]

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 (Abrysvo and Arexvy only) 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. Ensure epinephrine hydrochloride solution (1:1,000), oxygen and other appropriate agents and equipment are available for immediate use in case of anaphylactic or acute hypersensitivity reaction. Refer to Guidelines for Managing Adverse Events Following Immunization.

Health Officer Signature Date

Health Officer Signature Date

3. Vaccine schedule for RSV Vaccine

Dose and Route: 0.5 mL, IM[1,2,7] (Abrysvo only)			
Dose	**Minimum acceptable age**	**Indication**	**Notes**
1	N/A	One pregnancy*	Administer at 32–36 weeks of pregnancy during or just prior to the start of the RSV season.†

*RSV vaccination during subsequent pregnancies is not recommended at this time. Infants born to people who were vaccinated during a prior pregnancy should receive nirsevimab.[7]

†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	Preferred age	Minimum acceptable age
1	≥75 years routinely and 50–74 years with increased risk of severe RSV disease*	≥50 years

*See risk factors in Recommendations for Use section.

4. Licensed RSV Vaccines[1-3]

Trade Name	Presentation	Acceptable Age Range
Abrysvo (bivalent, recombinant, stabilized prefusion F protein [preF])	0.5-mL single-dose diluent in prefilled syringe and vial with lyophilized antigen	≥50 years **or** during 32–36 weeks of pregnancy
Arexvy (adjuvanted, recombinant, stabilized prefusion F protein [preF])	0.5-mL single-dose vial of adjuvant suspension and single-dose vial of lyophilized antigen	≥50 years
mResvia (mRNA, stabilized prefusion F protein [preF])	0.5-mL single-dose prefilled syringe	≥50 years

5. Recommendations for use[4,5,6,7]

A. Pregnancy (Abrysvo only): Administer at 32–36 weeks' gestation using seasonal administration (September–January in most of the continental United States, including Oregon) for prevention of RSV-associated lower respiratory tract illness (LRTI) in infants aged <6 months. RSV vaccination during subsequent pregnancies is not recommended at this time. Infants born to people who were vaccinated during a prior pregnancy should receive nirsevimab.

B. Adults (any of the 3 licensed RSV vaccines):

a. All adults aged 75 and older should receive a single dose of RSV vaccine.

b. All adults aged 50–74 years[6] with certain chronic medical conditions or

other factors that increase risk of severe RSV disease should receive a single dose of RSV vaccine. Conditions and factors with increased risk include:[6]

- Chronic lung disease
- Chronic cardiovascular disease
- Moderate or severe immune compromise
- Diabetes mellitus with chronic kidney disease, neuropathy, retinopathy, end-organ damage, or requiring insulin or sodium-glucose cotransporter-2 (SGLT2) inhibitor
- Severe obesity (body mass index ≥40 kg/m^2
- Neurologic or neuromuscular conditions causing impaired airway clearance or impaired respiratory muscle weakness
- End stage renal disease or dialysis dependence
- Chronic liver disorders
- Chronic hematologic conditions
- Residence in a nursing home or other long-term care facility (LTCF)
- Other chronic medical conditions that healthcare provider determines increase the risk of severe disease due to viral respiratory infection (e.g., frailty)

c. RSV vaccination for adults will have the most benefit if given in late summer or early fall.

d. Adults who have already received a dose of RSV vaccine are not recommended to receive another dose.

6. Contraindications:[1,2,3]

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.
mResvia[3]	1.02 mg lipids, 0.25 mg tromethamine, 1.2 mg tromethamine hydrocholoride, 0.021 mg acetic acid, 0.10 mg sodium acetate trihydrate, 44 mg sucrose, water.

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

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

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.

