Centers for Disease Control and Prevention

Vaccines and Preventable Diseases

Frequently Asked Questions About RSV Immunization with Monoclonal Antibody for Children 19 Months and Younger

What is the difference between nirsevimab and 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 an 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).

Nirsevimab Indication, Dosage and Schedule

Who is recommended to receive nirsevimab?

Nirsevimab is recommended for:

- All infants younger than age 8 months who are born shortly before or during their first RSV season (typically fall through spring) 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 (see section on special population and situations).
- The following 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 who do not meet any of the criteria listed above are not recommended to receive nirsevimab.

For more information, see Use of Nirsevimab for the Prevention of Respiratory Syncytial Virus Disease Among Infants and Young Children: Recommendations of the Advisory Committee on Immunization Practices.

How do you determine if an infant younger than age 8 months should receive nirsevimab?

For most infants younger than age 8 months whose mother received RSV vaccine 14 or more days prior to birth, nirsevimab is not needed. However, nirsevimab can be considered in rare circumstances (for details, see special situation section below).

Infants younger than 8 months of age are recommended for nirsevimab if they meet the following criteria:

- Their birth mother did not receive RSV vaccine during pregnancy more than 14 days prior to birth **OR** maternal RSV vaccine status is unknown
- The day of nirsevimab administration is shortly before or during RSV season (typically October through March for most of the continental United States)
- They have not received a previous dose of nirsevimab during that RSV season

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). Those who have not received a dose of nirsevimab are recommended to receive nirsevimab when entering the RSV season, including those who may have been born towards the end of the previous RSV season.

How do you determine if children younger than age 20 months who are at increased risk for severe RSV disease should receive nirsevimab?

Children at increased risk for severe RSV disease are recommended to receive nirsevimab if all the following apply:

- They meet at least one of the following criteria:
  - 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 RSV season
  - Severe immunocompromise
  - Cystic fibrosis who have either
    - 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
    - Weight-for-length <10th percentile
  - American Indian and Alaska Native children
- They are younger than age 20 months on the day of immunization
  - Children at increased risk younger than age 8 months and entering their **second** RSV season should receive a dose of nirsevimab. For example, a child born in March should receive their first nirsevimab dose shortly after birth; they may be entering their second RSV season at 7 months of age in October and should be given a second dose of nirsevimab (dose: 50 mg if less than 5kg and 100 mg if 5kg or more).
  - Children age 8 through 11 months and at increased risk can receive nirsevimab (one dose of 200mg) during their **first** RSV season. For example, an infant at increased risk for severe RSV disease who was born in April and who did not receive nirsevimab before 8 months of age should get a dose of nirsevimab as soon as possible at age 8 months (i.e., in December).
- The day of immunization is either shortly before or during RSV season (typically October through March for most of the continental United States)
  - Although optimal timing of administration is just before the start of the RSV season, nirsevimab may be administered through the end of March if nirsevimab had not been given during that season
- They have not previously received a total of two doses of nirsevimab. Only one dose is recommended each RSV season except for children undergoing cardiac surgery with cardiopulmonary bypass nirsevimab package insert

- Children at increased risk for severe disease should not receive more than two doses of nirsevimab (one dose [50mg or 100 mg depending on weight] for the first RSV season and one dose [two 100 mg injections] for the second RSV season).

For children ages 8 through 19 months who are recommended to receive nirsevimab during their second RSV season, what is the minimum interval between doses given in first and second RSV season?

Only one dose of nirsevimab is recommended for each season. Each dose of nirsevimab provides protection for at least 5 months, and a second dose of nirsevimab is not recommended to be given within 5 months of the first dose.

Can I give nirsevimab to children ages 20 months and older who at increased risk for severe RSV disease?

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. Additionally, health insurance plans may not cover the cost administering nirsevimab to children age 20 months and older.

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 immunization. For example, a healthy child who was aged <8 months at the beginning of the RSV season but did not receive nirsevimab and is now aged ≥8 months and whose family is requesting nirsevimab during the RSV season is 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

Are there any contraindications/precautions for nirsevimab?

Nirsevimab is contraindicated in children and infants with a history of severe allergic reaction (e.g., anaphylaxis) after a previous dose of nirsevimab or to a product component.

While neither a contraindication nor a precaution, nirsevimab should be used with caution in infants and children with bleeding disorders. Use a 23-gauge or smaller caliber needle and steady pressure to the site for 1-2 minutes.

See Vaccinating Persons with Increased Bleeding Risk and nirsevimab package insert for additional information.

In accordance with CDC General Best Practice Guidelines for Immunization, children who have a moderate or severe acute illness should usually wait until they recover before getting nirsevimab.

Timing of Nirsevimab Administration

What time of the year should I give nirsevimab?

