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**North Carolina  
Medicaid Pharmacy**

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## Procedures for Prescribing Synagis for RSV Season 2008-2009

Prior approval will not be required for Synagis for the upcoming respiratory syncytial virus (RSV) season. However, prescribers and pharmacists are responsible for ensuring the appropriate usage of Synagis. The clinical criteria utilized by N.C. Medicaid are consistent with currently published American Academy of Pediatrics Red Book guidelines (on the web at <http://aapredbook.aappublications.org/cgi/content/full/2006/1/3.107>)—subscription required; or in *Red Book: 2006 Report of the Committee on Infectious Diseases, 27<sup>th</sup> Edition*).

The **Synagis for RSV Prophylaxis form** is used for patients who meet the clinical criteria for coverage. Please ensure the person completing the Synagis for RSV Prophylaxis form has verified that the conditions exist and are accurately reported. If a patient does not meet the clinical criteria for coverage but you still wish to prescribe Synagis, you must submit your request to DMA 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 Periodic Screening, Diagnostic and Treatment (EPSDT) guidelines. Please use the *Request for Medical Review for Synagis Outside of Criteria* form for a medical necessity review for Synagis under EPSDT guidelines. Requests for a sixth dose or more of Synagis, or for coverage outside of the defined seasonal period, should be made on the *Non-Covered State Medicaid Plan Services Request Form for Recipients under 21 Years of Age*, available online at <http://www.ncdhhs.gov/dma/forms.html> (look under Provider Forms, then Prior Approval).**

N.C. Medicaid will begin coverage of Synagis on October 15, 2008. During the season, five monthly doses of Synagis can be obtained. The number of doses should be adjusted if an infant received the first dose prior to a hospital discharge. Delays in request processing can occur if the patient does not have a Medicaid identification number or the form is not complete.

The **Synagis for RSV Prophylaxis form** must be signed by the prescriber and submitted to the pharmacy distributor of choice. The **Request for Medical Review for Synagis Outside of Criteria form** must be signed by the prescriber and faxed to DMA at 919-715-1255. Evidence of a complete and accurate Synagis for RSV Prophylaxis form or a DMA letter of approval must be on file in the pharmacy prior to dispensing Synagis. Please refer to the guidelines below when submitting a request for Synagis.

### Requesting Synagis for RSV Prophylaxis When Criteria Are Met

Submit on the Synagis for RSV Prophylaxis form. (If the recipient does **not** meet the criteria below, please see the section titled “Requesting Synagis for RSV Prophylaxis When Criteria Are Not Met”.)

For the following four diagnoses, date of birth (DOB) must be on or after **October 15, 2006**.

Chronic lung disease of prematurity (bronchopulmonary dysplasia): The infant has chronic lung disease (bronchopulmonary dysplasia) and has needed treatment (supplemental oxygen, bronchodilator, diuretic, corticosteroid) in the six months before the start of the season.

Hemodynamically significant congenital heart disease: Infants less than 12 months of age who are most likely to benefit include those receiving medication to control congestive heart failure (CHF), moderate to severe pulmonary hypertension, and/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.

Cystic fibrosis: The infant has cystic fibrosis and either requires chronic oxygen or has been diagnosed with nutritional failure.

Severe congenital immunodeficiency: The infant has severe combined immunodeficiency disease or severe acquired immunodeficiency syndrome.

In addition to the above four conditions, a premature infant may qualify for RSV prophylaxis, as follows:

- Born at an estimated gestational age (EGA) of  $\leq 28$  weeks, and DOB is on or after October 15, 2007; or
- Born at an EGA of 29–32 weeks, and DOB is on or after April 15, 2008; or
- Born at an EGA of 32 weeks and 1 day through 35 weeks and 0 days, and DOB is on or after April 15, 2008, and has **two** or more of the following risk factors:
  - School-age siblings
  - Attendance at day care
  - Severe neuromuscular disease
  - Exposure to prolonged wood-burning heaters as the primary source of heat for the family (tobacco smoke is **not** a risk factor because it can be controlled by the family)
  - Congenital abnormalities of the airways

#### **Requesting Synagis for RSV Prophylaxis When Criteria Are Not Met**

Please submit the request on the Request for Medical Review for Synagis Outside of Criteria form (fax it to DMA at 919-715-1255). This form is to be used for patients who do not explicitly meet the criteria on the Synagis for RSV Prophylaxis form.

