standing orders for
Administering RSV Vaccine to Adults

Purpose

To reduce morbidity and mortality from Respiratory Syncytial Virus (RSV) by vaccinating all adults who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices.

Policy

Where allowed by state law, standing orders enable eligible nurses, pharmacists, and other healthcare professionals to assess the need for vaccination and to vaccinate adults who meet any of the criteria below.

Procedure

1 **Assess Adults for Need of Vaccination** against RSV

- ACIP recommends that adults aged ≥60 years may receive a single dose of RSV vaccine, using shared clinical decision-making
- 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 (>74 years)
    - Lung Disease
    - Cardiovascular Disease
    - Diabetes Mellitus
    - Chronic Kidney Disease
    - Moderate to severely compromised immune system

2 Screen for Contraindications and Precautions

Contraindications for use of all RSV vaccines

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

Warnings and Precautions for use of RSV vaccines

- Persons with acute, moderate or severe illness with or without fever should delay immunization until symptoms have improved.
- Immunosuppressed patients may have a diminished response
- Pregnancy and Breastfeeding: these vaccines are not approved for persons <60 years of age. It is unknown whether they are excreted in human milk.

For a list of vaccine components, refer to the manufacturer's package insert (www.immunize.org/fda) or go to www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states.

3 Provide Vaccine Information Statements

Provide all patients with a copy of the most current federal Vaccine Information Statement (VIS). Provide non-English speaking patients with a copy of the VIS in their native language, if one is available and desired; these can be found at www.immunize.org/vis. (For information about how to document that the VIS was given, see section 6 titled "Document Vaccination.")

4 Prepare to Administer Vaccine

For vaccine that is to be administered intramuscularly, choose the needle gauge, needle length, and injection site according to the following chart:

gender and weight of patient	needle gauge	needle length	injection site
Female or male less than 130 lbs	22–25	5/8"†–1"	Deltoid muscle of arm
Female or male 130–152 lbs	22–25	1"	Deltoid muscle of arm
Female 153–200 lbs	22–25	1–1½"	Deltoid muscle of arm
Male 153–260 lbs	22–25	1–1½"	Deltoid muscle of arm
Female 200+ lbs	22–25	1½"	Deltoid muscle of arm
Male 260+ lbs	22–25	1½"	Deltoid muscle of arm
Female or male, any weight	22–25	1½"	Anterolateral thigh muscle

† A 5/8" needle may be used in patients weighing less than 130 lbs (<60 kg) for IM injection in the deltoid muscle only if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90-degree angle to the skin.

5 Reconstitute Vaccine According to Appendix A and Appendix B

6 **Administer RSV Vaccine** to adults according to the criteria and guidance in the table below:

type of vaccine	adult age group	dose	route	instructions
Abrysvo [a]	≥60 years	0.5 mL	Intramuscular (IM)	Administer vaccine in deltoid muscle.
Arexvy [b]	≥60 years	0.5 mL	Intramuscular (IM)	Administer vaccine in deltoid muscle.

7 Storage and Handling

Vaccine	Temp	Storage Issues	Notes
Abrysvo [a]	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 [b]	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 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

8 Document Vaccination

Document each patient's vaccine administration information and follow up in the following places:

Medical record: Record the date the vaccine was administered, the manufacturer and lot number, the vaccination site and route, and the name and address and, if appropriate, the title of the person administering the vaccine. You must also document, in the patient's medical record or office log, the publication date of the VIS and the date it was given to the patient. Note that medical records/charts should be documented and retained in accordance with applicable state laws and regulations. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, patient refusal); discuss the need for vaccine with the patient (or, in the case of a minor, their parent or legal representative) at the next visit.

Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic.

Immunization Information System (IIS) or "registry": Report the vaccination to the appropriate state/local IIS.

9 Be Prepared to Manage Medical Emergencies

Be prepared for management of a medical emergency related to the administration of vaccine by having a written emergency medical protocol available, as well as equipment and medications.

