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 2014) published guidelines for the administration of Synagis. The clinical criteria used by NC Medicaid for the 2019-20 RSV season are consistent with guidance published by the American Academy of Pediatrics (AAP): 2018 - 2021 Report of the Committee on Infectious Diseases, 31st 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, usually October-March/April).

The Newborn Critical Care Center will follow the AAP recommendations for administration of Synagis during the 2019-2020 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 31, 2018 to continue weekly through March 26, 2019.

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.
3. Prophylaxis **MAY** be administered in the first year of life to infants with hemodynamically significant **heart disease**.
4. 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.
5. Children younger than 24 months of age who may be profoundly immunocompromised **MAY** be considered for prophylaxis.

Dosing Criteria:

- For infants who qualify for prophylaxis in the first year of life, a maximum of **FIVE** monthly doses of Synagis (15 mg/kg per dose) may be given. For infants born during the RSV season, fewer than five monthly doses will be needed.

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. Clinical criteria utilized by N.C. Medicaid for the 2019/2020 RSV season are anticipated to be consistent with published guidelines by the AAP. Prior authorization (PA) requests for the upcoming season will be submitted electronically through the Synagis web-based application at www.documentforsafety.org.
    - A user name and password are required to access the system. Providers should register early in order to avoid delays in submitting requests. An outpatient pharmacy program also exists, and the same user name and password will access all available programs. Pharmacy support is available at 919-855-4300 and Technical Provider support is available at 919-926-3986.
    - The Document for Safety website remains the only method to submit a prior authorization request during the coverage period.
    - The provider should use the Non-Covered State Medicaid Plan Services Request Form for recipients under 21 years of age to request Synagis doses exceeding policy or for coverage outside the defined coverage period. Fax the form to 919-715-1255.
    - Technical support is available Monday through Friday from 8 AM to 5 PM at 855-272-6576 or 919-926-3986.
    - *Important Note:* User must have their National Provider Identifier (NPI) number to complete password authorization.

The coverage period for Synagis is October 29, 2019 through March 31, 2020.

Resources:

1. American Academy of Pediatrics (AAP): 2018 - 2021 Report of the Committee on Infectious Diseases (Red Book), 31st Edition.
2. NC Medicaid Outpatient Pharmacy Services Prior Approval Drugs and Criteria for Synagis
3. 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 Infection; Pediatrics Aug 2014, 134 (2) 415-420; DOI 10.1542/peds.2014-1665.

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