# Nirsevimab Frequently Asked Questions

## Is nirsevimab a vaccine?

Nirsevimab is a monoclonal antibody product that is a passive immunization. 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.

## Because nirsevimab is a monoclonal antibody product, who can administer it?

Nirsevimab comes in a prefilled syringe. In most states, anyone who can administer injections can administer nirsevimab.

## What does "shortly before or during” the RSV season mean? When should I start administering nirsevimab?

In most of the continental US, “shortly before or during the season” means that administration of nirsevimab should begin on October 1 and conclude on March 31. In tropical climates (southern Florida, Hawaii, Guam, Puerto Rico, US Virgin Islands and US-affiliated Pacific Islands) and Alaska, RSV circulation patterns may differ. Because timing of the onset, peak and decline of RSV activity may vary, providers can adjust administration schedules based on local RSV activity in the community. The Centers for Disease Control and Prevention (CDC) monitors

RSV activity in the United States in collaboration with state and county health departments and commercial and clinical laboratories. These data are available from the **National Respiratory and Enteric Virus Surveillance System**. Information about local epidemiology can be determined by contacting your local, state, tribal, or territorial health department or other local health authority. 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.

Per **CDC**, healthcare providers may choose to give nirsevimab before the start of RSV season if they feel that the child may not return for a visit when nirsevimab would be recommended. For example, a clinician may choose to give nirsevimab to an infant who presented for care in September who has not yet received a dose of nirsevimab and may be unlikely to return for a visit in October or November. Nirsevimab has been shown to protect against severe RSV disease for at least 5 months, and the ideal timing of administration may differ depending on the clinical situation.

## 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 and is expected reduce the risk of severe RSV disease by about 80%.

## How do I order commercial stock of nirsevimab?

Nirsevimab can be ordered from **VaccineShop.com**. Sanofi has reported that the 100 mg formulation for infants ≥ 5 kg is not available for new commercial ordering at the present time.

## When will nirsevimab be available through the Vaccines for Children program?

Nirsevimab has been available through VFC since early October. As of mid-October there is a pause in VFC ordering as they move to an allocation system to ensure equitable availability across all state immunization programs. See additional details in **AAP News**.

## Given the current shortage of the 100 mg formulation of nirsevimab, can I administer two 50 mg doses to my

## patient who is ≥ 5 kg instead? What are some other things I can do to protect my patients?

Using two 50 mg doses in place of a 100 mg dose has not been studied and is not recommended. Other strategies to consider during the nirsevimab shortage is: continue to use palivizumab for eligible high-risk children and encourage pregnant women to get vaccinated between 32-36 weeks' gestation with the new RSVpreF vaccine.

## 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 AAP 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, as this precaution avoids causing diagnostic confusion between the underlying illness and potential adverse effects of immunization. Similar to routine childhood vaccines, mild illness – with or without fever – should not be used as a reason to delay administration of nirsevimab.

## If an infant has been diagnosed with RSV this season, should they still receive nirsevimab?

Nirsevimab recommendations are the same regardless of prior RSV infection or RSV-associated hospitalization.

## If an infant's mother has received maternal RSV vaccine, should the infant receive nirsevimab?

Maternal RSV vaccine was approved by the FDA on August 21, 2023. The CDC does not recommend nirsevimab for most infants born to a mother who received maternal RSV vaccine, except for infants where less than 14 days have elapsed between vaccination and birth.

Nirsevimab can be considered when, per the clinical judgement of the healthcare provider, the potential incremental benefit of administration is warranted, including but not limited to the following rare circumstances:

- Infants born to pregnant people who may not mount an adequate immune response to vaccination or have conditions associated with reduced transplacental antibody transfer
- Infants who have undergone cardiopulmonary bypass or extracorporeal membrane oxygenation leading to loss of maternal antibodies
- Infants with substantial increased risk for severe RSV disease (eg, hemodynamically significant congenital heart disease, intensive care admission and requiring oxygen at discharge)

## I have a healthy patient who was 7 months old in October. They present to the clinic in November, at 8 months of age. Can they receive nirsevimab at this visit?

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

## Can a baby who is 9 months old but corrects to 6.5 months due to prematurity (delivery at 29 weeks gestational age) receive nirsevimab?

The CDC states on their **RSV FAQ page** that in accordance with their **General Best Practice Guidelines for Immunization**, preterm infants (infants born before 37 weeks' gestation), regardless of birth weight, should receive nirsevimab at their chronological age using the same guidance for full-term infants and young children.

Therefore, a 9 month old infant born prematurely is recommended to receive nirsevimab when entering their second RSV season if they meet one of more of the following criteria:

- 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.