While the timing of the onset and duration of RSV season may vary, nirsevimab may be administered October through the end of March in most of the continental United States. The timing of the onset, peak, and decline of RSV activity vary geographically, and providers may adjust timing of administration based on guidance from public health authorities (e.g., CDC, health departments) or regional medical centers. For example, health care providers in areas with known early RSV transmission may choose to begin administration of nirsevimab before October (e.g., Florida). Although optimal timing of administration is just before the start of the RSV season, nirsevimab may also be administered through the end of March to eligible infants and children.

For infants younger than age 8 months, potential administration timing for most of the continental United States during a typical RSV season (e.g., an RSV season that follows seasonality seen prior to the COVID-19 pandemic) by month of birth is described in the table below

Month of birth	Recommended timing of nirsevimab immunization
October–March	Within 1 week of birth
April–September	Beginning in October, for example at a 2-, 4-, or 6-month well child visit

Providers should use every opportunity to administer nirsevimab to eligible infants. This includes administration during well-child visits as well as other visits to ensure no missed opportunities for immunization.

Children aged 8 through 19 months at increased risk for severe RSV disease should receive nirsevimab in October in most of the continental United States. However, nirsevimab can be administered through the end of March if nirsevimab had not been given during that season.

Tropical climates may have RSV circulation patterns that differ from most of the continental United States or are unpredictable. Locations with tropical climates include southern Florida, Hawaii, Guam, Puerto Rico, US Virgin Islands, and US-Affiliated Pacific Islands. In Alaska, RSV circulation patterns are less predictable, and the duration of RSV season is often longer than the national average. Providers in these jurisdictions should consult state, local, or territorial guidance on timing of nirsevimab administration.

Can nirsevimab be given before the beginning of RSV season?

Healthcare providers may choose to give nirsevimab before the start of RSV season (typical season begins in late October in most of the continental United States) 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 and local circulation of RSV.

What should I do with nirsevimab that I still have after RSV season?*

Any nirsevimab (Beyfortus, Sanofi) inventory that has not expired should be stored between 2° C and 8° C (36° F and 46° F) to be used in the future.

April through July: Check the expiration date(s) of nirsevimab in your inventory.

- [ ] If nirsevimab has not expired:
  - [ ] Continue to store between 2° C and 8° C (36° F and 46° F) to be used in the future.
- [ ] Discard any expired nirsevimab. Note: If it was purchased with public funds, contact your immunization program and/or the manufacturer for guidance before discarding.

August through September: Prepare for upcoming RSV season.

- [ ] Check the current nirsevimab inventory and order more as needed.
- [ ] Check expiration dates of the nirsevimab in your inventory:
  - [ ] If nirsevimab has not expired, continue to store between 2° C and 8° C (36° F and 46° F).
  - [ ] Discard expired nirsevimab. If it was purchased with public funds, contact your immunization program and/or the manufacturer for guidance before discarding.
- [ ] Place storage labels on containers or bins, or attach labels directly to the shelf where vaccine is placed. CDC provides storage label graphics: Vaccines Storage and Handling Toolkit

* While the timing of the onset and duration of RSV season may vary, administer nirsevimab October through the end of March in most of the continental United States. Tropical climates may have RSV circulation patterns that differ from most of the continental United States or are unpredictable. Locations with tropical climates include southern Florida, Hawaii, Guam, Puerto Rico, US Virgin Islands, and US-Affiliated Pacific Islands. In Alaska, RSV circulation patterns are less predictable, and the duration of RSV season is often longer than the national average. Providers in these jurisdictions should consult state, local, or territorial guidance on timing of nirsevimab administration. Because the timing of the onset, peak, and decline of RSV activity might vary geographically, providers can adjust administration schedules based on local epidemiology.

Immunization Errors

What should be done for a pediatric patient who received the GSK RSV vaccine (Arexvy) or Pfizer RSV vaccine (Abrysvo) in error instead of administration of nirsevimab (Beyfortus)?

The GSK RSV vaccine (Arexvy) and the Pfizer RSV vaccine (Abrysvo) should not be administered to children aged <2 years. The Pfizer RSV vaccine (Abrysvo) is not approved or recommended for use in nonpregnant people aged <60 years and the GSK RSV vaccine (Arexvy) is not approved or recommended for use in people aged <60 years.

The safety and effectiveness of these RSV vaccines (Pfizer [Abrysvo] and GSK [Arexvy]) have not been established when administered to infants and children under age 2 years. Therefore, infants and young children who have received a GSK or Pfizer RSV vaccine in error should receive nirsevimab to prevent severe RSV disease, if otherwise eligible.

