

**Outpatient Pharmacy  
Prior Approval Criteria  
Palivizumab**

**Therapeutic Class Code:** W5D

**Therapeutic Class Description:** Monoclonal Antibody

**Medication**

Synagis® 50mg/0.5ml vial

Synagis® 100mg/1ml vial

**Eligible Beneficiaries**

NC Medicaid (Medicaid) beneficiaries shall be enrolled on the date of service and may have service restrictions due to their eligibility category that would make them ineligible for this service.

**EPSDT Special Provision: Exception to Policy Limitations for Beneficiaries under 21 Years of Age**

**42 U.S.C. § 1396d(r) [1905(r) of the Social Security Act]**

Early and Periodic Screening, Diagnostic and Treatment (EPSDT) is a federal Medicaid requirement that requires the state Medicaid agency to cover services, products, or procedures for Medicaid beneficiaries under 21 years of age **if** the service is **medically necessary health care** to correct or ameliorate a defect, physical or mental illness, or a condition [health problem] identified through a screening examination (includes any evaluation by a physician or other licensed clinician). This means EPSDT covers most of the medical or remedial care a child needs to improve or maintain his/her health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems. Medically necessary services will be provided in the most economic mode as long as the treatment made available is similarly efficacious to the service requested by the beneficiary's physician, therapist, or other licensed practitioner; the determination process does not delay the delivery of the needed service; and the determination does not limit the beneficiary's right to a free choice of providers.

EPSDT does not require the state Medicaid agency to provide any service, product, or procedure

- a. that is unsafe, ineffective, or experimental/investigational.
- b. that is not medical in nature or not generally recognized as an accepted method of medical practice or treatment.

Service limitations on scope, amount, duration, frequency, location of service, and/or other specific criteria described in the clinical coverage policies may be exceeded or may not apply as long as the provider's documentation shows that the requested service is medically necessary "to correct or ameliorate a defect, physical or mental illness, or a condition" [health problem]; that is, provider documentation shows how the service, product, or procedure meets all EPSDT criteria, including to correct or improve or maintain the beneficiary's health in the best condition

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possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.

**EPSDT and Prior Approval Requirements**

EPSDT DOES NOT ELIMINATE THE REQUIREMENT FOR PRIOR APPROVAL IF PRIOR APPROVAL IS REQUIRED. Additional information on EPSDT guidelines may be accessed at <https://medicaid.ncdhhs.gov/providers/clinical-coverage-policies/epsdt-policy-description>.

**2025/2026 Synagis Criteria**

The clinical criteria used by N.C. Medicaid for the 2025/2026 Respiratory Syncytial Virus (RSV) season are consistent with guidance published by the *American Academy of Pediatrics (AAP): 2024 – 2027 Report of the Committee on Infectious Diseases, 33<sup>rd</sup> Edition*. This guidance for Synagis use among infants and children at increased risk of hospitalization for RSV infection is available online by subscription. Providers are encouraged to review the AAP guidance prior to the start of the RSV season.

**2025 AAP Policy Statement**

*Citation: American Academy of Pediatrics Committee on Infectious Diseases. Recommendations for the Prevention of RSV Disease in Infants and Children: Policy Statement. Pediatrics. 2025; doi: 10.1542/peds.2025-073923*

**Palivizumab**

“Palivizumab is a short-acting monoclonal antibody product that is administered in monthly doses during the RSV season. Palivizumab is no longer routinely recommended for use and will be discontinued as of December 31, 2025.”

Synagis is covered by NC Medicaid for the 2025/2026 RSV Season. The coverage is from October 1, 2025 through March 31, 2026, with a maximum of five doses allowed. Providers should submit an EPSDT request for coverage of a sixth dose or for coverage of doses outside of the defined season dates.

**Guidelines for Evidenced-Based Synagis Prophylaxis**

- Infants younger than 12 months and in their FIRST RSV season with a diagnosis of:
  - Prematurity - born before 29 weeks 0 days gestation
- Infants in their FIRST RSV season with a diagnosis of:
  - Chronic Lung Disease (CLD) of prematurity (defined as birth at less than 32 weeks 0 days

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gestation and requiring greater than 21 percent oxygen for at least first 28 days after birth) [must submit documentation of CLD as defined to meet criteria approval, e.g. NICU discharge summary]

- Hemodynamically significant acyanotic heart disease (CHD), receiving medication to control congestive heart failure, and will require cardiac surgical procedures,
- Moderate to severe pulmonary hypertension
- Neuromuscular disease or pulmonary abnormality that impairs the ability to clear secretions from the upper airways because of ineffective cough
- Cystic Fibrosis with clinical evidence of CLD and /or nutritional compromise

**Note:** Infants in their FIRST RSV season with cyanotic heart disease may receive prophylaxis with cardiologist recommendation. Documentation of cardiologist recommendation required.

- Infants less than 24 months of age in their SECOND RSV season with a diagnosis of:
  - CLD of prematurity (see above definition) AND continue to require medical support supplemental oxygen, chronic corticosteroid or diuretic therapy) during the six- month period before start of second RSV season
  - Cystic Fibrosis with manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in first year or abnormalities on chest radiography or chest chest computed tomography that persist when stable) or weight-for-length less than 10<sup>th</sup> percentile
- Infants in their FIRST or SECOND RSV Season:
  - With profound immunocompromise during RSV season
  - Undergoing cardiac transplantation during RSV season

**Coverage Limitations**

Coverage of Synagis for CLD, profound immunocompromise, cardiac transplantation or cystic fibrosis will terminate when the beneficiary exceeds 24 months of age.

If any infant or young child receiving monthly palivizumab prophylaxis experiences a breakthrough RSV hospitalization, coverage of Synagis should be discontinued due to the extremely low likelihood of a second same season hospitalization <0.5%.

If nirsevimab or clesrovimab is administered during the season, coverage of additional palivizumab doses should discontinue.

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Palivizumab****Procedures:****Prior Approval Request**

The Synagis® prior authorization (PA) request form is found on the NCTracks pharmacy services page at <https://www.nctracks.nc.gov/content/public/providers/pharmacy/pa-drugscriteria-new-format.html>. Submit PA requests by fax to NCTracks at (855) 710–1969. Call the NCTracks Pharmacy PA Call Center at (866) 246–8505 for assistance with submitting a PA request.

Document-for-safety is discontinued for Synagis PA submission.

**Pharmacy Distributor Information**

Use of a point of sale PA override code is not allowed. POS claims should not be submitted by the pharmacy distributor prior to the season start date.

Pharmacy providers should always indicate an accurate days' supply when submitting claims to N.C. Medicaid. Claims for Synagis doses that include multiple vial strengths must be submitted as a single compound-drug claim. Synagis doses that require multiple vial strengths that are submitted as separate individual claims will be subject to recoupment. Physicians and pharmacy providers are subject to audits of beneficiary records by N.C. Medicaid.

**Submitting a Request to Exceed Policy**

The provider should use the **Non-Covered State Medicaid Plan Services Request Form for Recipients under 21 Years of Age** to request Synagis coverage outside of policy. The form is available on the [NCTracks Prior Approval web page](#). Information about EPSDT coverage is found on [Medicaid's Health Check and EPSDT web page](#).