To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

10 Report All Adverse Events to VAERS

Report all adverse events following the administration of influenza vaccine to the federal Vaccine Adverse Event Reporting System (VAERS). To submit a VAERS report online (preferred) or to download a writable PDF form, go to https://vaers.hhs.gov/reportevent.html. Further assistance is available at (800) 822-7967.

11 References

a. Pfizer. Abrysvo package insert, 2023. Available at: www.fda.gov/media/168889/download. Accessed 6 Sept. 2023.
b. GlaxoSmithKline. Arexvy package insert, May 2023. Available at www.fda.gov/media/167805/download. Accessed 6 Sept. 2023
c. 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 6 Sept 2023
d. Kroger A, Bahta L, Hunter P. General Best Practice Guidelines for Immunization. Best Practices Guidance of the Advisory Committee on Immunization Practices (ACIP), updated Aug 1 2023. Available at www.cdc.gov/vaccines/hcp/aciprecs/general-recs/downloads/general-recs.pdf. Accessed 6 Sept 2023.

Standing Orders Authorization

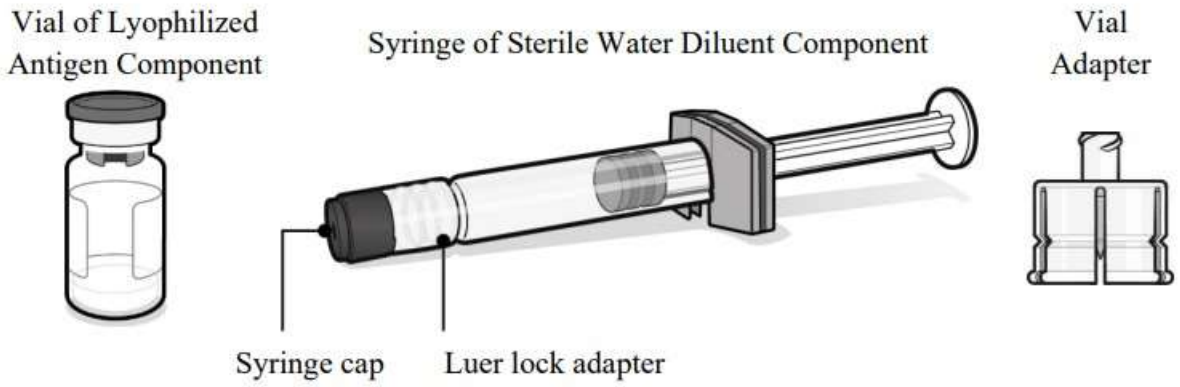
This policy and procedure shall remain in effect for all patients of the _____
NAME OF PRACTICE OR CLINIC

effective _____ until rescinded or until _____.
DATE DATE

Medical Director _____ / _____ _____
PRINT NAME SIGNATURE DATE

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

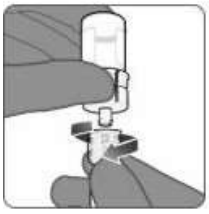
- Hold the syringe's Luer lock adapter and connect it to the vial adapter by turning clockwise.
- Stop turning when you feel resistance, overtightening the syringe may result in leaking during use.
- Once the syringe is securely attached to the vial adapter, there will be a small space between the top 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.

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.

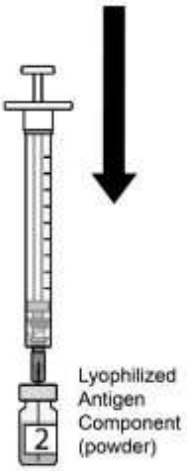


Figure 2. Slowly transfer entire contents of syringe into the lyophilized antigen component vial (powder). Vial 2 of 2.

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

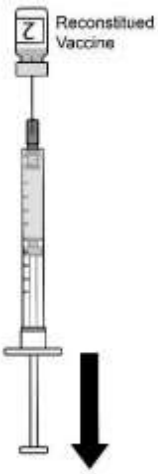


Figure 4. After reconstitution, withdraw 0.5 mL from the vial containing the reconstituted vaccine and administer intramuscularly.

Appendix B – Arexvy preparation