

2009/2010 Procedures for Prescribing Synagis for RSV Season

Effective with date of service November 2, 2009, N.C. Medicaid reimburses for respiratory syncytial virus (RSV) immune globulin (Synagis) **only** through the Outpatient Pharmacy Program. Synagis is not covered when billed through the Physician Drug Program or when billed on institutional claims by outpatient hospitals. This does not include an outpatient hospital pharmacy billing through point of sale.

The clinical criteria utilized by N.C. Medicaid for the 2009/2010 RSV season are consistent with currently published Red Book guidelines (on the Web at <http://aapredbook.aapublications.org/cgi/content/full/2009/1/3.110>; or in *Red Book: 2009 Report of the Committee on Infectious Diseases, 28th Edition*). Prescribers and pharmacists are responsible for ensuring the appropriate usage of Synagis.

The Synagis for RSV Prophylaxis form is used for recipients who meet the clinical criteria for coverage. Please ensure that the person completing the Synagis for RSV Prophylaxis form has verified that the conditions exist and are accurately reported. If a recipient does not meet the clinical criteria for coverage but you still wish to prescribe Synagis, submit your request for coverage as described below.

A medical necessity review for Synagis will be conducted for all requests for recipients under the age of 21 who do not meet the criteria listed on the Synagis for RSV Prophylaxis form. The medical necessity review will follow Early and Periodic Screening, Diagnosis, and Treatment (EPSDT) guidelines. Please use the N.C. Medicaid Prior Authorization Synagis Drug Request form (PA Synagis Drug Request form) for a medical necessity review for Synagis under EPSDT guidelines. Prescribers shall request coverage of Synagis doses exceeding policy or coverage outside of the defined seasonal period using the Non-covered State Medicaid Plan Services Request form for Recipients under 21 Years of Age, available online at <http://www.ncdhhs.gov/dma/provider/forms.htm> (under Prior Approval).

N.C. Medicaid will begin coverage of Synagis on November 2, 2009. During the season, N.C. Medicaid will cover up to five monthly doses of Synagis. Pharmacies shall bill N.C. Medicaid in accordance with policy and shall adjust the number of doses billed if an infant received the first dose prior to a hospital discharge. Delays in request processing can occur if the recipient does not have a N.C. Medicaid identification number or the form is not complete.

- The prescriber shall complete the Synagis for RSV Prophylaxis form and submit it to the pharmacy distributor of choice.
- If the recipient does not meet the criteria for coverage, complete the PA Synagis Drug Request form and fax it to ACS at 1-866-246-8507.
- N.C. Medicaid does not participate in RSV Connection. Do not submit N.C. Medicaid forms to RSV Connection for review.
- Before billing N.C. Medicaid for Synagis, the pharmacy shall have on file evidence of a complete and accurate Synagis for RSV Prophylaxis form or a PA notice of approval.
- Please refer to the guidelines below when submitting a request for Synagis.

Requesting Synagis for RSV Prophylaxis When Criteria Are Met

Submit the Synagis for RSV Prophylaxis form. (If the recipient does **not** meet the criteria, please refer below to **Requesting Synagis for RSV Prophylaxis When Criteria Are Not Met.**)

Criteria for a Maximum of Five Doses

For the following two diagnoses, date of birth (DOB) shall be on or after November 3, 2007.

- Chronic lung disease of prematurity (bronchopulmonary dysplasia): Infants and children younger than 24 months of age who have received treatment (supplemental oxygen, bronchodilator, diuretic, or chronic corticosteroid therapy) in the six months before the start of the season.

- Hemodynamically significant congenital heart disease: Infants younger than 24 months of age who are most likely to benefit include those receiving medication to control congestive heart failure (CHF), moderate to severe pulmonary hypertension, or cyanotic heart disease.
 - ◆ Infants not at increased risk from RSV who generally should **not** receive immunoprophylaxis include those with hemodynamically insignificant heart disease, such as secundum atrial septal defect, small ventricular septal defect (VSD), pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, patent ductus arteriosus (PDA), lesions adequately corrected by surgery unless the infant continues on medication for CHF, or mild cardiomyopathy for which the infant is not receiving medical therapy.

In addition to the two conditions listed above, a premature infant may qualify for five doses of Synagis as follows. Prematurity shall be counted to the exact day.

