# Protecting Your Baby From RSV

*Respiratory Syncytial Virus (RSV) Immunization Options*

## What are the options to protect babies from RSV?

1. Maternal RSV vaccine (Abrysvo™) for:
    - Pregnant women 32-36 weeks gestation who did not receive the maternal RSV vaccine during a previous pregnancy
    - During months of September-January
2. Nirsevimab (Beyfortus™) monoclonal antibody for:
    - All babies born during born during RSV season (October-March) should receive a dose in the first week of life.
    - All children ages <8 months entering their first RSV season should a receive a dose or nirsevimab prior to the start of RSV season.
    - All children ages 8-19 months entering their second RSV season who are higher risk of severe RSV disease should a dose of nirsevimab prior to the start of the second RSV season. This includes:
        - Children with chronic lung disease of prematurity which required medical support in the previous 6 months
        - Children who are severely immunocompromised ○ Children with cystic fibrosis with manifestations of severe lung disease ○ American Indian and Alaska Native children
    - American Indian and Alaska Native children aged 8-19 months entering their second RSV season based on medical provider recommendation
3. If the maternal RSV vaccine was not received at least 14 days prior to delivery and nirsevimab is unavailable, palivizumab (Synagis™) monoclonal antibody may be an options based on medical provider assessment for babies and young children with certain medical conditions in either their first or second RSV season.

## 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.

- Side effects were generally minor, including pain at the injection site, headache, muscle pain, and nausea
- There was 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. No increased occurrence of preterm births was observed in women who received the maternal RSV vaccine between September 2023 and January 2024.
- 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. This is continuing to be studied.
- 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 over 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.

## 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.