Please use the Non-Covered State Medicaid Plan Services Request Form for Recipients under 21 Years of Age to request a sixth or subsequent dose of Synagis or for Synagis administration outside the defined seasonal period. A medical review will consider a request for Synagis under EPSDT as follows:

1. The decision to approve or deny will be based on the recipient's **medical need** to correct or ameliorate a defect, physical [or] mental illness, or condition [health problem]. "Ameliorate" means to improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.
2. The specific coverage criteria (e.g., particular diagnoses, signs, or symptoms) specified in the referenced publications do NOT have to be met for recipients under 21 years of age if **MEDICALLY NECESSARY** to correct or ameliorate a defect, physical or mental illness, or condition [health problem].

3. Service limitations on scope, amount, duration, frequency, and/or other specific criteria described in the policy information 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's documentation shows how the service, product or procedure will correct or improve or maintain the recipient's health in the best condition possible, compensate for a health problem, prevent it from worsening, or prevent the development of additional health problems.
4. Other restrictions specified in the publications above may be waived under EPSDT as long as exceeding those restrictions is **medically necessary** to correct or ameliorate a defect or mental illness, or condition [health problem].

If the information provided on the Request for Medical Review for Synagis Outside of Criteria form or the Non-covered State Medicaid Plan Services Request Form for Recipients under 21 Years of Age justifies medical need, an approval letter will be faxed to the provider.

The Synagis for RSV Prophylaxis form and the Request for Medical Review for Synagis Outside of Criteria form are available on the DMA website at (<http://www.ncdhhs.gov/dma/synagis.html>). 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/EPSDTprovider.htm>).

Medicaid will allow Synagis claims processing to begin on October 13, 2008, to allow sufficient time for pharmacies to provide Synagis by October 15, 2008. Payment of Synagis claims prior to October 13, 2008, and after March 31, 2009, will not be allowed. 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. Physicians and pharmacy providers are subject to audits of Synagis records by DMA Program Integrity.

#### **Pharmacy Distributor Information**

The **Synagis for RSV Prophylaxis** form must be maintained at the pharmacy distributor's location. The pharmacy distributor must mail a copy of the submitted forms **weekly** to DMA. Please mail submitted forms to

NC 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.

A copy of the approval letter for recipients evaluated under the Outside of Criteria form or the Non-covered State Medicaid Plan Services Request Form for Recipients under 21 Years of Age must be maintained at the pharmacy distributor's location.

## Prior Authorization Program for Brand-Name Narcotics – Update

On August 4, 2008, the NC Medicaid Outpatient Pharmacy Program implemented a new prior authorization (PA) program for brand-name schedule II (CII) narcotics. Brand-name short-acting and long-acting CII narcotics will require PA. This PA program replaces the current Oxycontin PA program. PA is not required for recipients with a diagnosis of pain secondary to cancer.

If a pharmacy provider receives a point-of-sale message that PA is required for one of these medications, the prescriber must fax ACS at 866-246-8507 to request PA for the medication. **PA requests for these medications will be accepted by facsimile (fax) only.** The signature of the prescriber on the request form will be required as an important safeguard against fraud and abuse. The PA criteria and request form for brand-name narcotics is available on the NC Medicaid Enhanced Pharmacy Program website at (<http://www.ncmedicaidpbm.com>). Providers may call ACS at 866-246-8505 with questions concerning the PA program.

Refer to the June 2008 and July 2008 general Medicaid Bulletins (<http://www.ncdhhs.gov/dma/bulletin.htm>) for additional information.

## Additional North Carolina Medicaid Upper Limits Drugs

Effective August 1, 2008, the NC Medicaid Outpatient Pharmacy Program instituted upper limits on the drugs listed below based on the FDA guidelines. This will limit the maximum number of dosage units per prescription that can be covered at one time to 60 units. Multiple members of a family requiring treatment who are NC Medicaid eligible must each have their own prescription for the drugs and claims must be billed appropriately under each individual Medicaid ID number.

