LPCH Stanford Nirsevimab FAQ

Adapted from the CDC and AAP Nirsevimab FAQs

Background

What is nirsevimab and how is it different from a vaccine?

Nirsevimab (Beyfortus™) is a long-acting monoclonal antibody that prevents severe RSV disease. Although both monoclonal antibodies and vaccines provide protection, the way they provide protection is different. Nirsevimab is a pre-made antibody that provides direct protection against RSV to the recipient (passive immunization). A vaccine stimulates the recipient's own immune system to mount an immune response, which includes making antibodies (active immunization).

Should LPCH Stanford be following the AAP and CDC recommendations regarding nirsevimab shortage and patient prioritization?

Currently, LPCH Stanford has a sufficient supply of nirsevimab for the season and plans to use it according to the initial ACIP/AAP recommendations (8/15/23). If our supply runs low and we need to prioritize patients or take other measures due to a shortage, updated guidance will be communicated.

When is our local RSV season?

The onset of RSV season varies geographically, but typically spans **November through March** in Northern California. The LPCH Stanford Integrated Infectious Diseases Program closely monitors our local epidemiology and may adjust administration schedules based on local RSV activity.

Dosing and Schedule

Who is recommended to receive nirsevimab?

Nirsevimab is recommended for:

1) All infants **younger than age 8 months** born shortly before or during their first RSV season if:

    - The mother did not receive RSV vaccine during pregnancy
    - The mother's RSV vaccination status is unknown
    - The infant was born less than 14 days after maternal RSV vaccination

    Except in rare circumstances, nirsevimab is not needed for most infants younger than age 8 months who are born 14 or more days after their mother received RSV vaccine during pregnancy. For more information, refer to the Special Situations section below.

    Because the risk of severe disease is highest during the first months after birth, nirsevimab is recommended within 1 week of birth for infants born shortly before or during the RSV season (typically October through March for most of the continental United States). This can be given at the time of discharge from the birth hospital or in the outpatient setting. Older infants who have not received a dose of nirsevimab are recommended to receive nirsevimab when entering the RSV season.

2) Children **aged 8 through 19 months** who are at increased risk for severe RSV disease and entering their second RSV season, regardless of maternal RSV vaccination:

    - 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 with severe immunocompromise
    - Children with cystic fibrosis who have either

    - 1) 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
    - 2) weight-for-length <10th percentile
- American Indian or Alaska Native children

Children aged 8 months and older at the time of immunization who do not meet any of the criteria listed above are not recommended to receive nirsevimab.

What is the recommended dose of nirsevimab?

- Age less than 8 months
    - 50 mg for infants weighing <5 kg [<11 lb]
    - 100 mg for infants weighing ≥5 kg [≥ 11 lb]
- Age 8 through 19 months: 200 mg, administered as two 100 mg injections administered at different sites

Do the recommended ages for nirsevimab refer to the age at time of immunization?

Yes, the child's age on the day nirsevimab is administered should be used to determine if the child is eligible. For example, a healthy child who was <8 months at the beginning of the RSV season but did not receive nirsevimab and is now ≥8 months old is not recommended to receive nirsevimab.

I have a healthy patient who was 7 months old in October. They present to the clinic in December, at 9 months of age. Can they receive nirsevimab at this visit?

No. CDC recommends that only those healthy infants < 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?

In accordance with CDC 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, nirsevimab would not be recommended in this instance.

What is the recommendation for using nirsevimab in preterm infants?

In accordance with, 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. Preterm infants discharged from the hospital during the RSV season, including those with prolonged birth hospitalizations, should receive nirsevimab shortly before or promptly after discharge.

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.

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.

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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.

High-risk infants who are 19-24 months and meet current criteria for palivizumab should receive it.

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.

If a patient was born towards the end of March and did not receive nirsevimab, can they receive nirsevimab in October?

Yes. Per AAP's guidance, healthy infants born at the end of their first RSV season who did NOT receive nirsevimab and are <8 months of age entering the next RSV season may receive one dose of nirsevimab.

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.

Nirsevimab and RSV Infection

Should an infant who had a confirmed RSV infection this season still receive nirsevimab?

Nirsevimab recommendations are the same regardless of prior RSV infection or RSV-associated hospitalization. Reinfection with RSV, even during the same season, can occur.

How long after a child has RSV infection should I wait to give nirsevimab?

Children who are moderately or severely ill with or without fever, including those who have known current RSV infection, should defer nirsevimab until recovery from the acute illness.

Nirsevimab and Routine Childhood vaccines

Can nirsevimab be given with other routine childhood vaccines?

Yes. In accordance with CDC General Best Practice Guidelines for Immunization, simultaneous administration of nirsevimab with age-appropriate vaccines is recommended. Nirsevimab is not expected to interfere with the immune response to vaccines. On the basis of limited data from clinical trials, coadministration of nirsevimab with routine vaccines did not appear to cause an increase in adverse events compared with administration of routine vaccines alone.

