Standing Order for Administering Respiratory Syncytial Virus (RSV) Vaccine (Abrysvo) During Pregnancy

Purpose: To reduce morbidity and mortality from disease caused by respiratory syncytial virus (RSV) by vaccinating all individuals who meet the criteria established by the Centers for Disease Control and Prevention's Advisory Committee on Immunization Practices (ACIP), the Food and Drug Administration (FDA) product labeling, and the Department of Defense (DOD).

Policy: Under this standing order, eligible healthcare professionals working within their scope of practice may vaccinate patients who meet the criteria below.

Procedure:

- 1. Identify pregnant individuals at 32 and 0 days 36 weeks and 6 days of gestation who have not previously received any RSV vaccine:
 - Maternal RSV vaccination with Abrysvo is indicated for the prevention of RSV-associated lower respiratory tract disease in infants.
 - Abrysvo is currently the only RSV vaccine approved for use during pregnancy. For this reason, this standing order specifies the RSV vaccine by its brand name.
 - Abrysvo and Arexvy RSV vaccines are approved for use in individuals 60 years of age and older using shared clinical decision making.
 - Nirsevimab (Beyfortus) is recommended for infants whose mothers do not receive an effective dose of Abrysvo during pregnancy.
 - Due to the clinical judgment and discussion required, there are currently no DHA Immunization Healthcare Division (IHD) standing orders for these indications.
- 2. Using <u>DD Form 3111</u>, screen all patients for contraindications and precautions to RSV vaccine:

Contraindications:

- History of a serious reaction (e.g., anaphylaxis) after a previous dose of RSV vaccine or to an RSV vaccine component
- For information on vaccine components, refer to the package insert for <u>Abrysvo</u> and <u>The CDC Pink</u> <u>Book Appendix B</u>.

Precautions:

- Moderate or severe acute illness with or without fever
- Syncope (fainting) can occur in association with administration of injectable vaccines. Have procedures in place to avoid a falling injury (e.g., 15-minute observation after administration) and to restore cerebral perfusion.
- For questions or concerns, consider consulting the DHA-IHD Support Center at (877) 438- 8222, Option 1 or DSN 312-761-4245.

- 3. Provide all patients (or their parent/legal representative) with a copy of the most current federal <u>Vaccine</u> <u>Information Statement (VIS)</u>. You must document, in the patient's medical record, the publication date of the VIS and the date it was given to the patient (parent/legal representative). Provide non-English speaking patients with a copy of the VIS in their native language, if available and preferred.
- 4. Provide vaccine as follows:
 - Administer a single 0.5mL dose of Abrysvo RSV vaccine intramuscularly (IM) according to Table 1.
 - Abrysvo RSV vaccine:
 - Is for seasonal use (e.g., given September through January in the Northern Hemisphere).
 - Must be reconstituted prior to administration using only the manufacturer-supplied diluent.
 - After reconstitution, must be used immediately or stored at room temperature (15°C-30°C [59°F-86°F]) and discarded within 4 hours.
 - Areas where RSV seasonality differs from most of the continental US (e.g., Alaska and tropical climates [parts of Florida, Guam, Hawaii, Puerto Rico, U.S. Virgin Islands, and U.S.-affiliated Pacific Islands]) have flexibility to determine their administration timeframe.
 - Receipt of additional doses in subsequent pregnancies is not currently recommended.
 - 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.

TABLE 1. IM Needle Length and Injection Site Guide		
Use a 22 – 25-gauge needle. Choose needle gauge and length appropriate to the patient's age		
Patient Age	Needle Length	Injection Site
Less than 130 lbs	5/8* - 1 inch (16-25 mm)	
130-200 lbs	1 inch (25 mm)	Deltoid muscle of arm
More than 200 lbs	1.5 inches (38 mm)	
Any weight	1 inch* - 1.5 inches (38 mm)	Anterolateral thigh

Adapted from General Best Practice Guidelines for Immunization: Vaccine Administration. <u>https://www.cdc.gov/vaccines/hcp/acip-recs/general-recs/administration.html</u> * If skin is stretched tightly and subcutaneous tissues are not bunched.

† Preferred site.

- 5. There is a pregnancy exposure 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.
- 6. Document all immunizations administered in the patient's electronic health record and the appropriate immunization tracking system. Include date, immunization given, dose, anatomical location of administration, lot number, manufacturer, Vaccine Information Sheet (VIS) date, and the identification of the person administering the vaccine. If vaccine was not given, record the reason for non-receipt.
- 7. Be prepared to manage a medical emergency related to the administration of vaccines by having a written emergency medical protocol available, as well as equipment and medications.

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- 8. Adverse events occurring after administration of any vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS) online at <u>https://vaers.hhs.gov</u>. Additional information about VAERS is also available by telephone (800-822-7967).

Medical Director's Signature

Date