



Department of Health

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Non-Patient Specific Standing Order for the Administration of Respiratory Syncytial Virus (RSV) Vaccine (ABRYSVO, AREXVY, mRESVIA) for Persons Aged 50 Years and Older and Pregnant Persons (ABRYSVO) by Pharmacists (Updated 08/12/2025)

Purpose: To reduce morbidity and mortality from RSV by administering the RSV vaccination (brand name ABRYSVO, AREXVY, mRESVIA) 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 or Emergency Use Authorization (if applicable) by the U.S. Food and Drug Administration (FDA), state and federal laws, Executive Orders, COVID-19 Public Health Readiness and Emergency Preparedness (PREP) Act declarations, and the recommendations of the Advisory Committee on Immunization Practices (ACIP).

Target Population: RSV vaccine helps protect all adults 75 years and older from RSV disease and protects adults aged 50-74 years who are at increased risk of severe 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. For adults aged 50-74 years who are at increased risk of RSV disease and all adults 75 and older, the preferred time to get vaccinated is in late summer and early fall — just before RSV usually starts to spread in the community.

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

There are two (2) options for protection of infants against RSV: maternal vaccine for the pregnant 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 people 32 weeks 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 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 or clesrovimab 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 for use in persons aged 50 years and older **and** RSV vaccine for use in pregnant individuals ages 11 years and older who are 32 weeks through 36 weeks and 6 days of pregnancy during the RSV season, which is usually between September and January in New York State. ACIP and CDC recommend that all adults aged 75 years and older receive a single dose of RSV vaccine.
2. This standing order is for adults aged 50-74 years old to receive a single dose of RSV vaccine if they have certain risk factors that put them at an increased risk of RSV, including:
 - Cardiovascular disease (excluding isolated hypertension)
 - Chronic lung or respiratory disease
 - Advanced chronic kidney disease
 - Diabetes mellitus with end-organ damage
 - Severe obesity
 - Liver disorders
 - Neurologic or neuromuscular conditions
 - Severe obesity (body mass index ≥ 40 kg/m²)
 - Active treatment for solid tumor and hematologic malignancies
 - Moderate or severe immune compromise¹
 - Hematologic disorders
 - Residence in a long-term care facility
 - People with other chronic medical conditions or risk factors that a provider determines might increase the risk of severe disease due to respiratory infection.

More information can be found here: <https://www.cdc.gov/rsv/vaccines/adults.html>

3. Assess persons aged 50 years and older for eligibility for ABRYSCO or AREXVY or mRESVIA vaccine based on the following criteria:
 - a. Person is aged 50 years or older

¹ A list of moderately or severely immunocompromising conditions can be found in the COVID-19 vaccination interim clinical considerations. <https://www.cdc.gov/vaccines/covid-19/clinical-considerations/interim-considerations-us.html#immunocompromised>

- b. Person has not previously received RSV vaccination
 - c. Person is not acutely ill (moderate to severe illness)
- 4. Assess pregnant individuals ages 11 and older for eligibility for ABRYSSVO vaccine based on the following criteria:
 - a. The only vaccine approved for pregnant individuals is ABRYSSVO.
 - b. The pregnant person is 32 weeks through 36 weeks and 6 days of pregnancy and has not previously received an RSV vaccine.
 - i. If they have previously received an RSV vaccine their infant should receive a monoclonal antibody to protect them from RSV; the pregnant individual should not receive another RSV vaccine.
 - c. It is during the RSV season (typically between September and January in New York State).
 - d. The pregnant person 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 or clesrovimab for RSV protection.
- 5. 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, mRESVIA)
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 32 weeks through 36 weeks and 6 days of pregnancy.
 - 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.
- 6. 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 75 years and older receive a single dose of RSV vaccine and those aged 50-74 years may receive a single dose of RSV vaccine if they have certain risk factors and pregnant individuals age 11 and above should receive a single dose of ABRYSV0 only 32 weeks through 36 weeks 6 days of pregnancy; **(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)** Information about available alternative vaccines and the risks and benefits of those alternatives.
- iii. 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/current-vis/rsv.html>
- iv. Provide the v-safe information sheet to vaccine recipients or vaccine recipient's caregiver and encourage them to participate in v-safe. V-safe is one of several vaccine safety monitoring systems that helps CDC monitor vaccine side effects and vaccine safety. For more information, visit: www.cdc.gov/vsafe
- v. Obtain consent to administer the vaccine from the patient or the patient's legal guardian, as applicable, following the pharmacy's policies for consent.
- vi. Provide written instructions to the vaccine recipient or the parent or legal guardian of the vaccine recipient regarding appropriate course of action in the event of adverse reactions.

7. Prepare to administer vaccine

ABRYSV0

- a. ABRYSV0 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. ABRYSV0 is a clear and colorless solution.

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. After reconstitution, withdraw 0.5mL from the vial containing the reconstituted vaccine.

MRESVIA

- a. MRESVIA is supplied as a pre-filled syringe that contains a frozen suspension that must be thawed prior to administration.
- b. After thawing, do not refreeze. Syringes should not be returned to the refrigerator after standing at room temperature.
- c. Do not shake.
- d. Parenteral drug products should be inspected visually for particulate matter and discoloration prior to administration, whenever solution and container permit.

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 130 pounds. If used, skin must be stretched tightly (**do not bunch subcutaneous tissue**).

8. 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 (including Countermeasure Data Management System [CDMS], as applicable) : 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 § 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 pharmacist, 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 14 days 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 must transmit data from CDMS to NYSIIS for all patients ages 18 and younger and for those who are 19 and older, with consent.

9. 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. Pharmacists shall be responsible for having emergency anaphylaxis treatment agents, related syringes and needles at the immunization site, including sufficient epinephrine to administer at least 3 epinephrine prefilled syringes or autoinjectors, 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/imz-best-practices/preventing-managing-adverse-reactions.html>
- 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>.

10. 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 ABRYSSVO during pregnancy. Individuals who received ABRYSSVO 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.

11. Storage and Handling of Vaccine

- a. For storage and handling details of ABRYSSVO vaccine please refer to the package insert: <https://www.fda.gov/media/168889/download>
- b. For storage and handling details of AREXVY, please refer to the package insert: <https://www.fda.gov/media/167805/download>
- c. For storage and handling details of mRESVIA, please refer to the package insert: <https://www.fda.gov/media/179005/download>

Order: I am hereby prescribing this non-patient specific order for administration of RSV Vaccine (ABRYSSVO, AREXVY, mRESVIA). Specifically, pharmacists who are employees, volunteers, or contractors of a pharmacy licensed in New York State may administer RSV Vaccine (ABRYSSVO, AREXVY, mRESVIA), as permitted by its Biologics License Application (BLA) approval or Emergency Use Authorization (if applicable) by the U.S. Food and Drug Administration (FDA), state and federal laws, Executive Orders, COVID-19 Public Health Readiness and Emergency Preparedness (PREP) Act declarations, and the recommendations of the Advisory Committee on Immunization Practices (ACIP).

This non-patient specific order shall remain in effect for the vaccination of any individuals as set forth herein, beginning on August 12, 2025 through August 11, 2026. In the event that I discontinue this non-patient specific order prior to August 11, 2026, 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.

Signature:



Date: August 12, 2025

Name of Physician: James V. McDonald, M.D., M.P.H

Title: Commissioner, New York State Department of Health

NYS License No.: 186383

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Effective Date of Order: August 12, 2025