



Non-Patient Specific Standing Order for the Administration of Respiratory Syncytial Virus (RSV) Vaccine (ABRYSVO, AREXVY) for Persons Aged 60 Years and Older and Pregnant Women/Persons (ABRYSVO) by Pharmacists (11/8/2023)

Purpose: To reduce morbidity and mortality from RSV by administering the RSV vaccination (brand name ABRYSVO, AREXVY) as permitted by the policy and order sections of this Order. Pursuant to 8 NYCRR § 63.9, the Commissioner of Health is authorized to issue a statewide standing order where he finds that there is an outbreak of disease, or that there is imminent threat of an outbreak of disease.

Policy: Under this non-patient specific standing order, pharmacists who are employees, volunteers, and/or contractors of all pharmacies licensed in New York State and who are pharmacists authorized to administer vaccines pursuant to a certificate of administration from the Department of Education under non-patient specific orders in New York State and who are certified in cardio-pulmonary resuscitation may administer the RSV vaccination to eligible individuals, as permitted by its Biologics License Application (BLA) approval by the U.S. Food and Drug Administration (FDA), state and federal laws, ACIP recommendations, and the CDC's and New York State's Vaccination Program.

Target Population:

RSV vaccine helps protect adults 60 years and older from RSV disease. Older adults are at greater risk than young adults for serious complications from RSV because immune systems weaken with age. In addition, certain underlying medical conditions may increase the risk of getting very sick from RSV. Adults with conditions such as chronic heart or lung disease or weakened immune systems may be at increased risk for RSV disease. Adults living in long-term care facilities may especially benefit from getting an RSV vaccine.

RSV vaccine (ABRYSVO only) can be used in pregnant individuals at 32 through 36 weeks and 6 days gestational age for the prevention of lower respiratory tract disease (LRTD) and severe LRTD caused by RSV in infants from birth through 6 months of age.

There are two options for protection of infants against RSV: maternal vaccine for the pregnant woman/person or preventive antibodies given to the baby. Only one of these options is needed for most babies to be protected. CDC recommends a single dose of RSV vaccine for pregnant women/people from week 32 through 36 weeks and 6 days of pregnancy for the prevention of RSV disease in infants under 6 months of age. This vaccine is recommended to be given during the RSV season. In New York State this most often occurs from September through January.

Healthcare providers of pregnant women/people should provide information on both maternal vaccines and infant monoclonal antibody products and consider patient preferences when

determining whether to vaccinate the pregnant patient OR not vaccinate and rely on administration of nirsevimab to the infant after birth.

NOTE: Pharmacists must follow the requirements set forth in 8 NYCRR 63.9, including providing patients with requisite information, maintaining adequate records and adhering to reporting requirements.

Procedure:

1. This standing order is for use of RSV vaccine labeled for use in persons aged 60 years and older **and** for use in pregnant individuals of any age who are 32 to 36 weeks and 6 days of gestational age during the RSV season, usually between September and January in New York State.
2. ACIP and CDC recommend that adults aged 60 years and older may receive a single dose of RSV vaccine using shared [clinical decision making \(https://www.cdc.gov/rsv/high-risk/older-adults.html\)](https://www.cdc.gov/rsv/high-risk/older-adults.html) by discussing the risks and benefits with a healthcare provider.

Assess persons aged 60 years and older for eligibility for ABRYSVO or AREXVY vaccine based on the following criteria:

- a. Person is aged 60 years or older
- b. Person has not previously received RSV vaccination
- c. Person is not acutely ill (moderate to severe illness)
- d. Person may receive RSV vaccine regardless of the presence or absence of risk factors.

Factors associated with increased risk include:

- 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

3. Assess pregnant individuals of any age for eligibility for ABRYSVO vaccine based on the following criteria:

- a. The only vaccine approved for pregnant individuals is ABRYSSVO.
- b. The pregnant women/person is between 32 to 36 weeks and 6 days gestation.
- c. It is during the RSV season (typically between September and January in New York State).
- d. The pregnant person/woman has been counseled that if they receive ABRYSSVO and the infant is born ≥ 2 weeks from administration, that the infant in most situations will not need to receive nirsevimab for RSV protection.

4. Screen for contraindications and precautions

- a. **Contraindications:** Do not administer the RSV vaccine to anyone with a known history of:
 - i. a severe allergic reaction (e.g., anaphylaxis) to a prior dose of the RSV vaccine (i.e., ABRYSSVO, AREXVY),
or
 - ii. diagnosed allergy to any vaccine component listed in the prescribing information.
- b. **Precautions:**
 - i. Delay vaccination for those experiencing moderate to severe acute illness with or without fever.
 - ii. People with moderate to severe immunocompromise may have a diminished response. They may nonetheless be vaccinated.
 - iii. Potential risk of preterm birth. To avoid the potential risk of preterm birth with use of ABRYSSVO before 32 weeks of gestation, administer ABRYSSVO as indicated in pregnant individuals at 32 through 36 weeks and 6 days gestational age.
- c. **Notes:**
 - i. Coadministration with other vaccines: Coadministration of RSV vaccines with other adult vaccines during the same visit is acceptable. Administering RSV vaccine with one or more other vaccines at the same visit might increase local or systemic reactogenicity. Separate injection sites by 1 inch or more, if possible.

