

PRESCRIBER'S STATEMENT OF MEDICAL NECESSITY

Synagis® (palivizumab)

Maryland Medicaid Pharmacy Program

Tel# 800-492-5231- Option 3- Fax form to: 410-333-5398

(This form is for use for Fee-For-Service Maryland Medicaid Recipients ONLY- **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 measured: _____/_____/_____

Prescriber Information

A copy of Patient's NICU discharge summary must accompany this PA request. Prior-authorization requests will be handled as early as Oct 15, 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 (The Program adheres to the 2012 American Academy of Pediatrics guidelines):

- Infant < 24 months of age with **chronic lung disease of prematurity** (CLD) or bronchopulmonary dysplasia (BPD), 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 Infant have a need for supplemental O2 beyond the 28th day of life? Yes ___ No ___ ; Did Infant have a h/o lung injury at birth? Yes ___ No ___ Has Infant 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: _____

_____ Last CLD treatment date: _____/_____/_____

- Born at 28 6/7 wks gestation or earlier without CLD or without CHD. Preterm infant 12 mo. of age or younger at start of the RSV season 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 without CHD. Preterm infant 6 months of age or younger at start of the RSV season may receive prophylaxis for up to 5 doses.
- Born at 32 wks 0 day-34 wks 6 days gestation without CLD or without CHD. Preterm infant is younger than 3 months of age at start of the RSV season or born during the RSV season with one of the following two risk factors may receive up to a max of 3 doses until 3 months of life, whichever comes first:
 - ___ Child care attendance. Name of Day Care: _____ Date started: _____/_____/_____
 - ___ Sibling and/or other child <5 y/o living in same household. Multiple births younger than 1 year of age (i.e. twins, triplets, etc) do not qualify as fulfilling this risk factor.
- 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 <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 may benefit from a maximum of 5 doses during RSV season.
- Infants < 2y/o who continue to require prophylaxis after cardio-pulmonary by-pass requiring a post-op dose as soon as the infant is medically stable- Has this dose been given at the hospital? Yes-Specify date: _____/_____/_____ 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 recommendations cannot be made by AAP due to insufficient data on effectiveness.
- Immunocompromised infants- May benefit from prophylaxis although no specific recommendations are 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). Prophylaxis not recommended.
- Lesions adequately corrected by surgery- Not recommended unless Infant continues to require medication for CHF.
- Mild** cardiomyopathy not requiring medical therapy- Prophylaxis not recommended.
- RSV prophylaxis for severe CLD& CHD during 2nd RSV season. Effectiveness data are limited. Requires recommendation letter from child's pulmonologist or cardiologist. Child must be still on active therapy for persistent CLD or CHD.
- 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 to the State using the attached Synagis Service PA form.

Pharmacy selected: _____ Contact Person at Pharmacy: _____

Pharmacy Phone #: _____/_____/_____ Fax#: _____/_____/_____

Prescriber's Name: _____ Specialty: _____ Date: _____/_____/_____

Original Prescriber's signature- MD CNP- Address: _____

Tel# (_____) _____ - _____ Fax#: (_____) _____ - _____ (October 2012 DHMH)

ON-LINE BILLING INSTRUCTIONS FOR SYNAGIS®

Questions concerning billing instructions and prior-authorization for Synagis should be directed to MMPP at 1-800-492-5231-Option 3.

Billing of Synagis by Retail Pharmacy or IV Infusion Pharmacy Providers

Synagis may be dispensed and billed on-line between Oct. 15 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/ml- 1ml package size vial (NDC# 60574-4113-01) and “0.5” for 0.5ml of the 50mg/ml- 0.5ml vial (NDC# 60574-4114-01). The Program will allow the number of vials listed below based on the patient’s estimated body weight at time of drug administration.

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 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)

3. 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. The infant’s average weight increase per month is added to the prior month’s weight to arrive at the estimated weight based on which the Synagis dose will be calculated.
4. The Program will override the appropriate exception/denial codes to allow claims to go through for the correct number of vials needed for the Synagis dose. If the recipient should require additional vials due to unanticipated weight increase or due to a large discrepancy between the infant’s estimated weight and actual weight measurement, providers are to call the State for an adjustment to the number of vials that had been prior-approved. A new Service Prior-auth form should be faxed to the State documenting the infant’s new body weight with date of measurement. The Service PA form must list only “actual” and not “second-guessed” weight measurements. It is routine practice for the nurse to measure the infant’s body weight at each patient’s monthly office visit and document such weights in the patient’s chart.
5. Any vials that are returned unused, sealed or unopened 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 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 unopened may 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.