Newborn Critical Care Center (NCCC) Clinical Guidelines

Guidelines for RSV Prophylaxis

The coverage period for RSV prophylaxis is October 1, 2026 through March 31, 2027

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.

Nirsevimab-alip (Beyfortus®) and Clesrovimab-cfor (ENFLONSIA™) are monoclonal antibodies for passive immunization approved by the FDA for the prevention of RSV lower respiratory tract disease in neonates and infants who are born during or entering their first RSV season. Beyfortus® is also approved up to 24 months of age for infants who remain vulnerable to RSV during their second RSV season. Beyfortus® and ENFLONSIA™ are RSV F-protein directed fusion inhibitors.

Beyfortus® is the UNC formulary medication and the NCCC will begin administration on October 1, 2026.

ELIGIBILITY CRITERIA:

FIRST RSV season:

All infants are eligible **AT TIME OF DISCHARGE** for Nirsevimab (Beyfortus) during their first RSV season if Mom did not receive RSVpreF (Abrysvo) vaccination during their pregnancy **≥ 14 days prior to birth**. Nirsevimab (Beyfortus) 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)

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.

SECOND RSV season and age 8-≤19 months who are at increased risk for severe disease:

- Preterm birth at < 32 weeks gestation (regardless of need for medication or other medical support)

- Chronic lung disease of prematurity*
- Hemodynamically significant congenital heart disease*
- Anatomical pulmonary abnormalities or neuromuscular disorders that increase risk for severe RSV disease
- Severe immunocompromise*
- Down syndrome or other chromosomal differences that increase risk of severe RSV disease
- Cystic fibrosis*
- American Indian or Alaska Native
- Previously received Nirsevimab AND subsequently undergone cardiopulmonary bypass during the same RSV season

*** Additional Definitions:**

- **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 respiratory status is 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

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)
200 mg IM in **TWO** injections

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

SPECIAL CONSIDERATIONS

- *Patients who undergo cardiopulmonary bypass or other antibody-depleting treatments or procedures (eg exchange transfusions or ECMO) after dose need an additional dose as soon as patient is stable.*

FIRST RSV SEASON	
Weight	**Dose**
< 5 kg	50 mg IM x 1 dose (regardless of time elapsed)
≥ 5 kg	≤ 90 days since initial dose: 100 mg IM x 1 dose > 90 days since initial dose: 50 mg IM x 1 dose

SECOND RSV SEASON
≤ 90 days since initial dose: 200 mg IM x 1 dose > 90 days since initial dose: 100 mg IM x 1 dose

Resources:

1. Committee on Infectious Diseases & Kimberlin, D. (2024). *Red book : 2024-2027 report of the committee on infectious diseases*. American Academy of Pediatrics. Pages 832-838.
2. Committee on Infectious Diseases; Recommendations for the Prevention of RSV Disease in Infants and Children: Policy Statement. *Pediatrics* 2026; DOI: 10.1542/peds.2026-079049

Reviewed October 2026 – Allis NNP / Trembath MD / Brown PharmD / Severin PharmD / McKenna PharmD