

Protecting Your Baby From RSV

Respiratory Syncytial Virus (RSV) Immunization Options

What are the options to protect babies from RSV?

- Maternal RSV vaccine (Abrysvo™)** for:
 - Pregnant women 32-36 weeks gestation
 - During months of September-January
 - **This option is encouraged during the 2023-2024 RSV season due to limited supply of alternative option, nirsevimab.**
- Nirsevimab (Beyfortus™) monoclonal antibody recommendations for the 2023-2024 RSV season due to limited product supply:
 - All babies weighing <11 lbs born during RSV season (October-March) should receive a dose in the first week of life.
 - All babies <11 lbs born prior to October 2023 should receive a dose.
 - For babies weighing ≥11 lbs, a dose is recommended for those at highest risk of severe RSV:
 - Babies aged <6 months
 - American Indian and Alaska Native babies aged <8 months
 - Babies aged 6 to 8 months with conditions placing them at high risk of severe RSV disease
 - American Indian and Alaska Native children aged 8-19 months entering their second RSV season based on medical provider recommendation
- If nirsevimab is unavailable**, palivizumab (Synagis™) monoclonal antibody based on medical provider assessment for babies and young children with certain medical conditions in either their first or second RSV season may be an option.
 - Palivizumab is given as 5 monthly injections.
 - Palivizumab requires a prior authorization from payers.

Why should babies be protected against RSV?

- RSV is the most common cause of hospitalization of babies.
- RSV is the most common cause of bronchiolitis (inflammation of the small airways in the lungs) and pneumonia (infection of the lungs) in children under one year old in the United States.
- Most RSV hospitalizations occur in otherwise healthy babies with no underlying health conditions.

What should you know about the maternal RSV vaccine?

- Pregnant women are recommended to be immunized at 32-36 weeks gestation to pass antibodies on to the baby to protect against RSV during the first months of life.
- The maternal RSV vaccine can reduce a baby's risk of being hospitalized from RSV by 57% in the first six months after birth.
- It takes about 14 days from the time of maternal immunization for best maternal antibody development and transfer to the baby to occur.

- In addition to minor side effects such as pain at the injection site, headache, muscle pain and nausea, there were a small increase in preterm births observed in the clinical trial patients receiving the vaccine compared to those receiving placebo.
 - It is not clear if this is a true safety problem related to RSV vaccine or if this occurred for reasons unrelated to vaccination. To reduce the potential risk of preterm birth and complications from RSV disease, the U.S. FDA approved the maternal RSV vaccine for use during weeks 32-36 of pregnancy while additional studies are conducted.
 - Although not common, a dangerous high blood pressure condition called pre-eclampsia occurred in 1.8% of pregnant people who received the maternal RSV vaccine compared to 1.4% of pregnant people who received a placebo.
- The maternal RSV vaccine may be given at the same time as other recommended vaccines.

What should you know about nirsevimab?

- Nirsevimab reduces the risk of severe RSV disease in babies by about 80%.
- Nirsevimab is a monoclonal antibody product that protects against severe RSV for one RSV season.
- The protection that nirsevimab provides is called “passive immunity” because it does not come from the person’s own immune system, rather from antibodies produced outside a person’s body.
- Side effects tend to be minor and include pain, redness, swelling at the injection site and rash.
- Nirsevimab may be given at the same time as other recommended immunizations.

Which is better: nirsevimab or the maternal RSV vaccine?

- There has not been a clinical trial directly comparing nirsevimab to the maternal RSV vaccine.
- Both options are safe and effective.
- Both options provide short-term immunity from severe RSV infection for one RSV season to protect babies when they are most at risk.
- The maternal RSV vaccine avoids an injection for the baby.
- There is no risk of adverse pregnancy outcomes with nirsevimab.
- **Due to higher demand than anticipated, nirsevimab may have limited availability during the 2023-2024 RSV season.**

Are there out-of-pocket costs for nirsevimab or the maternal RSV vaccine?

- Most private health insurance plans cover the maternal RSV vaccine or nirsevimab.
- The Vaccines for Children (VFC) Program provides both nirsevimab and maternal RSV vaccine for children who are 18 or younger and American Indian/Alaskan Native, Medicaid-eligible, uninsured or underinsured.

What else should be considered?

- In most cases, either the maternal RSV vaccine OR nirsevimab should be used to protect a baby from severe RSV infection.
- There may be rare circumstances where both products should be used, based on medical provider clinical judgement.