

**NC Division of Medical Assistance
Medicaid Outpatient Pharmacy
Prior Approval Criteria
Palivizumab**

Revised Date: August 15, 2016

Therapeutic Class Code: W5D

Therapeutic Class Description: Monoclonal Antibody

Medication	Generic Code Number(s)	NDC Numbers(s)
Synagis 50mg/1ml vial	24818	60574411401
Synagis 100mg/1ml vial	24824	60574411301

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 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

<http://www.ncdhhs.gov/dma/epsdt/>.

2016/2017 Synagis Criteria and Procedure

The clinical criteria utilized by N.C. Medicaid (Medicaid) for the 2016/2017 Respiratory Syncytial Virus (RSV) season are consistent with guidance published in the Red Book 30th Edition (2015): 2015 Report of the Committee on Infectious Diseases, 30th Edition published by the American Academy of Pediatrics, 2015. This guidance for Synagis use among infants and children at increase risk of hospitalization for Respiratory Syncytial Virus (RSV) infection is available online by subscription. **Prior authorization (PA) is required** for Medicaid coverage of Synagis. The coverage season is November 1, 2016 through March 31, 2017. Providers are encouraged to review the new AAP guidance prior to the start of the RSV season. Early and Periodic Screening, Diagnosis and Treatment (EPSDT) criteria are evaluated for Synagis requests.

Guidelines for Evidenced Based Synagis Prophylaxis:

- Infants younger than 12 months at start of season with diagnosis:
 - Prematurity - born before 29 weeks 0 days gestation
 - Chronic Lung Disease (CLD) of prematurity (defined as birth at less than 32 weeks 0 days gestation and required greater than 21% oxygen for at least the first 28 days after birth)
 - Hemodynamically significant acyanotic heart disease and receiving medication to control congestive heart failure and will require cardiac surgical procedures and; moderate to severe pulmonary hypertension
 - infants with cyanotic heart disease may receive prophylaxis with cardiologist recommendation.
- Infants during first year of life with diagnosis:
 - Neuromuscular disease or pulmonary abnormality that impairs the ability to clear secretions from the upper airways
- Infants less than 24 months of age with diagnosis:
 - Profound immunocompromise during RSV season
 - CLD of prematurity (see above definition) and continue to require medical support (supplemental oxygen, chronic corticosteroid or diuretic therapy) during 6 month period before start of second RSV season
 - Cardiac transplantation during RSV season

PA Request

Submit all PA requests for coverage of Synagis during the coverage period electronically at www.documentforsafety.org. The web-based program will process PA information in accordance with the updated criteria. A PA request can automatically approve based on the criteria submitted. The program allows a provider to self monitor the status of a request pending medical review. Up to five doses can be approved for coverage. Coverage of Synagis for neuromuscular disease or congenital anomaly that impairs ability to clear respiratory secretions from the upper airway will terminate when the beneficiary exceeds 12 months of age. Coverage of Synagis for CLD, profound immunocompromise or cardiac transplantation will terminate when the beneficiary exceeds 24 months of age.

Dose Authorization

Each Synagis dose will be individually authorized to promote efficient product distribution. After the initial approval, providers must submit a “*next dose request*” to obtain an authorization for each subsequent dose up to the approved number of doses. Providers should ensure the previously obtained supply of Synagis is administered before submitting a next dose request. Providers will fax each single dose authorization to the pharmacy distributor of choice.

If an infant received one or more Synagis doses prior to hospital discharge, the provider should indicate as part of the request the most recent date a dose was administered and the number of doses administered by the provider should be adjusted accordingly. If any infant or young child receiving monthly palivizumab prophylaxis experiences a breakthrough laboratory confirmed RSV hospitalization, coverage of Synagis will be discontinued.

Pharmacy Distributor Information

Single dose vial specific authorizations, up to the maximum number of doses approved for the beneficiary, will be issued by Medicaid. It is important for the Synagis distributor to have the appropriate single dose authorization on hand and a paid claim prior to shipping Synagis. An individual dose authorization is required for each paid Synagis claim. The claim should not exceed the quantity indicated on the authorization. Payment for a Synagis claim will be denied if a dose request was not done by the provider.

Synagis claims processing will begin on October 26, 2016 to allow sufficient time for pharmacies to provide Synagis by November 1, 2016. Payment of Synagis claims with date of service before October 26, 2016 and after March 31, 2017 will not be allowed. Point of sale claims should not be submitted by the pharmacy distributor prior to the first billable date of service for the season. Pharmacy providers should always indicate an accurate days’ supply when submitting claims to 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 individual claims will be subject to recoupment. Physicians and pharmacy providers are subject to audits of beneficiary records by DMA. Maintain Synagis dose authorizations in accordance with required record keeping time frames.

Provider Information

Providers without internet access should contact the Medicaid Outpatient Pharmacy Program at (919)855-4300 to facilitate submission of a PA request for Synagis. More information about the Synagis program is available at: www.documentforsafety.org.

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 doses exceeding policy or for coverage outside the defined coverage period. The form is available on DMA’s website at <http://www.ncdhhs.gov/dma/epsdt/>. Information about EPSDT coverage is found at (see <http://www.ncdhhs.gov/dma/epsdt/index.htm>).

Technical Support

Technical support is available Monday to Friday from 8am to 5pm by calling 1-855-272-6576 (local: 919-926-3986). Technical support can assist with provider registration, user name and password issues, beneficiary searches, and other registry functions.