Newborn Critical Care Center (NCCC) Clinical Guidelines

Palivizumab (Synagis) Administration Guidelines

Please also see the AAP Recommendations for Synagis (Palivizumab)

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.

RSV Monoclonal Antibody, Palivizumab (Synagis) was licensed by the FDA in 1998. It is a humanized monoclonal antibody produced by recombinant DNA technology. Two large multi-center studies have demonstrated the efficacy of Synagis in reducing the rate of hospital admissions for a select group of patients. The American Academy of Pediatrics (initially in 1998, most recently updated in 2022) published guidelines for the administration of Synagis. The clinical criteria used by NC Medicaid for the 2022-2024 RSV season are consistent with guidance published by the American Academy of Pediatrics (AAP): 2021-2024 Report of the Committee on Infectious Diseases, 32nd Edition. This policy, reviewed by the American Academy of Pediatrics (AAP) Committee on Infectious Diseases (COID), replaces previous recommendations as published in the 2012 Red Book. It should be given in monthly IM injections at the beginning of RSV season and end on a date that affords protection through the end of RSV season (in North Carolina, from October 1, 2022 to March 31, 2023.

The Newborn Critical Care Center will follow the AAP recommendations for administration of Synagis during the 2022-2023 RSV season and distribute Synagis to eligible hospitalized NCCC infants with imminent discharge to home on the Thursday that most closely precedes their discharge. Synagis will be available on Thursdays beginning October 6, 2022 to continue weekly through March 31, 2023. Synagis may be administered on other days of the week, if necessary, by consultation with NCCC Pharmacist and batching.

Eligibility Criteria:

1. Prophylaxis **IS** recommended for infants born **before** 29 weeks 0 days gestation in the first year of life.
2. In the first year of life, prophylaxis **IS** recommended for preterm infants with **CLD** and birth age of < 32 weeks 0 days gestation **AND** an oxygen requirement of > 0.21 for at least 28 days after birth. (Documentation must be provided such as a NCCC/NICU discharge summary).
3. Prophylaxis **MAY** be administered in the first year of life to infants with hemodynamically significant **heart disease**, i.e. on medication to treat congestive heart failure, or those requiring cardiac surgical procedures. Documentation of cardiologist recommendation is required.
4. Prophylaxis **MAY** be administered to children with moderate to severe pulmonary hypertension.

5. Children with pulmonary or neuromuscular abnormalities which impair the ability to clear upper airway secretions **ARE** eligible for therapy and **MAY** be considered for prophylaxis in the first year of life.
6. Children younger than 24 months of age who may be profoundly immunocompromised **MAY** be considered for prophylaxis.
7. Infants in their **first or second** RSV season:
    a. With profound immunocompromise during the RSV season
    b. Undergoing cardiac transplantation during the RSV season
8. Infants less than 24 months of age in their **second** RSV season with a diagnosis of:
    a. CLD of prematurity (see above definition) AND continue to require medical support (supplemental oxygen, chronic corticosteroid medications or diuretic therapy) during the six-month period before the start of their **second** RSV season
    b. Cystic Fibrosis - with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year or abnormalities on chest radiography or chest computed tomography that persist when stable) or weight-for-length less than 10th percentile.

Dosing Criteria:

- For infants who qualify for prophylaxis in the first year of life, a maximum of **FIVE** monthly doses of Synagis may be given.

In UNC NCCC, dosing will be provided once weekly, on the Thursday closest to the discharge date for eligible patients. If an eligible patient will not be hospitalized in the NCCC on any Thursday during the administration time period, every attempt will be made to co-administer dosing with other eligible patients. (An announcement will be made during NCCC Board Rounds to find other eligible patients and minimize administration costs.)

ADMINISTRATION:

Synagis 15 mg/kg IM (preferably anterolateral thigh) once every 30 days

- Round dose to the nearest integer
- *Of note*: Synagis does not interfere with responses to other vaccines

FOLLOW-UP:

- Once infants have been identified as recipients of Palivizumab, notify the primary care provider so that they may order the appropriate number of doses for their practice, and to ensure that continuous coverage will be provided during the RSV season.
- All Synagis requests require prior authorization approval for coverage by NC Medicaid. Information about this process can be accessed at the following link: Procedures for Prior Authorization of Palivizumab (Synagis®) for RSV Season 2022/2023
    - Criteria for Prior Approval Drugs and Drug Request Forms can be found in the Pharmacy Services section of the NC Tracks website.

- Providers may submit prior authorization requests via fax, phone or through the secure NCTracks Provider Portal. The recommended method for submitting a PA request is to key it directly into the secure NCTracks Provider Portal. Requesting medications via the portal is the fastest and most efficient method for obtaining prior approval.
- Providers can begin the process of enrollment here. This page also contains contact information for the call center which can provide assistance with completion of the application.
- *Important Note:* User must have their National Provider Identifier (NPI) number to complete password authorization.

The coverage period for Synagis is October 1, 2022 through March 31, 2023.

Of note: A randomized control trial comparing Synagis to another monoclonal antibody is in progress. Please place names of Synagis eligible patients on the unit census board for research team availability. Contact Dr. Wesley Jackson for any questions about this study.

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.

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