NDC	DRUG Description
00023791560	ELIMITE 5% CREAM
00072210360	EURAX 10% CREAM
00072220316	EURAX 10% LOTION
00072220360	EURAX 10% LOTION
00378613106	ACTICIN 5% CREAM
00472024260	PERMETHRIN 5% CREAM
45802026937	PERMETHRIN 5% CREAM
51672527604	OVIDE 0.5% LOTION
60432083360	LINDANE 1% LOTION
60432083460	LINDANE 1% SHAMPOO
68188093190	LINDANE 1% SHAMPOO
68188093590	LINDANE 1% LOTION

### Deleted NDCs from CMS

The following products do not meet the definition of covered outpatient drugs and are not rebate-eligible. Therefore, they are being deleted from the CMS Master Drug Rebate (MDR) file of covered outpatient drugs effective as of **August 14, 2008**.

NDC	DRUG DESCRIPTION
58177092407	HYDRO-TUSSIN CBX 16 OZ
66813003601	DYNEX LA
68047018001	EXETUSS
68047018101	EXETUSS-GP
68047018301	EXE-TUSS-DM

The FDA has determined that the following drug is a DESI code 5; therefore, this drug will no longer be eligible for Medicaid coverage and rebate billing effective as of **July 23, 2008**.

NDC	DRUG DESCRIPTION
00091074010	Epifoam

### Basic Medicaid Seminars

Basic Medicaid seminars are scheduled for the month of October 2008. Seminars are intended to educate providers on the basics of Medicaid billing. The seminar sites and dates will be announced in the September 2008 general bulletin (<http://www.ncdhhs.gov/dma/bulletin.htm>). The October 2008 Basic Medicaid Billing Guide will be used as the training document for the seminars and will be available on DMA's website at (<http://www.ncdhhs.gov/dma/medbillcaguide.htm>) prior to the seminars.

Pre-registration will be required. Due to limited seating, registration will be limited to two staff members per office. Unregistered providers are welcome to attend if space is available.

### Federal Mac List Changes

Effective September 20, 2008, the following changes will be made to the Medicaid Drug Federal Upper Limit list:

#### FUL Deletions

##### Generic Name

##### FUL Price

Oxycodone Hydrochloride

10 mg, Tablets, Extended Release, Oral. 100

20 mg, Tablets, Extended Release, Oral. 100

40 mg, Tablets, Extended Release, Oral. 100

80 mg, Tablets, Extended Release, Oral. 100

**FUL Additions**

<u>Generic Name</u>	<u>FUL Price</u>
Alendronate Sodium	
EQ 35 mg Base, Tablet, Oral, 4	\$15.3675 B
EQ 70 mg Base, Tablet, Oral, 4	\$15.3675 B
Balsalazide Disodium	
750 mg, Capsule, Oral, 280	\$ 1.0796 B
Benzonatate	
200 mg, Capsule, Oral, 100	\$ 0.6338 B
Bupropion Hydrochloride	
150 mg, Tablet, Extended Release, Oral, 60	\$ 1.8330 B
Carvedilol	
3.125 mg, Tablet, Oral, 100	\$ 0.1425 B
6.25 mg, Tablet, Oral, 100	\$ 0.1425 B
12.5 mg, Tablet, Oral, 100	\$ 0.1425 B
25 mg, Tablet, Oral, 100	\$ 0.1425 B
Diclofenac Sodium	
0.1% Solution/Drops, Ophthalmic, 5 ml	\$ 4.2720 B
Ondansetron Hydrochloride	
EQ 4 mg Base, Tablet, Oral, 30	\$ 1.1000 B
EQ 8 mg Base, Tablet, Oral, 30	\$ 1.9000 B
Pravastatin Sodium	
80 mg, Tablet, Oral, 90	\$ 0.5753 B
Prednisolone Sodium Phosphate	
EQ 15 mg Base 5 ml, Solution, Oral, 237 ml	\$ 0.2089 B
Propranolol Hydrochloride	
80 mg, Capsule, Extended Release, Oral, 100	\$ 1.5447 B
120 mg, Capsule, Extended Release, Oral, 100	\$ 1.9160 B
160 mg, Capsule, Extended Release, Oral, 100	\$ 2.5088 B
Ranitidine Hydrochloride	
EQ 15 mg Base/ml, Syrup, Oral, 473 ml	\$ 0.4027 B
Ropinirole Hydrochloride	
EQ 1 mg Base, Tablet, Oral, 100	\$ 0.7515 B
EQ 2 mg Base, Tablet, Oral, 100	\$ 0.7515 B
EQ 3 mg Base, Tablet, Oral, 100	\$ 0.7515 B
EQ 4 mg Base, Tablet, Oral, 100	\$ 0.7515 B

