Nirsevimab (Beyfortus) Guidance for Prescribers and Staff

Respiratory Syncytial Virus (RSV) is a common cause of hospitalization and deaths in young infants and children with risk factors for severe disease[1]. In several landmark clinical trials, nirsevimab was found to be 70-74% effective in preventing RSV-associated healthcare visits and reduced hospitalizations for RSV illness by 62-83% compared to placebo, with no significant risk of adverse effects[2-6]. The FDA, Advisory Council for Immunization Practices (ACIP), and AAP have approved and recommended nirsevimab for all infants <8 months at the start of or born during the RSV season (October through March), as well as for certain high-risk children going into their second RSV season (aged 8-19 months). One dose provides long-lasting protection for the entire RSV season. Please use the following guidance to determine whether your patients should be offered a dose.

Has the patient's mother received the maternal RSV vaccine (Abrysvo) during this pregnancy?

- **No or unknown:** Proceed to the next question.
- **Yes:** AAP and ACIP suggest there may be little additional benefit of administering nirsevimab to the infant. Nirsevimab is not recommended for most infants in this case but may be considered in certain situations with shared decision-making.

Is the child in an inpatient or outpatient setting?

- **Inpatient:** Nirsevimab is on the CCHMC formulary, and the dose should be covered as part of the hospital's medication charges. Proceed to the next question.
- **Outpatient:** Vaccines for Children (VFC) will cover nirsevimab during the 2023-24 RSV season for patients with Medicaid or no insurance. Private insurance will cover nirsevimab for the majority of plans but reimbursement rates are not yet available for many providers. Some families covered by private insurers may receive a bill for nirsevimab based on their individual coverage benefits. If your patient has private/commercial insurance, we recommend that the family/caregiver check with their insurance provider to ensure nirsevimab is covered before administering.

Has the patient received a dose of palivizumab (Synagis) or nirsevimab during this RSV season?

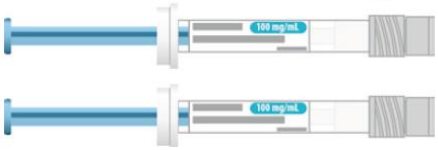
- **No:** Proceed to next question.
- **Yes, has received nirsevimab:** No further doses of nirsevimab or palivizumab are recommended for this season.
- **Yes, has received 1-4 doses of palivizumab:** Wait until 30 days has elapsed from last palivizumab dose, then give one dose of nirsevimab to complete this season (proceed to next question).

How old is the patient *today*?

- **<8 months:** Proceed to dosing table
- **8+ months and healthy:** Nirsevimab is not recommended.
- **8-19 months with the following high-risk conditions for severe RSV disease:**
    - 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

  If any of the above criteria are met, proceed to dosing table

Nirsevimab dosing:

Age/weight:	Dose and number of syringes to administer via intramuscular (IM) injection:
<8 months and <5 kg	Nirsevimab 50 mg/0.5 mL 
<8 months and ≥5 kg	Nirsevimab 100 mg/mL 
8-19 months and high risk, any weight	Nirsevimab 200 mg 
Supplemental dosing after cardiac bypass for any age and weight (previously received nirsevimab)	See nirsevimab package insert for details

IM Injection tips for nirsevimab (Adapted from AAP Nirsevimab Visual Guide)**:**

Use a 22-25 gauge needle. Choose the injection site and needle length that is appropriate to the child's age and body mass		
Age	**Needle length**	**Injection site**
Newborns (1st 28 days)	5/8"[A]	Anterolateral thigh muscle
Infants (1-12 months)	1"	Anterolateral thigh muscle
Toddlers (12-19 months)	1-1¼"	Anterolateral thigh muscle[C]
	5/8[B]-1"	Deltoid muscle of arm

A. If skin is stretched tightly and subcutaneous tissues are not bunched.
B. Alternate needle lengths may be used if the skin is stretched tightly and subcutaneous tissues are not bunched, as follows: a) a ⅝" needle in toddlers, children, and patients weighing less than 130 lbs (less than 60 kg) for IM injection in the deltoid muscle only, or b) a 1" needle for administration in the thigh muscle for adults of any weight.
C. Preferred site

FAQs:

1. Is nirsevimab a vaccine or a medication?

Answer: It is a monoclonal antibody and is therefore a medication/drug for the purposes of administration and billing. However, ACIP and AAP consider it to be like a vaccine for the purpose of disease prevention and it will be tracked in Epic's Health Maintenance and Immunizations tabs.

2. Should I give Nirsevimab while a patient is admitted, or wait until an outpatient visit?

Answer: If your patient meets criteria for administration of nirsevimab, ACIP/AAP recommend giving a dose on the day of discharge or shortly before discharge. Waiting to obtain insurance approval in the outpatient setting could delay administration and increase the risk of contracting RSV. ACIP/AAP do not recommend giving nirsevimab for prevention of hospital-acquired RSV. However, in cases of prolonged hospitalization with severe immunocompromise or other conditions that may result in worse outcomes, it may be reasonable to give during the hospital stay.

3. Can I give nirsevimab at the same time as other childhood vaccines?
Answer: Yes.

4. Who can administer nirsevimab?
Answer: Anyone who can administer intramuscular doses of medication can give nirsevimab.

Further reading:
AAP Webpage “Nirsevimab Frequently Asked Questions”
https://www.aap.org/en/patient-care/respiratory-syncytial-virus-rsv-prevention/nirsevimab-frequently-asked-questions/

AAP Nirsevimab Administration Visual Guide
https://downloads.aap.org/AAP/PDF/Nirsevemab-Visual-Guide_Sept2023.pdf

ACIP recommendations for the use of Nirsevimab
https://www.cdc.gov/mmwr/volumes/72/wr/mm7234a4.htm

Prepared by the CCHMC Antimicrobial Stewardship Program – contact Justin Markham PharmD with questions.

References:

1. Sommer C, Resch B, Simões EA. Risk factors for severe respiratory syncytial virus lower respiratory tract infection. Open Microbiol J. 2011;5:144-54. doi: 10.2174/1874285801105010144. Epub 2011 Dec 30. PMID: 22262987; PMCID: PMC3258650.
2. Griffin MP, Yuan Y, Takas T, et al. Single-dose nirsevimab for prevention of RSV in preterm infants. N Engl J Med 2020;383:415-25.
3. Hammitt LL, Dagan R, Yuan Y et al. MELODY Study Group. Nirsevimab for Prevention of RSV in Healthy Late-Preterm and Term Infants. N Engl J Med. 2022 Mar 3;386(9):837-846. doi: 10.1056/NEJMoa2110275. PMID: 35235726.
4. Domachowske J, Madhi SA, Simões EAF et al. MEDLEY Study Group. Safety of Nirsevimab for RSV in Infants with Heart or Lung Disease or Prematurity. N Engl J Med. 2022 Mar 3;386(9):892-894. doi: 10.1056/NEJMc2112186.
5. Domachowske JB, Chang Y, Atanasova V et al. Safety of Re-dosing Nirsevimab Prior to RSV Season 2 in Children With Heart or Lung Disease. J Pediatric Infect Dis Soc. 2023 Aug 31;12(8):477-480. doi: 10.1093/jpids/piad052.
6. Sanofi press release. “Nirsevimab delivers 83% reduction in RSV infant hospitalizations in a real-world clinical trial setting.” https://www.sanofi.com/en/media-room/press-releases/2023/2023-05-12-08-50-00-2667568. Accessed 10/3/2023.