Respiratory Syncytial Virus vaccines (RSV)

Options for Infant RSV Prevention

At-a-Glance

Two immunization products are available for the prevention of severe Respiratory Syncytial Virus (RSV) disease in infants: maternal RSV vaccine and infant RSV monoclonal antibody. All infants should be protected against severe RSV disease through use of one of these products.

Either maternal RSV vaccination or use of RSV monoclonal antibody in the infant is recommended. Administration of both products is not needed for most infants.

Maternal RSV vaccination: Use ONLY Pfizer RSVPreF vaccine (trade name Abrysvo™)

Maternal RSV Vaccine

RSVPreF vaccine (trade name Abrysvo™) is recommended for people during weeks 32 through 36 of pregnancy, using seasonal administration, to prevent severe RSV disease in infants. In clinical trials, there was a small increase in the number of preterm birth events in vaccinated pregnant people after vaccination. It is not clear if this is a true safety problem related to RSV vaccine or if this occurred for reasons unrelated to vaccination.

Infant RSV Monoclonal Antibody*

RSV monoclonal antibody (generic name nirsevimab, trade name Beyfortus™) is recommended for the following:

- Infants less than 8 months of age born during or entering their first RSV season if:
  - Mother did not receive maternal RSV vaccine or it is unknown if mother received RSV vaccine

    OR
  - Infant was born less than 14 days after maternal RSV vaccination†

  In rare circumstances, nirsevimab may be considered for infants born to mothers vaccinated 14 or more days before birth when the health care provider believes the potential incremental benefit is warranted. These situations include, but are not limited to:
  - Infants born to mothers who might not have mounted an adequate immune response to vaccination (e.g., people with immunocompromising conditions)
  - Infants born to mothers who have conditions associated with reduced transplacental antibody transfer (e.g., people living with HIV infection)
  - Infants who might have experienced loss of maternal antibodies, such as those who have undergone cardiopulmonary bypass of extracorporeal membrane oxygenation (ECMO)
  - Infants with substantial increased risk for severe RSV disease (e.g., hemodynamically significant congenital heart disease, intensive care admission with the requirement for oxygen at hospital discharge)
- Some infants and children aged 8 through 19 months who are at increased risk of severe RSV disease entering their second RSV season.
  - American Indian/Alaska Native children
  - Children with chronic lung disease of prematurity who require medical support during the six months before the start of their second RSV season
  - Children with severe immunocompromise
  - Children with severe cystic fibrosis

*Note: A different monoclonal antibody, palivizumab, is used in children under 24 months of age with certain conditions that place them at high risk for severe RSV disease. Please see AAP guidelines for palivizumab. AAP has published considerations on the use of nirsevimab and palivizumab: https://publications.aap.org/redbook/resources/25379. Children who have received nirsevimab should not receive palivizumab during the same RSV season.

†From time of maternal vaccination, at least 14 days are needed for the development and transplacental transfer of maternal antibodies to protect the infant.

Clinical Considerations for Use of Maternal RSV Vaccine or Infant RSV Monoclonal Antibody

(Administration of both products is not needed for most infants)