B. **Pregnancy and Breastfeeding**: Abrysvo vaccine is approved for persons during pregnancy at 32–36 weeks' gestation. Arexvy and mResvia have not been approved for use during pregnancy. It is unknown whether RSV vaccine is 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 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 an RSV vaccination or whose vaccination status is unknown; **but administration of both products is not needed for most infants.**

9. Side effects and adverse reactions[1-3]

Adverse Event	
Adults ≥50 years	
Injection site events (pain at the injection site, redness, swelling)	Up to 76%
Systemic events (fatigue, headache, muscle ache, fever)	Up to 40%
Inflammatory neurologic events	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.
mResvia[3]	-40°C to -15°C (-40°F to 5°F)	Thaw prior to use. Do not refreeze once thawed. Do not shake. Syringes should not be returned to the refrigerator after standing at room temperature.	To thaw carton of one or two pre-filled syringe(s): • Refrigerator 2°–8°C (36°–46°F) for 100 mins., then room temperature for 10–20 mins.; OR • At room temperature 15°–25°C (59°–77°F) for 40 mins. To thaw carton of 10 pre-filled syringes: • Refrigerator 2°–8°C (36°–46°F) for 160 mins. (2 hrs and 40 min), then room temperature for 10–20 mins.; OR • Room temperature 15°–25°C (59°–77°F) for 80 mins. (1 hr and 20 min) Thawed vaccine may be stored refrigerated at 2°–8°C (36°–46°F) up to 90 days prior to use or at room temperature up to 25°C [77°F]) for a total of 24 hours.

			When thawed at room temp, vaccine is ready to be administered.

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 monitor VAERS and the Vaccine Safety Datalink for Guillain-Barré Syndrome (GBS), acute disseminated encephalomyelitis (ADEM) and other inflammatory neurologic events after receipt of an RSV vaccine.

B. GSK will conduct 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 for GBS and atrial fibrillation after receipt of Abrysvo.

12. References

1. Pfizer. Abrysvo package insert, March 2024. Available at: www.fda.gov/media/168889/download. Accessed 7 Aug 2025.
2. GlaxoSmithKline. Arexvy package insert, June 2024. Available at www.fda.gov/media/167805/download. Accessed 7 Aug 2025.
3. Moderna. mResvia package insert, December 2024. Available at www.fda.gov/media/179005/download. Accessed 7 Aug 2025.
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, 2023. MMWR 2023; 72:793–801. Available at: www.cdc.gov/mmwr/volumes/72/wr/pdfs/mm7229a4-H.pdf. Accessed 7 Aug 2025.
5. Britton A, Roper L, Kotton C, et al. Use of respiratory syncytial virus vaccines in adults aged ≥60 Years: updated recommendations of the Advisory Committee on Immunization Practices – United States, 2024. MMWR 2024; 73:696–702. Available at: www.cdc.gov/mmwr/volumes/73/wr/mm7332e1.htm. Accessed 7 Aug 2025.
6. Surie B, Melgar M, Britton A. ACIP Adult RSV Workgroup Clinical Considerations. Presentation at the April 16, 2025 ACIP meeting. Available at: https://www.cdc.gov/acip/downloads/slides-2025-04-15-16/07-Surie-adult-RSV-

508.pdf. Accessed 7 Aug 2925.

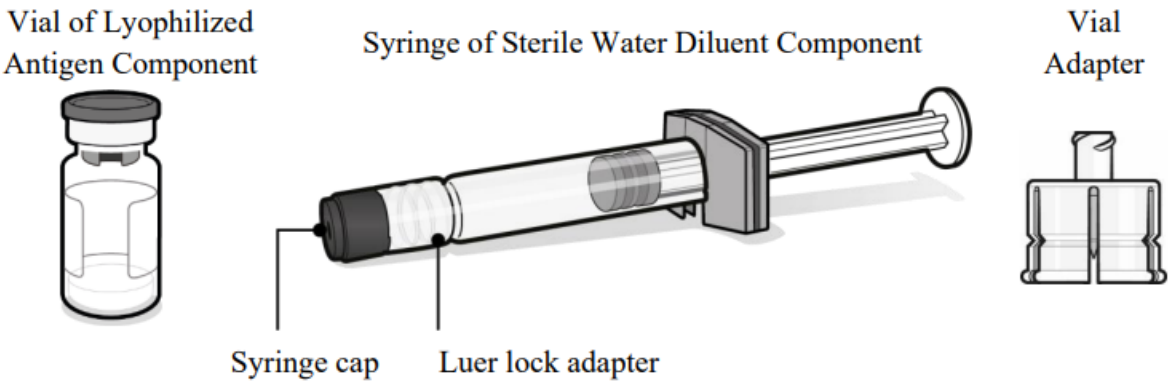
7. Fleming-Dutra KE, Jones JM, Roper LE, et al. Use of the Pfizer respiratory syncytial virus vaccine during pregnancy for the prevention of respiratory syncytial virus-associated lower respiratory tract disease in infants: recommendations of the Advisory Committee on Immunization Practices—United States, 2023. MMWR 2023; 72:1115–22. Available at www.cdc.gov/mmwr/volumes/72/wr/mm7241e1.htm. Accessed 7 Aug 2025.

