

RSV is a common respiratory virus that causes about 58,000 to 80,000 hospitalizations and 100 to 300 deaths per year in children under 5 years, according to data from the Centers for Disease Control and Prevention (CDC).

Nirsevimab (Beyfortus) is a long-acting monoclonal antibody product intended for use in newborns and infants to protect against lower-respiratory tract RSV disease. Nirsevimab is recommended for:

- All infants younger than 8 months born during or entering their first RSV season, including those recommended by the AAP to receive palivizumab (Synagis)
- Infants and children aged 8-19 months who are at increased risk for severe RSV disease and entering their second RSV season, including those recommended by the AAP to receive palivizumab (Synagis)

### **Is nirsevimab a vaccine?**

Nirsevimab is a monoclonal antibody product that is a passive immunization given via an intramuscular injection. While not technically a “vaccine” in a traditional sense (active immunization), it is being used in a manner similar to routine childhood vaccines and may be referred to as a vaccine by some entities. Nirsevimab confers long-lasting protection from RSV, with protection expected to last at least 5 months (about the length of a typical RSV season). Nirsevimab is part of the Vaccines for Children program, which covers children who have no insurance or Medicaid insurance.

### **When should my child receive the Nirsevimab?**

Nirsevimab should be given “shortly before or during the RSV season” - typically between October 1 and March 31. Optimal timing for nirsevimab administration is shortly before the RSV season begins, however, it may be given to eligible infants and toddlers who have not yet received a dose at any time during the season.

Optimal timing for administration is within 1 week after birth during the RSV season. Administering nirsevimab through the end of the season is important because the risk of severe disease is highest during the first few months of life.

### **How long does the RSV protection conferred by nirsevimab last?**

Protection is expected to last at least 5 months, about the length of an RSV season.

### **Are there any contraindications to receiving nirsevimab? Can an infant or young child receive nirsevimab when they are sick?**

Nirsevimab is contraindicated in infants and young children with a history of serious hypersensitivity reactions, including anaphylaxis, to nirsevimab or to any of its components.

Illness or febrile diseases are not contraindications to receiving nirsevimab. The American Academy of Pediatrics suggests following [CDC General Best Practice Guidelines for Immunizations](#), which recommends that vaccination should be deferred for persons with a moderate or severe acute illness. Similar to routine childhood vaccines, mild illness – with or without fever – should not be used as a reason to delay administration of nirsevimab.

### **My child was 7 months old in October, but now it is November and they are 8 months of age. Can they receive nirsevimab now?**

No. CDC recommends that only those healthy infants younger than 8 months of age at the time of administration receive nirsevimab.

### **Will infants born during the RSV season receive nirsevimab before they are discharged from the hospital?**

It is recommended that infants born shortly before and during the RSV season receive nirsevimab within the first week of life, including in hospital settings. Infants with prolonged birth hospitalizations because of prematurity or other causes should receive nirsevimab shortly before or promptly after discharge. During the 23-24 RSV season, if a hospital has been unable to implement administration of nirsevimab, the infant should receive nirsevimab at their primary care office as soon as available. We have not received notification as to whether local birthing centers will be administering nirsevimab prior to discharge.

### **Which children should receive a dose of nirsevimab in their second RSV season?**

- Children with chronic lung disease of prematurity who required medical support (chronic corticosteroid therapy, diuretic therapy or supplemental oxygen) any time during the 6-month period before the start of the second RSV season.
- Children who are severely immunocompromised.
- Children with cystic fibrosis who have manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest imaging that persist when stable) or have weight-for-length that is <10th percentile.
- American Indian and Alaska Native children (note that this is a new group for whom second-season prophylaxis is recommended in contrast to the current palivizumab recommendations).
- If a child does not meet one of the above criteria, healthy newborns born at the end of RSV season who received nirsevimab around the time of delivery (first RSV season) should not receive a second dose entering their second season even if they are < 8 months of age.

## **Can you give nirsevimab with routine childhood vaccines?**

Nirsevimab is approved to be given simultaneously with age-appropriate vaccines. It has not been shown to interfere with the immune response or affect the safety and efficacy profile of the simultaneously given vaccines.

## **What should I do if nirsevimab is not available for my child who is at high risk for severe RSV illness?**

If nirsevimab is unavailable and the child is eligible to receive palivizumab (Synagis), then palivizumab should be administered. If < 5 doses of palivizumab are administered and nirsevimab becomes available, the child should receive 1 dose of nirsevimab. No further palivizumab should be administered following receipt of nirsevimab. The recommended interval between the last dose of palivizumab and a dose of nirsevimab is 30 days (similar to the interval if the infant were to receive another dose of palivizumab).

## **What are some common side effects of nirsevimab?**

Rash, pain, and swelling at the injection site are the most common side effects. Allergic reactions are rare but can occur.

## **Is Nirsevimab covered by insurance?**

Nirsevimab is covered through the Vaccine for Children (VFC) program for some patients, including those who have Medicaid or do not have insurance. Most commercial insurance plans have not yet stated whether Nirsevimab will be covered fully, will be covered but go toward deductibles, or will not be covered. Pediatrics of NEPA is actively working with local and national insurance plans to determine if and when this new product will be covered for babies. We are awaiting this information and will update patients when more information is available via the portal and our Facebook page.