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TECHNICAL BULLETIN

DATE: November 2, 2023
TOPIC: FDA Approves Use of Respiratory Syncytial Virus (RSV) Immunization for Pregnant Individuals to Prevent RSV in Infants
CONTACT: Joseph Crump, RN, Nevada State Immunization Program
TO: All Health Care Providers and Facilities; Pharmacists; Local Health Authorities

BACKGROUND

On August 21, 2023, the U.S. Food and Drug Administration approved ABRYSVO (Respiratory Syncytial Virus Vaccine), the first vaccine approved for use in pregnant individuals to prevent lower respiratory tract disease (LRTD) and severe LRTD caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age. ABRYSVO is approved for use at 32 through 36 weeks gestational age of pregnancy. ABRYSVO is administered as a single dose, intramuscular injection. The FDA also approved ABRYSVO in May 2023 for the prevention of LRTD caused by RSV in individuals 60 years of age and older.

In most parts of the United States, RSV circulation is seasonal and typically starts during the fall and peaks in the winter and the virus is transmitted from person to person through close contact with someone infected.

Those eligible to receive a single 0.5 mL dose of ABRYSVO, include:

- Pregnant individuals at 32 through 36 weeks gestation.
- Individuals aged 60 years and older.

ABRYSVO must be reconstituted prior to administration.

STORAGE AND HANDLING

Store refrigerated at 2°C to 8°C (36°F to 46°F) in the original carton. Do not freeze. Discard if the carton has been frozen.

After reconstitution, administer ABRYSVO immediately or store at room temperature [15°C to 30°C (59°F to 86°F)] and use within four hours. Do not store reconstituted vaccine under refrigerated conditions [2°C to 8°C (36°F to 46°F)]. Do not freeze reconstituted vaccine.

CLINICAL PHARMACOLOGY

Active immunization

ABRYSVO induces an immune response against RSVpreF that protects against lower respiratory tract disease caused by RSV.

Passive immunization

Antibodies to RSV antigens from individuals vaccinated in pregnancy are transferred transplacentally to protect infants younger than 6 months of age against LRTD and severe LRTD caused by RSV.

Precautions and contraindications for ABRYSVO include, but are not limited to, the following:

- RSVpreF (ABRYSVO, Pfizer) should not be administered to a person with a history of severe allergic reaction, such as anaphylaxis, to any component of this vaccine. Information about ABRYSVO can be found in the manufacturer's package insert.
- Adults with a minor acute illness, such as a cold, can receive RSV vaccination. Moderate or severe acute illness, with or without fever, is a precaution to vaccination; vaccination should generally be deferred until the patient improves.

To learn more, see Advisory Committee on Immunization Practice (ACIP) Contraindications Guidelines for Immunization, General Best Practice Guidelines for Immunization.

VACCINE SAFETY/ADVERSE EFFECTS

Among pregnant people in the clinical trial who received either the maternal RSV vaccine or a placebo during weeks 32 through 36 of pregnancy, preterm birth occurred in 4.2% of pregnant people who received the RSV vaccine compared to 3.7% of pregnant people who received a placebo.

Although not common in the clinical trials, hypertensive disorders of pregnancy (including pre-eclampsia) occurred in 1.8% of pregnant people who received the RSV vaccine compared to 1.4% of pregnant people who received a placebo.

Pre-eclampsia, low birth weight (meaning less than 5.5 lbs.), and jaundice in newborns occurred more frequently in infants born to mothers who received the RSV vaccine compared to infants born to mothers who received a placebo. These conditions are often associated with preterm birth.

Adverse reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS). Health care providers will usually file this report, or individuals may complete the form. Visit the VAERS website or call 1-800-822-7967. VAERS is only for reporting reactions. VAERS staff members do not give medical advice.

Questions

For updated guidance, review the Division of Public and Behavioral Health Technical Bulletin web page regularly. Email nviz@health.nv.gov for other questions regarding RSV.

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