# Newborn Critical Care Center (NCCC) Clinical Guidelines

## Guidelines for RSV Prophylaxis

***The coverage period for RSV prophylaxis is October 3, 2024 through March 31, 2025***

*Please also see the AAP Recommendations for RSV Prevention*

Respiratory Syncytial Virus (RSV) is a negative strand RNA virus of the family *Paramyxoviridae*. RSV causes acute upper respiratory tract infections in patients of all age groups and is one of the most common diseases of childhood. Most infants are infected during their first year of life, most children having been infected by the second year of life. The risk of severe RSV infection is increased by characteristics such as premature birth, cyanotic or complex congenital heart disease and chronic lung disease.

In previous years, Palivizumab (Synagis®) was the drug of choice for our patient population.

In July 2023, Nirsevimab-alip (Beyfortus®) was the first monoclonal antibody for passive immunization approved by the FDA for the prevention of RSV lower respiratory tract disease in neonates and infants born during or entering their first RSV season. Beyfortus® is approved for children up to 24 months of age who remain vulnerable to RSV during their second season. Beyfortus® is a RSV F-protein fusion inhibitor.

The NCCC will begin administration of Beyfortus® on October 3, 2024. Administration begins for in-patients and may be given shortly before discharge.

### ELIGIBILITY CRITERIA

Nirsevimab (Beyfortus) is not needed for ***MOST*** infants born at ≥ 34 weeks gestation whose mothers received RSVpreF (Abrysvo) vaccination during their pregnancy **≥ 14 days prior to birth** but may be considered for infants born to vaccinated mothers when the potential incremental benefit of administration is warranted:

- Infants born to mothers who might not have mounted an adequate immune response to vaccination (eg, persons with immunocompromising conditions), or conditions associated with reduced transplacental antibody transfer (eg, persons living with HIV infection)
- Infants who might have experienced loss of maternal antibodies, such as those who have undergone cardiopulmonary bypass or extracorporeal membrane oxygenation (ECMO)
- Infants with substantially increased risk for severe RSV disease (eg, hemodynamically significant congenital heart disease, intensive care admission requiring oxygen at hospital discharge)

**First RSV season, age <8 months, and mother did not receive RSV vaccine during pregnancy >14 days prior to birth:**

- Infants born before 29+0 weeks
- Chronic lung disease of prematurity*
- Hemodynamically significant acyanotic heart disease*
- Cyanotic congenital heart disease (baseline SpO2 <90%)

- Moderate to severe pulmonary hypertension
- Neuromuscular disease that impairs ability to clear secretions from upper airway
- Cystic fibrosis*
- Severe immunocompromise*
- American Indian or Alaska Native
- Previously received nirsevimab AND subsequently undergone cardiopulmonary bypass during the same RSV season

**Second RSV season and age 8-19 months:**

- Chronic lung disease*
- Severe immunocompromise*
- Cystic fibrosis*
- American Indian or Alaska Native
- Previously received nirsevimab AND subsequently undergone cardiopulmonary bypass during the same RSV season

*** Additional Definitions:**

- **Chronic lung disease of prematurity:** Birth < 32+0 AND a requirement for > 21% oxygen for > 28 days after birth
- **Hemodynamically significant acyanotic heart disease:** Need for future corrective surgery or a need for medications to treat heart failure
- **Cystic fibrosis:** Manifestations of severe lung disease (i.e., previous hospitalization for pulmonary 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
- **Chronic lung disease**: Requiring > 28 days of supplemental oxygen at birth and who continued to require medical support (i.e., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) any time during the 6-month period before the start of the second RSV season.
- **Severe immunocompromise:** See definition of immunocompromise here

**INPATIENT ELIGIBILITY CRITERIA**

Nirsevimab (Beyfortus) will be considered on a case-by case basis for NCCC **inpatient** dosing for infants > 6 months of age with chronic BPD or tracheostomy/ventilator dependence since this population is at extremely high risk of morbidity with inpatient acquisition of RSV.

**DOSING**

| **FIRST RSV SEASON (< 8 MOS OF AGE)** | |
|---|---|
| **Weight** | **Dose** |
| < 5 kg | 50 mg IM x 1 dose |
| ≥ 5 kg | 100 mg IM x 1 dose |

| SECOND RSV SEASON (≥ 8 MOS OF AGE) | |
|---|---|
| **Timing (since initial dose)** | **Dose** |
| ≤ 90 days | 200 mg IM in **TWO** injections |
| > 90 days | 100 mg IM x 1 dose |

**ADMINISTRATION**

- IM injection in the anterolateral aspect of the thigh
- Should two injections be required to complete the total dosage, different injection sites should be used.

**Resources:**


1. American Academy of Pediatrics (AAP): American Academy of Pediatrics (AAP): 2022 – 2024 Report of the Committee on Infectious Diseases, 32nd Edition.
2. 2018 - 2021 Report of the Committee on Infectious Diseases (Red Book), 31st Edition.
3. NCDHHS NC Medicaid Outpatient Pharmacy Services Prior Approval Drugs and Criteria for Synagis®
4. Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus
5. Infection; Pediatrics Aug 2014, 134 (2) 415-420; DOI 10.1542/peds.2014-1665.


*Reviewed October 2024 – Soza NNP / Wood MD / Brown PharmD*