RSVPreF Vaccine Recommended in Pregnancy

Summary
Respiratory syncytial virus (RSV) is the leading cause of infant hospitalization in the United States. Infants aged <8 months are at the highest risk of hospitalization and death from RSV. Infants in some Alaska regions, including Western Alaska, are at particularly high risk of severe RSV illness. Alaska clinicians now have two ways to protect infants from severe illness caused by RSV: a dose of monoclonal antibody (nirsevimab) for infants, or maternal vaccination during pregnancy. For infants aged <8 months born during or entering their first RSV season whose mother’s receipt of RSVPreF is unknown or who were born <14 days after maternal vaccination, administration is recommended prior to hospital discharge after birth. For infants aged <6 months are born to vaccinated mothers. These include:

- Infants born <14 days after maternal vaccination.
- Infants born to mothers who were pregnant during September through January and the pregnant woman received nirsevimab because of potential increased efficacy.

Vaccination Safety and Efficacy
RSVPreF was determined to be safe and efficacious by the US Food and Drug Administration (FDA) and the ACIP. Vaccine efficacy was assessed among infants from birth through 180 days of life. Clinical trials determined that efficacy against medically attended RSV-associated LRTI was 53.7% when vaccination was given at the recommended dosing interval (32–26 weeks gestation). Maternal RSV vaccine reduced the risk of any severe RSV infection by 81.8% up to 6 months of age, 69.4% up to 6 to 6 months. For comparison, administration of nirsevimab to the infant reduced hospitalization risk by 90% during the infant’s first RSV season.

No statistically significant increase in adverse events were seen in clinical trials; however, a difference in preterm births and hypertensive disorders in pregnancy were seen. For this reason, RSVPreF was approved for 32–36 weeks gestation instead of the 24–36 weeks gestation range used in clinical trials. Any adverse events following vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS).

Timing
RSVPreF vaccination should occur during 32–36 weeks of pregnancy beginning in September and extending through January. Clinicians will be notified if Alaska-specific data warrant extending administration beyond January. There is currently no national guidance available regarding the potential need for additional doses of RSVPreF during subsequent pregnancies.

Precautions and Contraindications
Moderate or severe acute illness with or without fever is a precaution to vaccination. RSV vaccines are contraindicated for persons with a severe allergy to any vaccine component.

RSVPreF and Nirsevimab
For most infants, either maternal vaccination or the use of nirsevimab is sufficient for protection during the infant’s first RSV season. Nirsevimab protection might last longer and does not rely on transplacental transfer or potential risks to pregnancy but does require infant injection. Maternal vaccination provides protection immediately after birth and may be more resistant to RSV mutations, but protection might be reduced if fewer antibodies are made or transferred and there is a potential risk for preterm birth and hypertensive disorders of pregnancy.

There are some situations where offering nirsevimab in addition to maternal vaccination may be clinically warranted for infants born to vaccinated mothers. These include:

- Infants born at <34 weeks gestation.
- Infants born <14 days after maternal vaccination.
- Infants with substantially increased risk for severe disease to warrant nirsevimab because of potential increased efficacy.

Nirsevimab is recommended for infants aged <8 months born during or entering their first RSV season whose mother’s receipt of RSVPreF is unknown or who were born <14 days after maternal vaccination.

Available Vaccines
Pharmacies, health care clinics, and other facilities may offer RSV vaccines. RSV vaccines will be available to Alaskans via private purchase by health care providers, the Alaska Vaccine Assessment Program (AVAP), and the Vaccines for Children Program (VFC) for pregnant women aged <19 years.

References

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