Stanford Children's Health | Lucile Packard Children's Hospital Stanford

Nirsevimab Monoclonal Antibody Memo (2023-2024)

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 2023-2024 RSV season. RSV is a common viral infection in early childhood that primarily causes upper respiratory tract symptoms but can also lead to lower respiratory tract (LRT) disease and is a significant cause of pediatric hospitalizations.

The Food and Drug Administration (FDA) approved nirsevimab 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. Following drug approval, the American Academy of Pediatrics (AAP) and Advisory Committee on Immunization Practices (ACIP) published formal guidelines recommending nirsevimab for:

- **All infants <8 months of age born during or entering their first RSV season -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 (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) at any time during the 6-month period 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 and/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 maternal RSV vaccination: A maternal RSV vaccine (Abrysvo™) was recently approved for seasonal administration (September to January) to pregnant women between 32 to 36 weeks gestation to prevent RSV lower respiratory tract infection in infants. **Either** maternal RSV vaccination **or** nirsevimab in the infant is recommended to prevent RSV lower respiratory tract infection, but administration of both products is not needed for most infants. See guidance under "LPCH Implementation Plan."

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 is being incorporated into the Vaccines for Children Program (VFC) in accordance with recommendations from AAP/ACIP.
2. The onset of RSV season varies geographically, but typically spans from November through March at LPCH. Given an increase in local RSV activity in recent weeks, we are planning to start inpatient administration of nirsevimab on **October 24th**.
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), they can receive 1 dose of nirsevimab. No further palivizumab should be administered.

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 children undergoing 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/or rash (0.9%).
8. **Contraindications:** Nirsevimab is contraindicated if a patient has a history of serious hypersensitivity reactions, including anaphylaxis, to nirsevimab or to any of the excipients.
9. **Precautions**: As with any IM injection, nirsevimab should be given with caution to patients with thrombocytopenia, any coagulation disorder, or to individuals on anticoagulation therapy.

LPCH Implementation Plan:

1. Nirsevimab will replace palivizumab and will be offered from **October 24th to March 31st**.
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 RSV season **within 48 - 72 hours of discharge** for:
    a. All admitted infants < 8 months of age if:
        i. They have not yet received nirsevimab AND
        ii. Their mother did not receive the RSV vaccine (Abrysvo™) during pregnancy OR maternal RSV vaccine status unknown OR the infant was born within 14 days of maternal RSV vaccination
    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 in the section above.
4. Nirsevimab is not necessary in otherwise healthy infants if their mother received the RSV vaccine (Abrysvo™) at least 14 days or more prior to birth. However, nirsevimab may still be considered in some infants (regardless of maternal vaccination status) with certain clinical circumstances:
    a. Infants born to pregnant people who may not mount an adequate immune response to vaccination (e.g., mother with immunocompromising condition) or have conditions associated with reduced transplacental antibody transfer (e.g., HIV infection)
    b. Infants who have undergone cardiopulmonary bypass, which leads to loss of maternal 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 drug availability, utilization, and availability of nirsevimab in the community.

Additional information regarding nirsevimab is available at the links below:

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

Please contact us with any questions or concerns.
Sincerely,

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