

STANDING ORDERS FOR Administering Pfizer Respiratory Syncytial Virus (RSV) Vaccine (Abrysvo) During Pregnancy

Purpose

To reduce morbidity and mortality from severe lower respiratory tract disease in infants age 6 months or less by vaccinating pregnant individuals who meet the criteria established by the Centers for Disease Control and Prevention's (CDC) Advisory Committee on Immunization Practices.

Note:

Only Abrysvo is approved for use during pregnancy. For this reason, this template specifies the RSV vaccine by its brand name.

Alternative options for infant RSV prevention:

If an effective dose of Abrysvo is not given during pregnancy, a dose of RSV preventive antibody should be administered to the infant before or during their first RSV season. There are two preventive antibody options:

1. Clesrovimab (Enflonsia, by Merck) is an option for infants younger than 8 months. Clesrovimab is not recommended for children age 8 months or older. The standing order template for clesrovimab is available at www.immunize.org/catg.d/p3099.pdf.
2. Nirsevimab (Beyfortus, by Sanofi) is an option for infants younger than 8 months. It is also recommended for certain high-risk children age 8 through 19 months entering their second RSV season. The standing order template for nirsevimab is available at www.immunize.org/catg.d/p3097.pdf.

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 pregnant individuals who meet the criteria below.

Procedure

1 Assessment:

Note: One dose of Abrysvo is licensed and routinely recommended by ACIP for use during a single pregnancy.

Eligibility for a single dose of Abrysvo (must meet all of the following criteria):

- **Time of year:** September 1 through January 31 in most of the continental United States. Jurisdictions with RSV seasonality that differs should follow state, local, or territorial health guidance on Abrysvo administration timing. These jurisdictions may include Alaska, southern Florida, Guam, Hawaii, Puerto Rico, U.S.-affiliated Pacific Islands, and the U.S. Virgin Islands.
- **Gestational age:** between 32 weeks and 0 days through 36 weeks and 6 days of gestation
- **Vaccination history:** No history of a previous dose of any RSV vaccine. If there is a history of a previous dose, do not vaccinate during this pregnancy: counsel them about the need for their infant to receive RSV preventive antibody after birth.
- **Maternal preference:** Either maternal Abrysvo vaccination or RSV preventive antibody administration to the infant is recommended. Both Abrysvo and RSV preventive antibody are not needed for most infants. If both products are options, the pregnant person may choose maternal vaccination or infant immunization.

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2 Screen for Contraindications and Precautions

Contraindications

Do not give Abrysvo to a recipient who has experienced a serious reaction (e.g., anaphylaxis) to any of its components. For information on vaccine components, refer to the manufacturers' package insert (www.immunize.org/official-guidance/fda/pkg-inserts/), or go to www.fda.gov/vaccines-blood-biologics/vaccines/vaccines-licensed-use-united-states.

Precaution (requires evaluation before vaccination)

Moderate or severe acute illness with or without fever

3 Provide Vaccine Information Statement

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. The RSV VIS and its translations can be found at www.immunize.org/vaccines/vis/rsv/. For information about how to document that the VIS was given, see section 6 titled "Document Vaccination."

4 Prepare to Administer Vaccine

Choose the needle gauge, needle length, and injection site according to the following chart:

WEIGHT OF PATIENT	NEEDLE GAUGE	NEEDLE LENGTH	INJECTION SITE
Less than 130 lbs	22-25	$\frac{5}{8}$ "* - 1"	Deltoid muscle of arm
130-152 lbs	22-25	1"	Deltoid muscle of arm
153-200 lbs	22-25	1"	Deltoid muscle of arm
200+ lbs	22-25	1½"	Deltoid muscle of arm
Any weight	22-25	1"* - 1½"	Anterolateral thigh muscle

* Alternative needle lengths may be used for IM injections if the skin is stretched tight, the subcutaneous tissue is not bunched, and the injection is made at a 90° angle to the skin as follows: a) a 5/8" needle for patients weighing less than 130 lbs (<60 kg) or b) a 1" needle for administration in the thigh muscle for adults of any weight.

5 Administer Vaccine

During the appropriate time of year, administer Abrysvo as a one-time intramuscular injection of 0.5 mL, between 32 weeks and 36 weeks and 6 days of gestation.

Abrysvo can be given at the same visit or at any time before or after other recommended vaccines (e.g., Tdap, influenza, or COVID-19 vaccine), using different anatomic sites.

6 Document Vaccination

Document each patient's vaccine administration information and update the following:

- 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. 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, patient preference for nirsevimab administration to infants); discuss the need for vaccine with the patient (or, in the case of a minor, their parent or legal representative) at the next visit, if still eligible.
- Personal immunization record card: Record the date of vaccination and the name/location of the administering clinic. Documentation will be necessary for the infant's healthcare provider when evaluating the infant's need for nirsevimab for RSV prevention.

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- Immunization Information System (IIS) or “registry”: Report the vaccination to the appropriate state/local IIS, if available.

7 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. For Immunize.org's “Medical Management of Vaccine Reactions in Adult Patients,” go to www.immunize.org/catg.d/p3082.pdf. To prevent syncope, vaccinate patients while they are seated or lying down and consider observing them for 15 minutes after receipt of the vaccine.

8 Report All Adverse Events to VAERS

Report all adverse events following the administration of Abrysvo RSV 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 <http://vaers.hhs.gov/reportevent.html>. Further assistance is available at (800) 822-7967.

Standing Orders Authorization

This policy and procedure shall remain in effect for all patients of the _____			
NAME OF PRACTICE OR CLINIC			
effective _____	DATE	until rescinded or until _____	DATE
.			
Medical Director _____	PRINT NAME	/ _____	SIGNATURE
			DATE