

## **2011/2012 PA Request for Synagis**

The clinical criteria utilized by N.C. Medicaid for the 2011/2012 RSV season are consistent with published guidelines in the *Red Book: 2009 Report of the Committee on Infectious Diseases, 28<sup>th</sup> Edition*. **Prior approval (PA) is required** for Medicaid coverage of Synagis during the upcoming RSV season. The coverage season is November 1, 2011, through March 31, 2012. An Early and Periodic Screening, Diagnosis and Treatment (EPSDT) medical necessity review is performed for all Synagis requests.

Requesting PA for Synagis for the upcoming season will be an electronic process. Prompts, alerts, dropdown choices, attachment capability as well as free text opportunities will allow the provider to submit a request with all information essential to justify medical necessity. When available, a note documenting the patient's pulmonary or cardiac status should always be submitted as an attachment. The electronic system can automatically approve requests and allows the provider to monitor the status of a pending request.

The electronic PA method will approve coverage of up to five monthly doses of Synagis. Each dose will be individually authorized on a monthly basis. After the initial approval, providers will submit very limited information such as the most recent weight of the child and date the prior dose was administered for authorization of subsequent doses. The number of doses requested for authorization by the provider should be adjusted if an infant received the first dose prior to a hospital discharge.

It is important for a pharmacy to have a Synagis authorization notification on hand prior to billing a claim to Medicaid. These notifications must be submitted to the pharmacy by the provider and will include the number of vials approved for the patient. A claim transmitted at POS will be denied if a prior approval request was not submitted by the provider or if the request was not approved. It is the responsibility of the provider to ensure the pharmacy has a prescription for Synagis.

### **Provider Registration**

Providers must register for access to the web-based system prior to submitting PA requests for Synagis. The registration process is completed online using the website [www.smartDUR.com](http://www.smartDUR.com). Providers receive a user ID and temporary password within several days of submitting a complete registration request. Providers who are already registered users of [www.documentforsafety.com](http://www.documentforsafety.com) may use the same user ID and password to access [www.smartDUR.com](http://www.smartDUR.com). Please call technical support at (855) 272-6576 for assistance with registration. System access will be restricted to registration for a limited period.

Registered providers can begin submitting prior approval requests for Synagis using the website [www.smartDUR.com](http://www.smartDUR.com) in early October. An email alert with the start date will be sent to providers who have completed registration.

### **Maximum of Five Doses**

Up to five doses during the season can be authorized for chronic lung disease (CLD) and hemodynamically significant congenital heart disease (HSCHD) for infants and children less than 24 months of age.

#### **CLD**

The diagnosis causing the long-term respiratory problems must be specific. Treatment, such as supplemental oxygen, bronchodilator, diuretic or chronic corticosteroid therapy, in the six months before the start of the season is required.

#### **HSCHD**

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 not requiring medication.

In addition to the two conditions listed above, a premature infant (prematurity must be counted to the exact day) may qualify for five doses as follows:

- Born at an EGA of  $\leq$ 28 weeks 6 days and DOB is on or after November 2, 2010;
- Born at an EGA of 29 weeks 0 days to 31 weeks 6 days and DOB is on or after May 2, 2011; or
- Born at an EGA of  $\leq$ 34 weeks 6 days and DOB is on or after November 2, 2010, and also has severe neuromuscular disease that compromises handling of respiratory secretions; **or** congenital abnormalities of the airways that compromises handling of respiratory secretions.

The conditions of severe neuromuscular disease and congenital airway abnormalities should have an applicable ICD9-CM.

### **Five Dose Authorization Exceptions**

Coverage of Synagis for CLD and HSCHD will terminate when the recipient exceeds 24 months of age AND has received at minimum three doses during the season. Coverage of Synagis for congenital abnormalities of the airways and severe neuromuscular disease that compromises handling of respiratory secretions will terminate when the recipient exceeds 12 months of age AND has received at minimum three doses during the season. For these occurrences, coverage will continue to ensure a medication supply for three doses.

### **Maximum Three Doses; Last Dose Given at Three Months of Age (90 Days of Life)**

Infants meeting clinical criteria as follows may be approved for up to three doses of Synagis during the season:

Born at an EGA of 32 weeks 0 days to 34 weeks 6 days, and DOB is on or after August 2, 2011, 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)]. The child care facility must be identified.
- ◆ Has a sibling younger than five years of age in the home. A multiple birth sibling does not meet this requirement.

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

- a positive RSV episode during the current season
- repeated pneumonia
- sickle cell
- multiple birth with approved sibling
- apnea or respiratory failure of newborn

### **Submitting a Request to Exceed Policy**

For doses exceeding policy or for Synagis administration outside the defined coverage period, the provider should use the **Non-Covered State Medicaid Plan Services Request Form for Recipients under 21 Years of Age** to request Synagis. The form is available on DMA's website at <http://www.ncdhhs.gov/dma/epsdt/>. A medical necessity review will be done under EPSDT (see <http://www.ncdhhs.gov/dma/epsdt/index.htm>); if the information provided justifies medical need, the request will be approved.

### **Pharmacy Distributor Information**

Medicaid will allow Synagis claims processing to begin on October 26, 2011, to allow sufficient time for pharmacies to provide Synagis by November 1, 2011. Payment of Synagis claims prior to October 26, 2011, and after March 31, 2012, will not be allowed. POS 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 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 individual claims will be subject to recoupment by DMA Program Integrity.

Providers will fax the approval notification to the pharmacy distributor of choice. Single dose vial specific authorizations will be done by DMA up to the maximum number of doses approved for the patient. Please ensure that an authorization notification is received before billing a Synagis claim to Medicaid. The authorizations should be maintained in accordance with required record keeping time frames.

### **Provider Information**

- Provider should call (855)272-6576 for assistance with registration or technical issues. Contact DMA at (919)855-4300 for other concerns including policy questions.
- Providers without internet access should contact Charlene Sampson at (919)855-4300 to facilitate submission of a PA request for Synagis.
- Providers are responsible for the accuracy of information inputted for a Synagis request. Physicians and pharmacy providers are subject to audits of patient records by DMA Program Integrity.