5. Provide information on the RSV vaccine and obtain consent

- a. Prior to vaccine administration:
 - i. Inform each patient, as applicable, of the risks, benefits, and alternatives of receiving the RSV vaccine.
 - ii. As the vaccination provider, you must communicate to the recipient or their caregiver, information consistent with the Vaccine Information

Statement for RSV, including: (1) ACIP and CDC recommend that adults aged 60 years and older may receive a single dose of RSV vaccine using shared clinical decision making and pregnant individuals should receive a single dose of ABRYSSVO only between 32 to 36 weeks 6 days gestation (2) The recipient or their caregiver has the option to accept or refuse RSV Vaccine; (3) The significant known and potential risks and benefits of RSV vaccine, and the extent to which such risks and benefits are unknown; and (4) Provide the patient or their legal guardian, as applicable, a copy of the “Vaccine Information Statement or direct the individual to <https://www.cdc.gov/vaccines/hcp/vis/vis-statements/rsv.pdf>.

- iii. For adults 60 years and older, provide the v-safe information sheet to vaccine recipients’ or vaccine recipient caregivers and encourage them to participate in v-safe. For more information, visit: www.cdc.gov/vsafe
- iv. Obtain consent to administer the vaccine from the patient or the patient’s legal guardian, as applicable, following the pharmacy’s policies for consent.

4. Storage and Handling of Vaccine

BEFORE RECONSTITUTION

- a. ABRYSSVO and AREXVY vaccines and diluents must be stored at 2°C to 8°C (36°F to 46°F).
- b. Store in original carton and protect from light.
- c. Do not freeze. Discard if carton has been frozen.

AFTER RECONSTITUTION

- a. ABRYSSVO: Reconstituted vaccine may be stored at room temperature only, 15°C to 30°C (59°F to 86°F). Use within 4 hours. Discard vaccine if not used within 4 hours. **Do not store reconstituted vaccine in refrigerator.** Do not freeze reconstituted vaccine.
- b. AREXVY: Reconstituted vaccine may be stored in the refrigerator between 2°C to 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. Do not freeze reconstituted vaccine.

5. Prepare to administer vaccine

ABRYSSVO

- a. ABRYSSVO is a single-dose vial of Lyophilized Antigen Component containing 120 mcg of RSV stabilized prefusion F proteins (60 mcg RSV preF A and 60 mcg RSV preF B) per 0.5 mL.
- b. Reconstitute with provided syringe of Sterile Water Diluent Component and vial adapter provided in the kit. Details for preparation can be found at <https://www.fda.gov/media/168889/download>.

- c. ABRYSSVO is a clear and colorless solution.
- d. 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.

AREXVY

- a. AREXVY is supplied in two (2) vials that must be combined prior to administration.
 - i. Prepare AREXVY by reconstituting the lyophilized antigen component (a sterile white powder) with the accompanying adjuvant suspension component (an opalescent, colorless to pale brownish sterile liquid).
- b. Use only the supplied adjuvant suspension component for reconstitution.
- c. The reconstituted vaccine should be an opalescent, colorless to pale brownish liquid.
- d. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.
- e. If either of these conditions exists, the vaccine should not be administered. Details for preparation can be found at: <https://www.fda.gov/media/167805/download>.
- f. After reconstitution, withdraw 0.5mL from the vial containing the reconstituted vaccine.

Needle Length Considerations

Patient Gender	Patient Weight	Needle Length
Female	< 130 lbs	5/8* – 1”
	130–152 lbs	1”
	153–200 lbs	1–1½”
	200+ lbs	1½”
Male	< 130 lbs	5/8* – 1”
	130–152 lbs	1”
	153–260 lbs	1–1½”
	260+ lbs	1½”

*Some experts recommend a 5/8-inch needle for vaccine recipients who weigh less than 130 pounds. If used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

6. Administer vaccine

- a. Visually inspect each dose in the dosing syringe prior to administration.
 - i. Verify the final dosing volume of 0.5 mL.
 - ii. Confirm there are no particulates, and that no discoloration is observed.