- Born at an estimated gestational age (EGA) of \leq 28 weeks 6 days and DOB is on or after November 3, 2008
- Born at an EGA of 29 weeks 0 days to 31 weeks 6 days and DOB is on or after May 3, 2009
- Born at an EGA of \leq 34 weeks 6 days **and** DOB is after March 31, 2009 and has either severe neuromuscular disease or congenital abnormalities of the airways, either of which compromises handling of respiratory secretions

Criteria for a Maximum of Three Doses; Last Dose Administered at 3 Months of Age (90 Days of Life)

Born at an EGA of 32 weeks 0 days to 34 weeks 6 days, and DOB is on or after August 3, 2009, and has at least one of the two following defined risk factors:

- Attends child care (defined as a home or facility where care is provided for any number of infants or young toddlers [toddler age is up to the third birthday]).
- Has a sibling younger than 5 years of age in the home.

The Red Book includes a detailed chart (shown for beginning prophylaxis on November 1) of maximum number of Synagis [palivizumab] doses for RSV prophylaxis of preterm infants without chronic lung disease, on the basis of birth date, gestational age, and presence of risk factors (American Academy of Pediatrics. Respiratory Syncytial Virus. In: Pickering LK, Baker CJ, Kimberlin DW, Long SS, eds. Red Book: 2009 Report of the Committee on Infectious Diseases. 28th ed. Elk Grove Village, IL: American Academy of Pediatrics; 2009: 560-569; Table 3.61). The chart is available online at <http://aapredbook.aappublications.org/cgi/content-nw/full/2009/1/3.110/TABLE3-61>. With the exception of following a November 2, 2009 season start date, N.C. Medicaid follows guidance the chart provides, accordingly, on the recommended number of doses.

Requesting Synagis for RSV Prophylaxis When Criteria Are Not Met

Prior authorization (PA) will be required for Synagis when criteria are not met. Submit prior authorization requests on the PA Synagis Drug Request Form by faxing it to ACS at 1-866-246-8507. This PA form is to be used for recipients who do not explicitly meet the criteria on the Synagis for RSV Prophylaxis form.

Generally, the following conditions do not singularly justify medical necessity for Synagis prophylaxis:

- an RSV episode during the current season
- repeated pneumonia
- sickle cell disease
- being one member of a multiple birth, another member of which is approved for Synagis
- apnea or respiratory failure of newborn

Please 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 Synagis administration outside the defined seasonal period. A medical review will be done to consider a request for Synagis under EPSDT (refer to <http://www.ncdhhs.gov/dma/epsdt/>). If the information provided justifies medical need, an approval notification will be faxed to the provider and pharmacy.

Submitting Synagis Request Using N.C. Medicaid Forms and Point of Sale Override

The N.C. Medicaid Synagis for RSV Prophylaxis form and the PA Synagis Drug Request form are available on the DMA Website at <http://www.ncdhhs.gov/dma/pharmacy/>. The PA Synagis Drug Request form is also available on the ACS website at <http://www.ncmedicaidpbm.com/>. The forms will be available on the websites prior to October 5, 2009. For further information about EPSDT or a copy of the Non-covered State Medicaid Plan Services Request Form for Recipients under 21 Years of Age, go to <http://www.ncdhhs.gov/dma/epsdt/>.

The N.C. Medicaid PA Synagis Drug Request form can be submitted to ACS starting on October 5, 2009. Please call the ACS Prior Authorization help desk at (866) 246-8505 for questions about the form.

N.C. Medicaid will allow Synagis claims processing to begin on October 27, 2009, to allow sufficient time for pharmacies to provide Synagis by November 2, 2009. Payment of Synagis claims prior to October 27, 2009, and after March 31, 2010, will not be allowed.

Point of sale (POS) claims billed for recipients requesting Synagis using the N.C. Medicaid Synagis for RSV Prophylaxis form require an override code. A "1" in the PA field (461-EU) will override the PA edit. The override code should be used only in instances where the form is complete and the recipient meets N. C. Medicaid criteria. Inappropriate use of the override will result in recoupment of payment for Synagis claims. These overrides will be monitored by Program Integrity.

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

Pharmacy Distributor Information

The pharmacy distributor shall maintain the **Synagis for RSV Prophylaxis** form on site. This form is required to support the use of the POS override code. The pharmacy distributor shall mail a copy of the submitted forms **weekly** to DMA. Please mail submitted forms to

N.C. Division of Medical Assistance
Pharmacy Program
2501 Mail Service Center
Raleigh NC 27699-2501

Pharmacy distributors who fill a large volume of Synagis claims are asked to submit information from the forms on a compact disk. Please call Charlene Sampson at 919-855-4300 to coordinate this process.

The pharmacy distributor shall maintain on site a copy of the approval notification for recipients evaluated under the PA Synagis Drug Request form or the Non-covered State Medicaid Plan Services Request Form for Recipients under 21 Years of Age.