Sertraline Hydrochloride	
EQ 25 mg Base, Tablet, Oral, 100	\$ 0.1283 B
EQ 50 mg Base, Tablet, Oral, 100	\$ 0.1283 B
EQ 100 mg Base, Tablet, Oral, 100	\$ 0.1283 B
Trandolapril	
1 mg, Tablet, Oral, 100	\$ 0.6666 B
2 mg, Tablet, Oral, 100	\$ 0.6666 B
4 mg, Tablet, Oral, 100	\$ 0.6666 B
Zaleplon	
5 mg, Capsule, Oral, 100	\$ 0.7191 B
10 mg, Capsule, Oral, 100	\$ 0.7386 B
Zolpidem Tartrate	
5 mg, Tablet, Oral, 100	\$ 0.0704 B
10 mg, Tablet, Oral, 100	\$ 0.0704 B

### Changes in Drug Rebate Manufacturers

The following changes have been made in manufacturers with Drug Rebate Agreements. They are listed by manufacturer's code, which are the first five digits of the NDC.

#### Additions

The following labelers have entered into Drug Rebate Agreements and have joined the rebate program effective on the dates indicated below:

<i>Code</i>	<i>Manufacturer</i>	<i>Date</i>
25021	Sagent Pharmaceuticals, Inc.	08/06/2008
42457	Emmaus Medical, Inc.	08/12/2008
68016	Chain Drug Consortium, LLC.	07/29/2008

#### Reinstated Labeler

<i>Code</i>	<i>Manufacturer</i>	<i>Date</i>
38779	Medisca, Inc.	08/15/2008

**Terminated Labelers**

The following labelers will be terminated from the Medicaid Drug Rebate Program effective October 1, 2008:

Nexus Pharmaceuticals, Inc.	(Labeler 14789)
Advance Pharmaceuticals, Inc.	(Labeler 17714)
Martec USA, LLC	(Labeler 52555)
Coats Aloe International, Inc.	(Labeler 58826)
Dartmouth Pharmaceuticals, Inc.	(Labeler 58869)
Altaire Pharmaceuticals, Inc.	(Labeler 59390)
Advent Pharmaceuticals, Inc.	(Labeler 60242)
The Medicines Company	(Labeler 65293)
Aero Pharmaceuticals, Inc.	(Labeler 66440)
Cura Pharmaceutical Co., Inc.	(Labeler 66860)

### Checkwrite Schedule

August 12, 2008	September 09, 2008	October 07, 2008
August 19, 2008	September 16, 2008	October 14, 2008
August 28, 2008	September 25, 2008	October 21, 2008
		October 30, 2008

### Electronic Cut-Off Schedule

August 07, 2008	September 04, 2008	October 02, 2008
August 14, 2008	September 11, 2008	October 09, 2008
August 21, 2008	September 18, 2008	October 16, 2008
		October 23, 2008

*Electronic claims must be transmitted and completed by 5:00 p.m. on the cut-off date to be included in the next checkwrite. Any claims transmitted after 5:00 p.m. will be processed on the second checkwrite following the transmission date. POS claims must be transmitted and completed by 12:00 midnight on the day of the electronic cut-off date to be included in the next checkwrite.*

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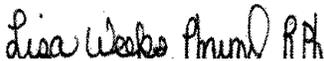
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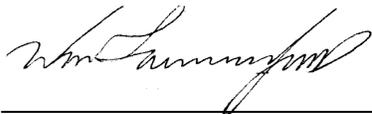
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