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Are there maximum volumes of injectable vaccine, antibiotic, or other products that can be administered into each muscle group for different ages? For example, at the 6-month well-child visit, could an infant receive nirsevimab, COVID-19, influenza, PCV, and DTaP-IPV-HepB-Hib?

In accordance with the CDC's General Best Practice Guidelines for Immunization, simultaneous administration of nirsevimab with age-appropriate vaccines is recommended. CDC does not address the issue of maximum volumes that can be injected into each muscle group in different age groups. CDC is in the process of creating a job aid for healthcare providers to help address the issue and offers the suggested volumes as follows:

- Deltoid: Average 0.5 mL (range 0.5–2 mL)
- Vastus Lateralis: Average 1–4 mL (range 1–5 mL)

Healthcare providers should always use professional judgement when administering injections. Muscle size can vary greatly from one patient to another.

Special Populations and Situations

Can nirsevimab be administered to infants whose mothers received RSV vaccination 14 or more days before birth?

Except in rare circumstances, nirsevimab is not needed for most infants younger than age 8 months who are born 14 or more days after their mother received RSV vaccine.

Nirsevimab can be considered in rare circumstances when the healthcare provider believes the potential benefit of giving it is warranted. These circumstances may include, but are not limited to:

- Infants born to pregnant people who may not mount an adequate immune response to RSV vaccination (e.g., people with immunocompromising conditions)
- Infants born to pregnant people who have medical conditions associated with reduced transplacental antibody transfer (e.g., people living with HIV infection)
- Infants who have undergone cardiopulmonary bypass or extracorporeal membrane oxygenation (ECMO), leading to loss of maternal antibodies
- Infants with substantial increased risk for severe RSV disease (e.g., hemodynamically significant congenital heart disease, intensive care admission with a requirement of oxygen at discharge)

Is it safe for a baby to receive nirsevimab if their mother received the RSV vaccine?

There are no studies of infants who have been given nirsevimab after their mother received an RSV vaccine. However, the available evidence does not suggest a higher risk for adverse events in that situation. Children and adults (including pregnant people) are frequently exposed to circulating RSV viruses. Following RSV infection, pregnant people produce antibodies that are transferred to infants across the placenta, and many of the babies in the nirsevimab study had maternal RSV antibody. CDC and FDA will monitor safety of both products.

Can I give nirsevimab and palivizumab during the same RSV season?

Because a single dose of nirsevimab provides protection for 5 months, children who received nirsevimab should not receive palivizumab during the same RSV season. However, if palivizumab was initially administered during the season (<5 doses), they can receive 1 dose of nirsevimab, if eligible. No further palivizumab should be administered.

What is the guidance for immunizing children undergoing cardiac surgery with cardiopulmonary bypass?

Children undergoing cardiac surgery with cardiopulmonary bypass should receive an additional dose of nirsevimab at age-appropriate dosing after surgery during RSV season if age eligible. Refer to Lexi-comp and the LPCH HSM for appropriate dosing for this scenario.

For solid organ transplant patients, who should receive nirsevimab?

Solid organ transplant recipients 19 months of age and younger are eligible to receive nirsevimab. Post-transplant patients 20-24 months of age should be evaluated for palivizumab eligibility. Patients who are listed for solid organ transplant and who do not otherwise meet nirsevimab criteria should follow protective precautions and, if eligible, receive palivizumab.

If a high-risk child mistakenly received a 100 mg dose of nirsevimab when they should have received a 200 mg dose, should we have them return for the other 100mg?

If a half dose is inadvertently given, another half dose should be administered **as soon as possible**, but no later than the end of the season (for most of the continental US, this would be through the end of March, unless local guidance is given to administer during a modified time period). This counts as a 200 mg dose.

Adverse Events After Nirsevimab Administration

What are the potential side effects of nirsevimab?

CDC recently published an Immunization Information Statement (VIS-like document) for families. It states, "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. The most common adverse reactions were rash (0.9%) and injection site reactions (0.3%).

Where can I report adverse events (side effects) that occur after receipt of nirsevimab?

For adverse reactions after administration of nirsevimab alone: report to MedWatch online (https://www.fda.gov/medwatch), by fax, by mail, or by contacting FDA at 1-800-FDA-1088.

For adverse reactions after the coadministration of nirsevimab with another vaccine: report to the Vaccine Adverse Event Reporting System (VAERS). Reports should specify that the patient received nirsevimab on the VAERS form specifically, in Section 9: "Prescriptions, over-the-counter medications, dietary supplements, or herbal remedies being taken at the time of vaccination." Reports can be submitted to VAERS online, by fax, or by mail. Additional information about VAERS is available by telephone (1-800-822- 7967) or online(https://vaers.hhs.gov). When adverse reactions that occur after the coadministration of nirsevimab with a vaccine are reported to VAERS, additional reporting of the same adverse reactions to MedWatch is not necessary.