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: www.oregon.gov/standing-protocols.

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

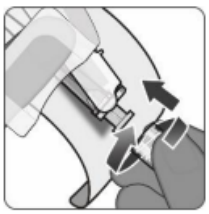
- Inject the entire contents of the syringe containing the Sterile Water Diluent Component into the vial.
- Do not remove the empty syringe.
- While holding the plunger rod down, gently swirl the vial in a circular motion until the powder is completely dissolved (less than 1 minute).
- Do not shake.

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.

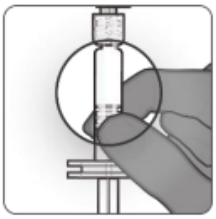
Step 7. Disconnection of syringe

- 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.

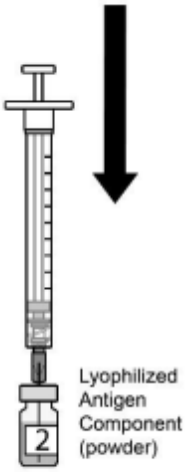


Figure 2. Slowly transfer entire contents of syringe into the lyophilized antigen component vial (powder). Vial 2 of 2.

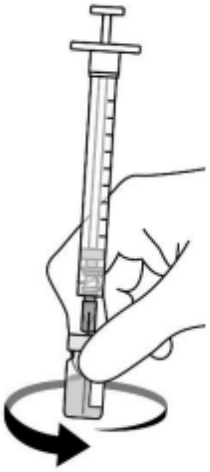


Figure 3. Gently swirl the vial until powder is completely dissolved. **Do not shake vigorously.**

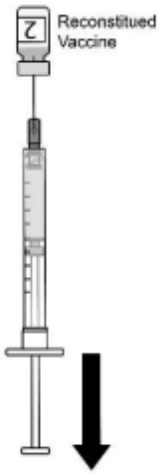


Figure 4. After reconstitution, withdraw 0.5 mL from the vial containing the reconstituted vaccine and administer intramuscularly.

15. Appendix B – mResvia preparation, storage and handling[3]

A. Preparing for administration

mResvia is supplied as a pre-filled syringe that contains a frozen suspension that must be thawed prior to administration; either in the refrigerator or at room temperature.

Configuration	Thaw in Refrigerator	Thaw at Room Temperature
Carton of one or two pre-filled syringe(s)	Thaw between 2°- 8°C (36°-46°F) for 100 minutes. Let each pre-filled syringe stand at room temperature for 10-20 minutes before administering.	Thaw between 15°-25°C (59°- 77°F) for 40 minutes. If mResvia is thawed at room temperature, the vaccine is ready to administer.
Carton of 10 pre-filled syringes	Thaw between 2°- 8°C (36°–46°F) for 160 minutes (2 hours and 40 mins). Let each pre-filled syringe stand at room temperature for 10–20 mins. before administering.	Thaw between 15°–25°C (59°–77°F) for 80 minutes (1 hr and 20 min). If mResvia is thawed at room temperature, the vaccine is ready to administer.

After thawing, **do not refreeze. Do not shake.** Do not return syringes to the refrigerator after standing at room temperature.

B. Storage and handling

During storage, protect pre-filled syringes from light. Do not refreeze once thawed. Do not shake.

Frozen Storage:

Store frozen between -40°C to -15°C (-40°F to 5°F) until expiration date.

Storage after Thawing

- Refrigerate at 2°C to 8°C (36°F to 46°F) up to 90 days prior to use; OR
- Room temperature at 8°C to 25°C (46°F to 77°F) for a total of 24 hours after removal from refrigerated conditions. Discard if not used within 24 hours. Syringes should not be returned to the refrigerator after being thawed at room temperature.

Transportation of Thawed Pre-filled Syringes

Thawed pre-filled syringes can be transported at 2°C to 8°C (36°F to 46°F). Do not refreeze and store at 2°C to 8°C (36°F to 46°F) until use.