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RSVPreF Vaccine Recommended in Pregnancy

Summary

Respiratory syncytial virus (RSV) is the leading cause of infant hospitalization in the United States.¹ Infants aged <6 months are at the highest risk of hospitalization and death from RSV.¹ Infants in some Alaska regions, including Western Alaska, are at particularly high risk of severe RSV illness.² 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.³⁻⁵ For infants aged <8 months, receiving one dose of nirsevimab during their first RSV season provides strong protection against severe RSV.³ In September 2023, the Advisory Committee on Immunization Practices (ACIP) recommended one dose of RSVPreF (Abrysvo, Pfizer) RSV vaccine for patients during 32–36 weeks gestation to prevent RSV-associated lower respiratory tract infection (LRTI) in infants.⁶

Vaccination Safety and Efficacy

RSVPreF was determined to be safe and efficacious by the US Food and Drug Administration (FDA) and the ACIP.⁵ Vaccine efficacy was assessed among infants from birth through 180 days of life.⁵ Clinical trials determined that efficacy against medically attended RSV-associated LRTI was 57.3% when vaccination was given at the recommended dosing interval (32–26 weeks gestation).⁵ Maternal RSV vaccination reduced the risk of any severe infant RSV disease by 81.8% up to age 3 months and 69.4% up to age 6 months. For comparison, administration of nirsevimab to the infant reduced hospitalization risk by 90% during the infant's first RSV season.³

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.⁵ For this reason, RSVPreF was approved for 32–36 weeks gestation instead of the 24–36 weeks gestation range used in clinical trials.⁵ Any adverse events following vaccination should be reported to the Vaccine Adverse Event Reporting System (VAERS).⁵

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.⁵

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.⁵ Nirsevimab protection might last longer and does not rely on transplacental transfer or pose potential risks to pregnancy but does require infant injection.⁵ 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.

- Maternal immunocompromise or maternal condition resulting in decreased transplacental antibody transfer.
- Infants who have undergone cardiopulmonary bypass, leading to loss of maternal antibodies.
- 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.⁵ Administration is recommended prior to hospital discharge after birth, but ideally within the first week of life.³ High-risk infants/children aged 8–19 months (including Alaska Native/American Indian children) who are entering their second RSV season are recommended to receive nirsevimab regardless of maternal RSVpreF vaccination.⁵

Summary Recommendations

- Clinicians should offer either the maternal vaccine or nirsevimab (to infants) in order to protect infants against RSV-associated LRTI. While there are some exceptions (see above), administration of both products is not needed to protect most infants.⁵
- Clinicians should offer RSVPreF vaccination at 32–36 weeks gestation during September through January and discuss the relative advantages and disadvantages of both nirsevimab and the RSVPreF vaccine with expectant parents to determine their plans and preferences.
- RSVPreF may be administered with other adult vaccines during the same visit, including those for influenza, COVID-19, and tetanus.^{5,6}
- Clinicians should be attentive to administer the correct RSV vaccine to pregnant women. RSVPreF (Abrysvo) is approved for use during pregnancy and for adults aged ≥60 years; however, *RSVPreF3 (Arexvy)* is a similar-sounding RSV vaccine that is *not approved for use during pregnancy* and is only appropriate for use in adults aged ≥60 years.

Availability of 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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