IOWA | Health and Human Services

Vaccines for Children (VFC) Program Maternal RSV Vaccine -Vaccine Summary January 9, 2024

Purpose

- Effective January 9, 2024, maternal RSVpreF vaccine (ABRYSVO), manufactured by Pfizer is available to order through the Iowa VFC Program.

Food and Drug Administration (FDA)

On August 21, 2023 the FDA approved Pfizer's maternal RSVpreF vaccine (ABRYSVO) for the prevention of 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.

Advisory Committee on Immunization Practices (ACIP)

On September 22, 2023, CDC's Advisory Committee on Immunization Practices (ACIP) recommended Pfizer's Abrysvo maternal RSVpreF vaccine for pregnant persons 32 through 36 weeks gestation to protect infants from RSV from birth through the first six months of life. The recommendations were adopted by the CDC director and are official.

VFC Program Resolution

The Federal VFC Program follows the ACIP recommendations for the use of Abrysvo vaccine as an option for vaccinating eligible pregnant people aged <19 years.

Abrysvo is considered a non-routine vaccine for most VFC providers based on the populations they serve. As a non-routine vaccine for most VFC providers, providers are not required to stock RSV maternal vaccine as part of their routine inventory.

ACIP Recommended Schedule for Abrysvo Vaccine

- A one-time dose at 32 through 36 weeks gestation, using seasonal administration, which is during September through January in most of the continental United States.
- Either RSV vaccination during pregnancy at 32 through 36 weeks gestation or RSV monoclonal antibody product administration for infants age <8 months shortly before or during the RSV season is recommended to prevent RSV lower respiratory tract infection, but both products are not indicated for most infants.

Recommended Dosage and Administration

The recommended dose is 0.5mL administered as an intramuscular injection. It is supplied in a kit that includes a vial of lyophilized antigen component (a sterile white powder), a prefilled syringe containing Sterile Water Diluent Component and a vial adapter. Refer to the package inserts for further details. Maternal RSVpreF vaccine may be simultaneously administered with other indicated vaccinations.

Vaccine Storage and Handling

Storage Before Reconstitution

- Store refrigerated at 2 - 8°C (36 - 46°F) in the original carton.
- Do not freeze.
- Do not use product if exposed to out of range temperatures.
- Do not use after expiration date shown on the label.

Storage After Reconstitution

- After reconstitution, administer immediately or store at room temperature 15°C and 30°C (59°F and 86°F) and use within 4 hours. Discard reconstituted vaccine if not used within 4 hours.
- Do not store reconstituted vaccine under refrigerated or freezer conditions.

Precautions

- Potential risk of preterm birth. To avoid the potential risk of preterm birth with use of ABRYSVO before 32 weeks of gestation, administer ABRYSVO as indicated in pregnant individuals at 32 through 36 weeks gestational age.

Contraindications

- History of severe allergic reaction (e.g., anaphylaxis) to any component of ABRYSVO.

Always consult the package insert for precautions, warning and contraindications and the most current guidance from CDC.

Reporting of Adverse Events

Adverse events following administration of any vaccine should be reported to the Vaccine Adverse Event Reporting System (VAERS). Reports can be submitted to VAERS online, by fax, or by mail. Additional information about VAERS is available by telephone (1-800-822-7967) or online (https://vaers.hhs.gov).

CPT Code

90678