C.S. MOTT CHILDREN'S HOSPITAL
MICHIGAN MEDICINE

GUIDELINES FOR INPATIENT ADMINISTRATION OF NIRSEVIMAB TO INFANTS AND CHILDREN

1. **INDICATIONS FOR NIRSEVIMAB ADMINISTRATION – FIRST RSV SEASON**
   - **A. Infants aged <8 months born during or entering their first RSV season whose mothers did not receive the RSV vaccine (Abrysvo) (or with unknown maternal RSV vaccination status) or who were born <14 days from maternal vaccination.**
     1. Data are limited in infants of mothers who received maternal RSV vaccination or had RSV infection during pregnancy. Nirsevimab may be considered in some scenarios. (See Footnote a)

2. **INDICATIONS FOR NIRSEVIMAB ADMINISTRATION – SECOND RSV SEASON**
   - **A. Children aged 8-19 months who are at increased risk of severe RSV disease and entering their second RSV season.**
     1. Children with chronic lung disease of prematurity who required medical support (chronic corticosteroids, diuretics, or supplemental oxygen therapy) any time during the 6-month period before the start of the second RSV season
     2. Children who are severely immunocompromised
     3. Children with cystic fibrosis AND one or more of the following:
        - Previous hospitalization for pulmonary exacerbation in the first year of life
        - Abnormalities on chest imaging at clinical baseline
        - Weight-for-length <10th percentile
     4. American Indian and Alaska Native children

3. **INDICATIONS FOR NIRSEVIMAB ADMINISTRATION – CARDIAC BYPASS SURGERY**
   - **A. Patients who undergo cardiac bypass surgery after an initial dose of nirsevimab should receive a second dose, regardless of previous risk factors, upon hospital discharge, if still within the same RSV season.**

4. **NIRSEVIMAB DOSING**
   - **A. Patient's first RSV season:**
     - < 5 kg: 50 mg IM x 1
     - ≥ 5 kg: 100 mg IM x 1
   - **B. Patient's second RSV season:** 200 mg IM x 1 (administered as two 100 mg injections)
   - **C. Supplemental dose following cardiac bypass surgery**
     - Patient's first RSV season
       - < 5 kg: 50 mg IM x 1
       - ≥ 5 kg AND ≤ 90 days from initial dose: 100 mg IM x 1
       - > 90 days from initial dose: 50 mg IM x 1
     - Patient's second RSV season
       - ≤ 90 days from initial dose: 200 mg IM x 1
       - > 90 days from initial dose: 100 mg IM x 1

5. **NIRSEVIMAB TIMING**
   - **A. Period of inpatient administration**
     1. Nirsevimab administration should only occur during or shortly before periods of active RSV circulation. Administration will begin October 1st and conclude no later than March 31st based on the typical RSV season in Michigan. Administration may cease sooner if RSV PCR positivity at Michigan Medicine falls below 3%.
     2. Outside of the typical RSV season, nirsevimab administration will begin when RSV PCR positivity at Michigan Medicine exceeds 3% in 2 consecutive weeks and will cease when RSV PCR positivity falls below 3%.

B. Timing during admission

1. For healthy newborns, a single dose of nirsevimab should be administered within the first week of life.
2. Patients with extended birth hospitalizations should receive nirsevimab shortly before discharge.
3. Eligible patients who have not previously received nirsevimab and are admitted after birth may receive nirsevimab shortly before discharge.
4. Patients also eligible for palivizumab who are expected to age out of nirsevimab eligibility during hospitalization may receive nirsevimab sooner to avoid needing palivizumab at discharge.

II. GENERAL NIRSEVIMAB INFORMATION

A. Coadministration with routine childhood vaccines

1. In accordance with the CDC's general best practices for immunizations, simultaneous administration of nirsevimab with age-appropriate vaccines is recommended.
2. In clinical trials, when nirsevimab was administered concomitantly with routine childhood vaccines, the safety and reactogenicity profile of the concomitant regimen was similar to the childhood vaccines administered alone.
3. When concomitantly administered, nirsevimab is not expected to interfere with the immune response to other vaccines.

B. Duration of protection

1. The duration of effect of nirsevimab has been verified in clinical trials at 5 months. Pharmacokinetic data suggests protection against RSV could be as long as one year.[6]

III. CONSIDERATIONS FOR PATIENTS ALSO ELIGIBLE FOR PALIVIZUMAB

A. Mixed use of palivizumab and nirsevimab

1. Nirsevimab is preferred over palivizumab for protection against RSV infection in eligible infants.
2. Palivizumab continues to be indicated for the prevention of RSV in high-risk patients (GUIDELINES FOR ADMINISTRATION OF PALIVIZUMAB TO INFANTS) during periods of active RSV circulation who are ineligible for nirsevimab.
3. If nirsevimab is administered, palivizumab should not be administered later in the same season.
4. If palivizumab was administered initially for the season and <5 doses were administered, eligible infants should receive 1 dose of nirsevimab 30 days after the preceding palivizumab dose. No further doses of palivizumab should be administered.
5. If palivizumab was administered in season 1 and the child is eligible for RSV prophylaxis with nirsevimab in season 2, the child should receive nirsevimab in season 2.
6. If nirsevimab is not available, palivizumab should be administered as previously recommended.

	Footnotes
a	Most infants who are born ≥14 days after maternal RSV vaccination do not require nirsevimab. However, nirsevimab can be considered when, per the clinical judgement of the healthcare provider, the potential incremental benefit of administration is warranted, including but not limited to the following circumstances: ▪ Infants born to pregnant people who may not mount an adequate immune response to vaccination or have conditions associated with reduced transplacental antibody transfer. ▪ Infants who have undergone cardiopulmonary bypass or extracorporeal membrane oxygenation leading to loss of transplacental antibodies. ▪ Infants with substantial increased risk for severe RSV disease (e.g., hemodynamically significant congenital heart disease; intensive care admission and requiring oxygen at discharge).

	Current CDC recommendations make no distinction between those born to mothers who had RSV disease during pregnancy and those that did not. These patients were not specifically excluded from trials. Nirsevimab is still indicated in patient's born to mothers who had RSV infection during pregnancy. Data are very limited for these clinical scenarios. Page antimicrobial stewardship with questions (pager # 36149).

References:

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