

PRESCRIBER'S STATEMENT OF MEDICAL NECESSITY

Prior-Authorization - Synagis (palivizumab)

Maryland Pharmacy Program- Division of Pharmacy Services

Tel#: 410-767-1455 or 1-800-492-5231- Option 3- Fax form to: 410-333-5398

(This form is for use for Fee-For-Service Maryland Medicaid Recipients ONLY- Prior-Auth must be obtained from the particular MCO if Recipient is enrolled in managed care or HealthChoice. Incomplete forms will be returned)

Patient Information

Patient location: ___ home; ___ hospital ___ Clinic ___ Office- Check one: ___ Request is for 1st RSV season; 2nd season

Patient Name: _____ MA ID#: _____

Tel.#: (_____) _____ - _____ Weight at birth: _____ lb _____ kg Date of Birth: ____/____/____

Gestational age: _____ wks _____ days; Most Current Weight: _____ lb _____ kg Date weighed: ____/____/____

Prescriber Information

A summary of Patient's hospital discharge must accompany this PA request. Prior-authorization requests will be handled as early as Oct 23, but administration of the drug should be given between Nov 1 and Mar 31. List all previously administered Synagis injections (if any) with dates given: _____

Must meet ONE of the following criteria [Refer to the 2009 American Academy of Pediatrics (AAP) guidelines]:

- Infant or child < 24 months of age with **chronic lung disease of prematurity** (or bronchopulmonary dysplasia), who receive medical therapy for CLD within 6 months of RSV season should receive a max of 5 doses. Was CLD confirmed by chest X-Rays? Yes ___ No ___. Was CLD related to prematurity and birth before 32 wks gestation? ___ Yes ___ No. How long was patient on O2 at birth? ___ days. Did Patient have a need for supplemental O2 beyond the 28th day of life? Yes ___ No ___; Does Patient have a h/o lung injury at birth? Yes ___ No ___ Has patient been treated for CLD within 6 months of start of RSV season? Yes ___ No ___ List medical therapy for CLD (O2, bronchodilators, diuretics, or corticosteroid therapy) within 6 months before the start of RSV season: _____ or Last CLD treatment date: ____/____/____
- Born at 28 6/7 wks gestation or earlier without CLD or with no hemodynamically significant CHD. Patient is currently 12 mo. of age or younger and may receive prophylaxis during the RSV season for up to 5 doses.
- Born at 29 wks 0 day to 31 wks 6 days gestation without CLD or with no hemodynamically significant CHD. Patient is 6 months of age or younger at the start of the RSV season and may receive prophylaxis up to a max. of 5 doses.
- Born at 32 wks 0 day-34 wks 6 days gestation without CLD or with no hemodynamically significant CHD. Infant is younger than 3 months of age at the start of the RSV season or born during the RSV season with one of the following two risk factors and should receive a maximum of 3 doses until Infant reaches 3 months of life, whichever comes first:
 - ___ Child care attendance. Name of Day Care: _____ Date started: ____/____/____
 - Address: _____ Phone #: _____
 - ___ Sibling(s) and/or other child(ren) <5 y/o living in same household.
- Infant with significant congenital abnormalities of the airway or significant neuromuscular diseases that compromise handling of respiratory secretions needing a max of 5 doses during the first year of life.
- Infant or child <2 yrs of age with hemodynamically significant cyanotic or acyanotic congenital heart disease (CHD): ___ moderate to severe pulmonary artery hypertension; ___ cyanotic heart disease; ___ congestive heart failure (CHF) and on CHF medication (list medications: _____) Infant/child may benefit from a maximum of 5 doses during RSV season.
- Children < 2y/o who continue to require prophylaxis after cardio-pulmonary by-pass requiring a post-op dose as soon as the patient is medically stable- Has this dose been given at the hospital? Yes No

The following conditions, for which prophylaxis may not be medically necessary, will be reviewed on a case-by-case basis. Consultation with a cardiologist, neonatologist, pediatric intensivist, pulmonologist, infectious disease or sub-specialist is required.

- Cystic fibrosis patients: Routine prophylaxis is not recommended by AAP. Requests to be reviewed on a case-per-case basis.
- Infant/ young child with severe combined immunodeficiency or advanced AIDS- Specific recommendations not made by AAP.
- Hemodynamically insignificant heart disease (eg, secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild aorta coarctation and patent ductus arteriosus).
- Lesions adequately corrected by surgery, unless patient continues to require medication for congestive heart failure.
- Mild cardiomyopathy not requiring medical therapy.
- RSV prophylaxis for CLD& CHD patients during 2nd year of life. Effectiveness data are limited during the 2nd year of life.
- Other _____

RX- Synagis (palivizumab) _____ mg IM q month – For refills, the nurse is to fax Patient's most current body weight with a history of 3 prior dated weight measurements (if available) to the State using the attached Synagis Service PA form.