## Should I recall patients that will be less than 8 months of age at the start of the RSV season?

Yes. Healthy infants become ineligible for nirsevimab at 8 months of age. To realize the full benefits of nirsevimab during the 2023-2024 season, it is recommended that age eligible infants be recalled at the start of the RSV season, before they become ineligible based on age, if nirsevimab is available. **Reminder and recall tools** are available through the AAP. Nirsevimab may be administered in conjunction with a health maintenance visit or as part of a separate visit.

## Should I administer nirsevimab to an infant who is born at the very end of the RSV season?

Yes. 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.

## 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 in an ambulatory setting as soon as available. Currently, few hospitals participate in the VFC program, and additional advocacy to support hospital participation is ongoing. Timely and well-coordinated communication between birth hospital and the medical home is important. Equitable access to nirsevimab will require those in a community to work together.

## 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).

## Why are infants 8-12 months old ineligible to receive nirsevimab (unless they are considered high-risk)?

The highest risk for severe RSV is in children under 6 months of age. Infants 8 months and older will be entering their second RSV season and have likely already experienced their first RSV infection and will not receive the full benefits of nirsevimab.

## What is the guidance for high risk infants who are 19-24 months of age, particularly given nirsevimab has been FDA approved for infants and toddlers 24 months of age and younger who are at high risk for severe RSV illness?

A dose of nirsevimab is recommended for some children aged 8 through 19 months who are at increased risk for severe RSV and who are entering their **second** RSV season (note this is inclusive of 19 months). Nirsevimab provides at least 5 months of protection and should be offered to eligible children when entering the RSV season.

Nirsevimab is not recommended for any child who is age 20 months and older. Children ages 20 months and older have likely already experienced two RSV seasons and been infected with RSV, and thus are less likely to benefit from nirsevimab.

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

If nirsevimab is unavailable and the child is eligible to receive palivizumab, 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.

## If both nirsevimab and palivizumab are available for high risk patients (including those born at < 29 weeks gestational age), which should they receive?

While either product may be administered, the ability to provide one dose of nirsevimab versus monthly doses of palivizumab make it the better choice.

## Is there a minimum interval between palivizumab and nirsevimab, if an infant has received at least 1 dose (but less than 5 doses) of palivizumab?

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).

## Can nirsevimab be co-administered with other routine vaccines?

Yes. In accordance with CDC general best practices for immunizations, simultaneous administration of nirsevimab with age-appropriate vaccines is recommended. Nirsevimab is not expected to interfere with the immune response to other vaccines and had similar safety and reactogenicity profiles to vaccines administered without nirsevimab.

## Will there be a Vaccine Information Statement (VIS) available for nirsevimab?

CDC has developed a "VIS-like" document – called an Immunization Information Sheet on nirsevimab. You are encouraged to share this document with parents/families when administering nirsevimab. You can download a copy on the **CDC site**.

## What are the potential side effects of nirsevimab?

CDC recently published an **Immunization Information Statement** (VIS-like document) for families. It states that "After getting an RSV preventive antibody, your child might have temporary pain, redness, swelling where the injection was given, or a rash." In addition, the

nirsevimab package insert has additional information on adverse reactions. “Most common adverse reactions were rash (0.9%) and injection site reactions (0.3%).”

## If a patient has an adverse reaction to nirsevimab, where should it be reported?

Adverse events when giving nirsevimab alone should be reported to the FDA’s MedWatch Adverse Event Reporting Program.

If an adverse event occurs while co-administering nirsevimab with a vaccine, it should be reported to the Vaccine Adverse Event Reporting System.

## How do I code and bill for nirsevimab? Will I be paid appropriately?

See current coding and billing recommendations, including Coding Vignettes, on the nirsevimab Coding and Payment page.

## Is nirsevimab financially feasible for my practice? What flexibilities are available when I implement nirsevimab in my practice?

- Payment terms for this season for those ordering direct from Sanofi are 150 days from time of shipment.
- There is no minimum order size. Nirsevimab is packaged as five single dose prefilled syringes per carton in both formulations.
- Nirsevimab is fully returnable upon expiration. Sanofi offers credit (credit based on exact amount returned and the invoice purchase price that is net of prompt pay or other discount(s)) upon expiration on all full and open box Sanofi product(s) directly purchased from Sanofi that are returned within 1 year after the expiration date.

## Do I need to report nirsevimab administration to my state immunization information system (IIS)?

Yes. You should report nirsevimab administration to the state IIS in accordance with state policies for reporting of vaccine administration.

## Should American Indian and Alaska Native infants and young children from birth–19 months of age receive palivizumab if nirsevimab is unavailable?

If nirsevimab is unavailable, only those high-risk American Indian and Alaska Native infants and young children who meet current criteria for palivizumab should receive it. American Indian or Alaska Native heritage is not an indication for first or second season palivizumab.

## Don't see what you're looking for? Submit your question for consideration.

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