Additionally, some experts suggest:

- There is no specific recommendation for a minimum interval between inadvertent administration of the GSK or Pfizer RSV vaccine and nirsevimab. Administration of nirsevimab may be done as soon as the error is identified, but it could be reasonable to consider waiting 48 to 72 hours between administration of the vaccine and nirsevimab administration. This time frame is when local or systemic reaction(s), if they occur, after the GSK and Pfizer RSV vaccine, would be most likely to occur.
- If GSK or Pfizer RSV vaccine is given in error, and nirsevimab will be administered at the same visit or within 72 hours, nirsevimab should be administered at a different anatomic site. Providers may consider administering nirsevimab in the opposite limb to where the GSK or Pfizer RSV vaccine was administered to help reduce the occurrence of injection site reactions on the side where the GSK or Pfizer RSV vaccine was given.
- No special monitoring is needed, if GSK or Pfizer RSV vaccine is given in error. The most common types of reactions after routine vaccination given in this age group can include drowsiness, fussiness, fever or injection site pain/tenderness. Advise parents and caregivers to contact their healthcare provider if they have concerns about their child's health.

Healthcare providers are encouraged to report vaccination errors involving RSV vaccine to the Vaccine Adverse Event Reporting System (VAERS), even if there is no adverse event associated with the error.

How can vaccine providers minimize the likelihood of immunization errors?

Vaccine providers who carry the monoclonal antibody nirsevimab (for use in infants and young children), and the GSK RSV vaccine (Arexvy, for use in adults aged ≥60 years) or the Pfizer RSV vaccine (Abrysvo, for use in adults aged ≥60 years and pregnant people at 32-36 weeks' gestation) should be especially diligent in following vaccine administration safety procedures to prevent errors. To minimize risk of errors:

- Store GSK or Pfizer RSV vaccines and the RSV monoclonal antibody product (nirsevimab) in their original packaging on different shelves and clearly label the shelves.
- Educate staff about the differences in indication including age for use, preparation, and dosage.
- Confirm with the patient or caregiver the product(s) they are expecting to receive.

For additional guidance on ACIP recommendations for RSV prevention see:

- RSV (Respiratory Syncytial Virus) Immunizations

For additional guidance on storage and handling of RSV vaccines and nirsevimab see:

- At-A-Glance Resource Guide: Vaccine Administration and Storage and Handling-June 18, 2018 (cdc.gov) .

Nirsevimab and RSV infection

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

In general, nirsevimab recommendations are the same regardless of prior RSV infection or RSV-associated hospitalization.

However, in healthcare settings with limited supply of nirsevimab, it is reasonable to defer administering nirsevimab to infants who have a prior history of RSV infection, documented by diagnostic testing, since the risk of severe disease is lower with subsequent RSV infections. In settings with limited supply, infants at highest risk for severe RSV disease should be prioritized for nirsevimab administration.

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

Does nirsevimab interfere with RSV Diagnostic Tests?

Nirsevimab does not interfere with rapid antigen detection RSV diagnostic assays or reverse transcription polymerase chain reaction (RT-PCR) that employ commercially available antibodies targeting antigenic site I, II, or IV on the RSV fusion (F) protein. When clinical observations are consistent with RSV infection and immunological assay results are negative, it is recommended to confirm using an RT-PCR-based assay.

Nirsevimab and Routine Childhood vaccines

Can I give nirsevimab with 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 resulted in a similar rate of adverse events compared with administration of vaccines alone.

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.

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.

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.

Additional information on considerations for 2023-24 RSV season regarding palivizumab and nirsevimab administration to high-risk infants during the same RSV season is provided by the American Academy of Pediatrics.

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 after surgery during RSV season if age eligible. See nirsevimab package insert at https://www.accessdata.fda.gov/drugsatfda_docs/label/2023/761328s000lbl.pdf

First RSV season:

- If cardiac surgery with cardiopulmonary bypass is performed within 90 days after receiving nirsevimab, give an additional dose based on body weight at the time of the additional dose (50mg if less than 5kg and 100mg if 5kg or greater).
- If cardiac surgery with cardiopulmonary bypass is performed more than 90 days after receiving nirsevimab, give an additional dose of 50 mg regardless of body

Second RSV season:

- If cardiac surgery with cardiopulmonary bypass is performed within 90 days after receiving nirsevimab, give an additional dose of 200 mg regardless of body
- If cardiac surgery with cardiopulmonary bypass is performed more than 90 days after receiving nirsevimab, give an additional dose of 100 mg regardless of body

Adverse Events After Nirsevimab Administration

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

Adverse reactions might occur after administration of nirsevimab alone; these reactions may be reported to MedWatch online (https://www.fda.gov/medwatch), by fax, by mail, or by contacting FDA at 1-800-FDA-1088.

Adverse reactions might occur after the coadministration of nirsevimab with a vaccine; these reactions should be reported to the Vaccine Adverse Event Reporting System (VAERS), and 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.

Last Reviewed: March 27, 2024