Nirsevimab (Beyfortus®) for RSV Prevention

What is nirsevimab and why does my baby need it?

Nirsevimab is a monoclonal antibody injection that can prevent severe respiratory syncytial virus (RSV) infection in babies.

RSV is one of the most common causes of respiratory (lung) infections in children of all age groups. Most children have cold-like symptoms. However, babies are more likely to have a more severe infection that can lead to bronchiolitis or pneumonia. RSV can cause **apnea** [AP-nee-uh] in young babies, which is when they suddenly stop breathing. Often, they need hospitalization to get better.

How does it work?

Nirsevimab is a monoclonal antibody made from man-made proteins that provide "passive immunity." It is called "passive" because the protection comes from antibodies produced outside a person's body.

The protection that vaccines provide is called "active immunity" because the antibodies are made by a person's own immune system. "Active immunity" requires a person's immune system to take action to defend itself.

Protection is most effective in the weeks right after nirsevimab is given and lessens over time. Nirsevimab does not provide long-term protection against RSV disease, but it does protect infants when they are most at risk of getting very sick from RSV.

One dose of nirsevimab protects infants for at least 5 months, the length of an average RSV season.

Who should get it and when?

Babies born between October and March:

The CDC recommends that nirsevimab be given to newborns during their first week (recommended) to month of life when born during their first RSV season (typically fall through spring) if:

- Their mother did not receive RSV vaccine during this pregnancy
- Their mother's RSV vaccination status is unknown
- The infant was born within 14 days of the mother's RSV vaccination

Infants born in February or March who did not receive the immunization during their first season may be eligible the following season before they turn 8 months old.

Babies born between April and September:

The CDC recommends that nirsevimab be given to all infants less than 8 months of age at the beginning of their first RSV season, at the earliest time available after October 1st if:

- Their mother did not receive RSV vaccine during this pregnancy
- Their mother's RSV vaccination status is unknown
- They were born within 14 days of the mother's RSV vaccination

Babies and young children who are between 8 and 19 months old may need nirsevimab before the start of their second RSV season if they are at higher risk of severe disease at the earliest time available after October 1st. This includes those who:

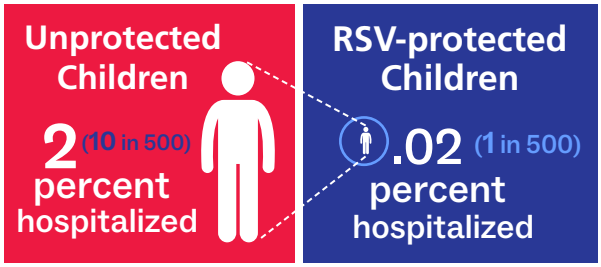
- Were born prematurely and have chronic lung disease
- Are severely immunocompromised
- Have severe cystic fibrosis disease
- Are American Indian or Alaskan Native

Is it effective?

Intermountain tracked the effectiveness at our facilities during last season and this is what we learned:

- Nirsevimab and abrysvo were 88% effective at preventing RSV-associated hospitalizations.
- Children who received either nirsevimab or abrysvo were:
  - About 9 times less likely to be hospitalized
  - About 7 times less likely to need care in the ICU
- For nirsevimab alone, those who received it were about 8 times less likely to be hospitalized (87.2% effective).

Overall, about **10 in 500 unprotected children** were hospitalized compared to **1 in 500 RSV-protected children.**



What are the possible side effects?

Side effects after nirsevimab are uncommon. The most common side effects are pain, redness, or swelling where the injection was given, and a rash. No serious allergic reactions occurred in the clinical trials.

As with any immunization, there is a very remote chance that nirsevimab could cause a severe allergic reaction, other serious injury, or death.

If you have any questions about side effects from nirsevimab, talk with your child's health care provider.

Children who have a bleeding disorder, such as hemophilia should get nirsevimab. However, it is important that they talk to their care provider first so they can take proper precautions.

Who should NOT get nirsevimab?

Infants and children should not get nirsevimab if:

- Their mothers got the RSV vaccine at least 14 days before delivery
- They are 8 months old or older and are NOT at increased risk of severe RSV disease
- They have a history of serious allergic reactions to nirsevimab or any of its components
- They have a moderate or severe acute illness. In this case, they should wait until they recover before getting nirsevimab. Children with minor illnesses, such as a cold, can receive nirsevimab.

Where can I learn more?

You can find more information on nirsevimab at the links below.

- **CDC:** cdc.gov/rsv/hcp/vaccine-clinical-guidance/infants-young-children.html
- **CDC Immunization Information Statement:** cdc.gov/vaccines/vpd/rsv/downloads/Immunization-Information-Statement.pdf
- **American Academy of Pediatrics:** healthychildren.org/English/safety-prevention/immunizations/Pages/RSV-immunizations-new-ways-to-protect-babies.aspx

This handout was adapted from information provided by the CDC
https://www.cdc.gov/rsv/hcp/vaccine-clinical-guidance/infants-young-children.html