Product	Maternal RSV Vaccine	RSV Monoclonal Antibody
Description	RSVPreF vaccine Trade name: Abrysvo™	Generic name nirsevimab Trade name: Beyfortus™
Immunity	Mother – Active immunity Infant – Passive immunity	Passive immunity
Duration of Protection	Approximately 3 to 6 months for infant	Approximately 5 months or more
How Supplied	A kit that includes a vial of lyophilized antigen component, a prefilled syringe containing sterile water diluent, and a vial adapter. The lyophilized antigen component is reconstituted with the sterile water diluent to form a single dose.	Single dose pre-filled syringe with a purple (for 50 mg dosage) or light blue (for 100 mg dosage) plunger rod. No reconstitution needed.
Recommended Dosage	0.5 mL Currently recommended for administration as a single dose. It is not yet known whether additional doses might be needed in later pregnancies.	**Age less than 8 months** • Less than 5 kg: 50 mg (0.5mL) • 5 kg and greater: 100 mg (1mL) **Age 8 through 19 months‡** • 200 mg (administered as two IM injections)
Number of Doses	One	One§
How Administered	IM injection	IM injection
Coadministration	Can be administered without regard to timing of other routine immunizations, including simultaneous administration	Can be administered without regard to timing of other routine immunizations, including simultaneous administration
Gestation or Age for Immunization	32 through 36 weeks	• Less than age 8 months depending on mother's RSV vaccination status • Ages 8 through 19 months if at increased risk for severe RSV disease.‡
When to Administer (Seasonality)	Beginning of September through end of January in most of the continental United States. In jurisdictions with RSV seasonality that differs from most of the continental United States, including Alaska, southern Florida, Guam, Hawaii, Puerto Rico, U.S.-affiliated Pacific Islands, and U.S. Virgin Islands, healthcare providers should follow state, local, or territorial guidance on timing of maternal RSV vaccination.	Beginning of October through end of March in most of the continental United States. In jurisdictions with RSV seasonality that differs from most of the continental United States, including Alaska, southern Florida, Guam, Hawaii, Puerto Rico, U.S.-affiliated Pacific Islands, and U.S. Virgin Islands, healthcare providers should follow state, local, or territorial guidance on timing of nirsevimab administration.
Contraindications (Product Should Not Be Administered)	History of severe allergic reaction (e.g., anaphylaxis) to any component of the maternal RSV vaccine	History of severe allergic reaction (e.g., anaphylaxis) after a previous dose or to a component of nirsevimab

Clinical Considerations for Use of Maternal RSV Vaccine or Infant RSV Monoclonal Antibody

(Administration of both products is not needed for most infants)

Product	Maternal RSV Vaccine	RSV Monoclonal Antibody
Precautions (Administration Should Typically Be Deferred)	The presence of a moderate or severe acute illness, with or without a fever.	The presence of a moderate or severe acute illness, with or without a fever.
Safety	• **Local and systemic reactions** In clinical trials, the most common reactions after maternal RSV vaccine in pregnant people were pain at the injection site, headache, muscle pain, and nausea. • **Severe allergic reactions** As with any medicine or vaccine, there is a remote chance of RSV vaccine causing a severe allergic reaction • **Preterm birth** In clinical trials, among people who were vaccinated during weeks 24 through 36 weeks of pregnancy, more preterm births were reported among maternal RSV vaccine recipients than among placebo recipients. This difference was not statistically different. Available data are insufficient to establish or exclude a causal relationship between preterm birth and maternal RSV vaccine. To reduce the potential risk of preterm birth when administering maternal 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. • **Hypertensive disorders of pregnancy** 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.	• **Local and systemic reactions** In clinical trials, the most common adverse events after nirsevimab were rash and injection-site reactions, each occurring in <1% of infants and young children. • **Severe allergic reactions** As with any medicine or vaccine, there is a remote chance of nirsevimab causing a severe allergic reaction. • **Serious adverse event** The incidence of serious adverse events was not increased in the nirsevimab arm compared with that in the placebo arm. No serious allergic reactions or immune complex disease were reported in the clinical trials.

‡Children 8–19 months who are at increased risk of severe RSV disease (American Indian and Alaska Native children; children who are severely immunocompromised; children with cystic fibrosis with severe disease; and children with chronic lung disease of prematurity who require medical support during the six months before the start of their second RSV season) should receive nirsevimab 200 mg dose administered as two IM injections (2 x 100 mg light blue plunger rod) shortly before the start of their second RSV season.

§One dose for each RSV season except for children undergoing cardiac surgery with cardiopulmonary bypass where an additional dose is recommended as soon as the child is stable after surgery. See label (fda.gov).

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