I certify that immunoprophylaxis meets the AAP guidelines. Supporting documentation of the patient's diagnoses and weight changes are available for audit in the patient's medical record. **Pharmacy selected:** _____

Phone: ____/____/____ Fax#: ____/____/____ Contact Person: _____

_____, M.D/CNP- Date: ____/____/____ Prescriber's Name: _____

Prescriber's signature- MD CNP- Address: _____

Tel# (_____) _____ - _____ Fax#: (_____) _____ - _____

BILLING INSTRUCTIONS FOR SYNAGIS

Questions concerning billing instructions and prior-authorization for Synagis should be directed to the Division of Pharmacy Services at 410-767-1455 or 1-800-492-5231- Option 3 (out-of-area only).

Billing of Synagis by Retail Pharmacy or IV Infusion Pharmacy Providers

Synagis may be dispensed and billed on-line between Oct. 23 and Mar 31. After receiving notification of approval of payment for Synagis for the entire RSV season, and after verifying that the recipient is still enrolled in fee-for-service MA by the service date, pharmacy providers must bill on-line and take care of all system edits before shipping the drug:

1. Bill the non-compound code 1 and DAW 0. Bill days supply= 28 (and not 30 as Prior-auth will be based on 28).
2. Bill the NDC and corresponding quantity (unit=ml) dispensed. For a dose of 132mg, bill quantity of "1" for "1 ml" for the 100mg/1ml package size liquid vial (NDC# 60574-4113-01) and "0.5" for 0.5ml of the 50mg/ml liquid vial (NDC# 60574-4114-01). Due to the high cost of the drug, the Program will allow the number of vials listed below based on 15mg (+/-5%)/kg. The dosing is based on the patient's estimated body weight at the time of injection.
3. **Calculated Dose/Month (15mg/Kg) Number of Required Vials**

From 0 to 52mg	1 x 50mg vial (Bill qty = 0.5 for 0.5ml of the 50mg/0.5ml vial NDC)
From 53 to to 105mg	1 x 100mg vial (Bill qty =1 for 1ml of the 100mg/ml vial NDC)
From 106mg to 157mg	1 x 100mg vial (Bill qty= 1 for 1 ml for the 100mg/ml vial NDC) + 1x 50mg vial (Qty =0.5 for 0.5ml for the 50mg/ml vial NDC)
From 158mg to 210mg	2 x 100mg vials (Bill Qty = 2 for 2ml of the 100mg/ml vial NDC)
From 211mg to 262mg	2 x 100mg vials (Bill Qty = 2 for 2ml of the 100mg/ml vial NDC) + 1 x 50mg vial (Bill Qty= 0.5 for 0.5ml of the 50mg/ml vial NDC)
From 263mg to 315mg	3 x 100 mg vials (Bill Qty = 3 for 3ml of the 100mg/ml vial NDC)

4. When submitted on-line, claim will deny with multiple exception codes requiring service prior-authorization from the State. Providers are to fax to the Program the Synagis Service Prior-Auth form that must be completed and signed by the nurse or medical staff. A history of at least 3 most recent weight measurements is required for processing the Synagis service PA request in order to estimate the average weight increase per month to be added to the child's prior month's weight.
5. Based on the estimated weight at time of scheduled first Synagis injection, the Program will override the appropriate exception or denial codes to allow claims to go through for the number of vials needed for the approved duration of prophylaxis. If the recipient should require additional vials due to unanticipated weight increase, providers are to call the State for an adjustment to the prior-authorized number of vials and fax a new Service PA form documenting the new body weight to the State for each request. The nurse should not overstate the body weight on the Synagis Service PA form and should record the actual body weight as measured at each patient's monthly office visit. Any weight adjustment will be automatically made by the State for the anticipated weight increase incurred by the patient (See Worksheet in Determining Number of Synagis Vials to Bill).
6. Any vials that are returned unused, sealed or unopen must be credited back to the Program as it is expected that the vials have been properly stored and handled by professionals. Providers only need to reverse the claim(s) from the system to negate any payment previously made by the Program and rebill the correct number of vials that are actually used. This can be done anytime within 12 months of the date of service.

Billing of Synagis by Prescribers

If the prescriber selects to purchase Synagis directly from the wholesaler, he/she must bill the drug under Physician Services, using the proper HCPC code for Synagis. The prescriber is responsible for arranging for the pick-up and/or delivery of the product to ensure that it is stored in the refrigerator and handled properly. Synagis should not be delivered to the patient's home and brought to the Office by the patient. Whether the drug is billed under Pharmacy Services or Physician Services, any ordered medication for Maryland Medicaid recipients that is received by the medical office but unused and unopen must be sent back to the pharmacy and credit must be issued to the Program.

The administration charge for Synagis is included in the office visit and therefore is not a separate billable service. Please contact Physicians Services at 410-767-1750 for any other related questions.

Coverage of Synagis for Medical Assistance Recipients Enrolled under Managed Care

Providers must verify recipient eligibility before requesting Synagis from the State. If the recipient is enrolled in HealthChoice (under managed care), providers must contact the specific MCO directly to request prior-authorization for payment of Synagis.

