State of California—Health and Human Services Agency
California Department of Public Health

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TO: California Vaccines for Children (VFC) Providers

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SUBJECT: RSVpreF Vaccine for Pregnant People Available Through VFC for Prevention of Severe RSV Disease

Key Takeaways

- Respiratory Syncytial Vaccine (RSV) vaccine (Abrysvo™) is recommended for pregnant people during 32 through 36 weeks' gestation, using seasonal administration (September-January), to prevent RSV lower respiratory tract infection in infants.
- RSV maternal vaccine has been added to the Vaccines For Children (VFC) program.
- Either prenatal vaccination or administration of nirsevimab in the infant is recommended to prevent RSV lower respiratory tract infection, but administration of both products is not needed for most infants.
- Healthcare providers of pregnant people should provide information on both products and consider patient preferences when determining whether to vaccinate the pregnant patient. Prenatal care providers should discuss potential nirsevimab supply concerns when counseling pregnant people about RSV vaccine.

SUMMARY AND BACKGROUND

RSVpreF Vaccine (Abrysvo™) is now available to order from VFC to prevent severe respiratory syncytial virus (RSV) disease in VFC-eligible pregnant persons under 19 years of age. VFC providers may order prenatal RSV vaccine monthly.

RSV is a common cause of respiratory infections. Each year, an estimated 58,000 to 80,000 children under 5 years of age are hospitalized and 100 to 300 children die due to RSV. Virtually all children have had an RSV infection by the time they are 2 years old, and infants and younger children are at increased risk of severe disease. Among pregnant individuals, RSV rates are estimated to be about 26 per 1000-person years.

The US Food and Drug Administration (FDA) has licensed and CDC's Advisory Committee for Immunization Practices (ACIP) recommends prenatal RSV vaccine, composed of RSVpreF lyophilized antigen component and a sterile water diluent component, to protect all infants from RSV. In clinical trials, prenatal RSV vaccine was 48.2% effective in preventing infant hospitalization for RSV infection. Protection from a dose of prenatal RSV vaccine is expected to last at least 3 months in the newborn.

CDPH encourages each VFC provider to review information on these products. It is important to educate all staff regarding the storage, preparation, administration, dose schedule, and recordkeeping for any new immunization products used in your practice.

RECOMMENDATIONS FOR USE OF ABRYSVO

Pregnant people should get a single dose of Pfizer's RSVpreF vaccine (Abrysvo) during weeks 32 through 36 of pregnancy during September through January.

Timing
Prenatal RSV vaccine should be given to pregnant persons during weeks 32 to 36 of pregnancy during September to January.

Route and Dosing
Administer RSVpreF vaccine (Abrysvo, Pfizer) intramuscularly. The preferred site of administration is the deltoid region of the upper arm. Do not administer RSV vaccine intravenously, intradermally, or subcutaneously.

Number of Doses
RSVpreF vaccine (Abrysvo, Pfizer) is currently approved and recommended for administration as a single dose. Sufficient evidence does not exist at this time to determine the need for additional doses in subsequent pregnancies.

Administration with other vaccines
Pregnant people can receive RSV, Tdap, COVID-19, and influenza vaccines at the same clinic visit when the vaccines are recommended. CDC's general best practice guidelines for immunization indicate that age-appropriate vaccinations can be given at the same visit, unless there is a specific reason not to.

Prior to the administration of RSV vaccine, parents or guardians of patients must be provided with an RSV Vaccine Information Statement (VIS).

Ingredients
RSVpreF (Abrysvo, Pfizer) consists of a bivalent, recombinant RSV F protein antigen (based on both the RSV-A and RSV-B subtypes), stabilized in the prefusion conformation (preF). The vaccine is supplied as a single-dose vial of 120 µg of lyophilized preF antigen component (60 µg from RSV-A, 60 µg from RSV-B) to be reconstituted with the accompanying vial of sterile water

diluent component. A single dose after reconstitution is approximately 0.5 mL. Consult the package insert for proper storage and handling details, shelf life, and reconstitution instructions: Package Insert – ABRYSVO.

POTENTIAL VACCINE REACTIONS

Patients should be counseled regarding the risks of a vaccine reaction and provided with the RSV Vaccine Information Statement. Encourage your patients to participate in CDC's V-safe program, which allows people to share with CDC how they feel after receiving the vaccine. In clinical trials, the most-reported side effects by pregnant people who received the RSVpreF (Abrysvo) vaccine were pain at the injection site, headache, myalgia, and nausea.

