Stanford MEDICINE
Children's Health

Nirsevimab Monoclonal Antibody Memo (2024-2025)

Dear Colleagues,

This memo summarizes the recommendations and implementation plan for **nirsevimab** (Beyfortus™), a long-acting monoclonal antibody with activity against respiratory syncytial virus (RSV), at Lucile Packard Children's Hospital (LPCH) Stanford and Clinics for the 2024-2025 RSV season. RSV is a common viral infection in early childhood that primarily causes upper respiratory tract symptoms but can cause lower respiratory tract (LRT) disease and is a significant cause of pediatric hospitalizations.

Nirsevimab is approved for the *prevention* of RSV LRT disease in neonates and infants born during or entering their first RSV season, and in children up to 24 months of age who remain vulnerable to severe RSV disease in their second RSV season. The American Academy of Pediatrics (AAP) and Advisory Committee on Immunization Practices (ACIP) recommend nirsevimab for:

- **Infants <8 months of age born during or entering their first RSV season whose birth parent did not receive the RSV vaccine Abrysvo® -AND-**
- **Children 8 – 19 months of age at increased risk of severe RSV disease and entering their second RSV season.** Those at increased risk include children:
    - With chronic lung disease of prematurity who require medical support (e.g., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) at any time during the 6 months before the start of the 2nd RSV season
    - Who are severely immunocompromised
    - With cystic fibrosis who have manifestations of severe lung disease (previous hospitalization for 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
    - Who are American Indian or Alaska Native

Nirsevimab has not been studied or recommended for children older than 24 months of age, for prevention of *hospital-acquired* RSV infection, or for *treatment* of RSV disease.

Nirsevimab in the Setting of Birth Parent RSV Vaccination: An RSV vaccine (Abrysvo®) is approved for pregnant people between 32-36 weeks gestation to prevent RSV LRT disease in infants. **Either** vaccination of the birth parent **or** nirsevimab administration is recommended to prevent RSV LRT disease; however, administration of both products is not needed for most infants. Birth parents who received Abrysvo® during a previous pregnancy should not receive additional doses during future pregnancies. Instead, the infant should receive nirsevimab.

Administration & Dosing: Since nirsevimab is a long-acting monoclonal antibody, only a single dose is needed for the entire RSV season. Doses come in pre-filled syringes (50 mg and 100 mg) to be administered intramuscularly (IM). Nirsevimab may be administered by RNs or MAs in California.

- Dosing by weight:
    - 50 mg if <5 kg
    - 100 mg if ≥5kg
    - 200 mg (2 x 100 mg injections in separates sites) for high-risk children 8-19 months of age entering 2nd RSV season

Other Important Information:

1. Nirsevimab is a manufactured monoclonal antibody that provides *passive* immunity against RSV; it is not a vaccine. However, it has been incorporated into the Vaccines for Children Program (VFC) in accordance with the AAP/ACIP recommendations.
2. The onset of RSV season varies geographically, but typically spans from **November through March** based on historical hospital surveillance data.
3. For eligible infants entering their first RSV season, nirsevimab should ideally be administered within the **first week of life** either during the birth hospitalization or in the outpatient setting. If patients have prolonged hospitalizations after birth, nirsevimab should be given shortly before or immediately after discharge.

4. Children who have received nirsevimab should not receive palivizumab (Synagis®). If palivizumab was initially administered during the season (<5 doses), the patient can receive 1 dose of nirsevimab and no further palivizumab should be administered for the season.
5. Nirsevimab may be given simultaneously with other age-appropriate vaccines. It is not expected to interfere with the immune response to other vaccines.
6. For eligible children who have already received nirsevimab and then undergo cardiac surgery with cardiopulmonary bypass, an additional dose of nirsevimab is recommended as soon as the child is stable after surgery.
7. In the initial studies, adverse effects were overall rare and primarily included injection site reactions (0.3%) and rash (0.9%).
8. **Contraindications:** Nirsevimab is contraindicated in patients with a history of serious hypersensitivity reactions, including anaphylaxis, to nirsevimab or to any of the ingredients (refer to package insert for full list of ingredients).
9. **Precautions**: As with any IM injection, nirsevimab should be given with caution to patients with thrombocytopenia, with coagulation disorders, or on anticoagulation therapy.

LPCH Implementation Plan:

1. Nirsevimab will be offered **October 1, 2024 to March 31, 2025**.
2. Nirsevimab is projected to be widely available. Providers **must confirm** that a patient has *not* already received nirsevimab before ordering it for administration. Please verify in the California Immunization Registry (CAIR) or other vaccine records.
3. Inpatient nirsevimab administration will be offered during the RSV season for:
    a. All admitted infants < 8 months of age if:
        i. They have not yet received nirsevimab
        AND
        ii. Their birth parent did not receive Abrysvo® during their pregnancy **OR**
        iii. Their birth parent received Abrysvo® < 14 days before the infant's birth **OR**
        iv. Their birth parent's Abrysvo® vaccination status is unknown
    b. Admitted patients 8 – 19 months of age who have not yet received nirsevimab during their 2nd RSV season and are at increased risk of severe RSV disease, as defined above.
4. Nirsevimab is not necessary in otherwise healthy infants if their birth parent received Abrysvo® ≥14 days before giving birth. Nirsevimab may be considered in some infants, regardless of birth parent vaccination status, in certain clinical circumstances:
    a. Infants whose birth parent may not mount an adequate immune response to vaccination (e.g., birth parent with immunocompromising condition) or have conditions associated with reduced transplacental antibody transfer (e.g., HIV)
    b. Infants who have undergone cardiopulmonary bypass, which leads to loss of transplacental antibodies
    c. Infants with increased risk for severe RSV disease (e.g., hemodynamically significant congenital heart disease, bronchopulmonary dysplasia and requiring oxygen at discharge, immunocompromising condition)
5. Outpatient administration is preferred whenever possible, and patients should not be admitted solely for the purpose of nirsevimab administration. Nirsevimab will be available for outpatient administration at some subspecialty clinics.

This plan is subject to change depending on utilization and availability of nirsevimab in the community.

Additional information regarding nirsevimab is available at the links below:

- AAP Recommendations for Nirsevimab
- AAP Nirsevimab FAQ
- RSV Preventive Antibody: Immunization Information Statement (IIS) – comparable to VIS
- Beyfortus® Package Insert / Prescribing Information

Please contact us with any questions or concerns,

Lauren Puckett PharmD, BCIDP, Lauren Kushner MD, Hayden Schwenk MD, MPH, and Shabnam Gaskari PharmD, on behalf of the LPCH Stanford Integrated Infectious Diseases Program