- iii. Do not administer if vaccine is discolored or contains particulate matter after reconstitution.
- iv. Call the manufacturer and the NYSDOH if the vaccine is discolored or contains particulate matter after mixing.
- b. Administer the RSV Vaccine, 0.5 mL, in the deltoid muscle via the intramuscular (IM) route.
- c. Document vaccination

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

Medical Record System: Ensure that the patient's name, the date the vaccine was administered, the name of the vaccine, the manufacturer and lot number, the vaccination site and route, address of administering site, and the name and title of the authorized person administering the vaccine, and the date it was given to the patient is documented in the patient's medical record or on a separate form retained by the authorized vaccinator who has administered the immunization, and in a retrievable format available to the State Education Department and the patient. If vaccine was not administered, record the reason(s) for non-receipt of the vaccine (e.g., medical contraindication, refusal). Documentation must be completed within 24 hours of administration. This information, whether in a medical record or separately kept, must be recorded and maintained in accordance with 8 NYCRR section 29.2(a)(3).

Signed Certificate of Immunization (given to the patient): Record the patient's name, date of vaccination, name/location of the administering clinic, administering vaccinator, name of vaccine, manufacturer and lot number, and recommendations for future immunizations.

New York State Immunization Information System (NYSIIS) and City Immunization Registry (CIR): Report all doses administered to those 18 years of age and younger to NYSIIS or CIR within 24 hours of administration. Report all doses administered to those 19 years of age and older to NYSIIS and CIR after obtaining consent. With respect to NYSIIS, if the dose was documented in CDMS, then the NYSDOH shall transmit data from CDMS to NYSIIS for all patients.

7. Management of medical emergencies

Be prepared for management of a medical emergency related to the administration of vaccine by maintaining written copies of the standing orders and protocols for administration of epinephrine and diphenhydramine. Vaccinator shall be responsible for having emergency anaphylaxis treatment agents, related syringes and needles at the immunization site, including sufficient epinephrine to administer at least three (3) doses to persons of any weight, H1 antihistamine, blood pressure cuff, and a stethoscope and timing device to assess pulse. To prevent syncope, vaccinate patients while they are seated or lying down and assess for signs of syncope such as extreme paleness, sweating,

coldness of the hands and feet, nausea, lightheadedness, dizziness, weakness or visual disturbances.

For more information, please see:

- CDC’s General Best Practice Guidelines for Immunization, “Preventing and Managing Adverse Reactions,” at <https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/adverse-reactions.pdf>
- Immunization Action Coalition’s “Medical Management of Vaccine Reactions in Adults in a Community Setting” at <https://www.immunize.org/catg.d/p3082.pdf>.
- Immunization Action Coalition’s “Medical Management of Vaccine Reactions in Children and Teens in a Community Setting” at <https://www.immunize.org/catg.d/p3082a.pdf>.

8. Reporting of adverse events

- a. Report any vaccine adverse events to the US Department of Health and Human Services. Visit <https://vaers.hhs.gov/> to file a report or call 1-800-822-7967.
- b. Conduct any follow-up requested by the U.S government, including CDC, FDA, or other designee, regarding adverse events to the extent feasible given the emergency circumstances.
- c. There is a registry that monitors pregnancy outcomes in individuals exposed to ABRYSVO during pregnancy. Individuals who received ABRYSVO during pregnancy are encouraged to contact, or have their healthcare provider contact, 1-800-616-3791 to enroll in or obtain information about the registry.

9. Additional Information

- [Respiratory Syncytial Virus Vaccine VIS \(cdc.gov\)](https://www.cdc.gov/vaccines/imz/ad/recommendations-respiratory-syncytial-virus-vaccine-vis.html)
- CDC Job Aid for shared clinical decision-making: <https://www.cdc.gov/vaccines/vpd/rsv/downloads/provider-job-aid-for-older-adults-508.pdf>
- AREXVY Package Insert: <https://www.fda.gov/media/167805/download>
- ABRYSVO Package Insert: <https://www.fda.gov/media/168889/download>
- Use of Respiratory Syncytial Virus Vaccines in Older Adults: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023: <https://www.cdc.gov/mmwr/volumes/72/wr/mm7229a4.htm>

Order: I am hereby prescribing this non patient-specific order for administration of RSV Vaccine (ABRYSVO, AREXVY). Specifically, pharmacists who are employees, volunteers, or contractors of the pharmacy licensed in New York State may administer RSV Vaccine

(ABRYSSVO, AREXVY), as approved by the Food and Drug Administration, state and federal laws, Executive Orders, ACIP recommendations, and the CDC's and New York State's Vaccination Program.

This non-patient specific order shall remain in effect for the vaccination of any individuals as set forth herein, beginning on 11/8/2023 through 11/8/2024. In the event that I discontinue this non patient-specific order prior to 11/8/2024 notice of such discontinuance shall be provided to those employees, volunteers, and contractors of the pharmacy licensed in New York State permitted to execute under this Order using the usual methods of communication.

A handwritten signature in black ink, appearing to read "James V. McDonald MD MPH". The signature is written in a cursive style and is contained within a rectangular box.

Signature:

Date: 11/8/2023

Name of Physician: James V. McDonald MD MPH

Title: Commissioner

Institution: New York State Department of Health

NYS License No.: 186383

Effective Date of Order: 11/8/2023

Medicaid No: 07693570