Preterm birth

People in the clinical trial received prenatal RSV vaccine during weeks 24 through 36 of pregnancy. More preterm births were observed among prenatal RSV vaccine recipients than among placebo recipients; however, this difference was not statistically different. Among pregnant people in the clinical trial who received either the prenatal 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.

Available data are insufficient to establish or exclude a causal relationship between preterm birth and RSVpreF (Abrysvo). To reduce the potential risk of preterm birth when administering prenatal RSV vaccine, FDA approved the vaccine for use during weeks 32 through 36 of pregnancy. The vaccine studies did not include people who already had a higher risk of preterm births.

Other safety outcomes

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.

CONTRAINDICATIONS AND PRECAUTIONS

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 ACIP Contraindications Guidelines for Immunization, General Best Practice Guidelines for Immunization.

STORAGE AND HANDLING

Storage Before Reconstitution
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.

Storage After Reconstitution
After reconstitution, administer ABRYSVO immediately or store at room temperature [15ºC to 30ºC (59ºF to 86ºF)] and use within 4 hours. Do not store reconstituted vaccine under refrigerated conditions [2ºC to 8ºC (36ºF to 46ºF)]. Do not freeze reconstituted vaccine.

ORDERING

Requirements
VFC providers are required to offer prenatal RSV if they see patients in the recommended age group, along with all other age-appropriate ACIP-recommended vaccines. As agreed upon during initial enrollment and recertification, all actively enrolled VFC Providers must “order all ACIP-recommended vaccines (including flu and special-order vaccines) to meet the needs of the total VFC-eligible patient populations reported for the VFC PIN” (Provider Agreement Addendum 8A).

Process
Submit your request for Abrysvo on the VFC order form this month, even if it is not time to place your routine VFC vaccine order. RSV vaccine is recommended to be administered through January 2024. Order enough doses needed for use in your VFC-eligible pregnant patients 18 years of age or younger within the recommended weeks of gestation. Abrysvo orders may be process as urgent through the remainder of the administration window. Please indicate if your practice is able to receive next day deliveries in the comments of your order.

Order Quantity
Abrysvo (NDC: 00069-0344-01) is provided through the VFC Program in a one-pack, one-dose vial. The minimum order quantity is one dose.

BILLING

CHDP
Claims may be submitted for VFC-supplied vaccine doses administered to CHDP-eligible patients through age 18 years. Please refer to the CHDP Provider manual and relevant CHDP Provider Information Notice. For questions, CHDP providers may contact their County CHDP Program.

Medi-Cal Fee-For-Service (FFS)
To bill Medi-Cal FFS for administration of VFC-supplied doses of prenatal RSV vaccine, use the appropriate CPT-4 code, followed by the “-SL” modifier; i.e., 90678-SL. Providers will only be reimbursed for the administration fee when using VFC vaccines for Medi-Cal FFS-eligible patients.

For specific information and details on Medi-Cal billing, please refer to the Medi-Cal provider manual on VFC. Providers with questions on Medi-Cal billing policies and procedures and Provider manual information may call the Telephone Service Center (TSC) at 1-800-541-5555.

Medi-Cal Managed Care
Please contact the specific Medi-Cal managed care health plan for information on immunization billing and reimbursement.

REPORTING VACCINE ADMINISTRATION TO CAIR

All VFC providers are required to enter all vaccine doses administered into CAIR or Healthy Futures/RIDE, in accordance with state law and the 2024 VFC Provider Participation Agreement. Please also make sure that the appropriate VFC Eligibility category is recorded for doses.

RESOURCES

- RSV Vaccine Information Statement (VIS)
- CDC: Healthcare Providers: RSV Vaccination for Pregnant People
- Bivalent Prefusion F Vaccine in Pregnancy to Prevent RSV Illness in Infants
- Use of the Pfizer Respiratory Syncytial Virus Vaccine During Pregnancy for the Prevention of Respiratory Syncytial Virus–Associated Lower Respiratory Tract Disease in Infants: Recommendations of the Advisory Committee on Immunization Practices — United States, 2023
- JID: Burden of respiratory syncytial virus-associated acute respiratory infections during pregnancy
- ACIP General Best Practice Guidelines for Immunization