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Procedures for PA Request for Synagis for RSV Season 2012/2013

The clinical criteria utilized by N.C. Medicaid for the 2012/2013 RSV season are consistent with published guidelines in the *Red Book: 2012 Report of the Committee on Infectious Diseases, 29th Edition*. **Prior approval (PA) is required** for Medicaid coverage of Synagis during the upcoming RSV season. The coverage season is November 1, 2012, through March 31, 2013. Early and Periodic Screening, Diagnosis and Treatment (EPSDT) criteria are considered for Synagis requests.

Submit all PA requests for coverage of Synagis for the upcoming season electronically. The Synagis Program, online at www.documentforsafety.org, will accept requests starting on October 9, 2012. Dropdown lists, free text selections, and the attachment option incorporated in the system design capture all information for a PA request. When the system offers an opportunity to upload supporting documents, the most recent progress note documenting the patient's pulmonary or cardiac status is required when a specialist is involved in the care. The electronic system can automatically approve a request based on the criteria submitted and allows a provider to self monitor the status of a request pending medical review.

For approved requests, each Synagis dose will be individually authorized to promote appropriate product distribution. After the initial approval, providers must submit a "next dose request" to obtain an authorization for each subsequent dose up to the approved number of doses. If an infant received one or more Synagis doses prior to hospital discharge, the provider should indicate as part of the request the most recent date a dose was administered. The number of doses administered by the provider should be adjusted accordingly. Providers should ensure the previously obtained supply of Synagis is administered before submitting a next dose request.

It is important for a Synagis distributor to have the appropriate single dose authorization on hand and a paid claim prior to shipping Synagis for a beneficiary. An individual dose authorization is required for each paid Synagis claim. The claim should not exceed the quantity indicated on the authorization. A Synagis claim will deny if a dose request was not done by the provider.

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.

Congenital abnormalities of the airway or neuromuscular disease

Infants born on or after November 2, 2011, with compromised handling of respiratory secretions secondary to congenital abnormalities of the airway or neuromuscular disease may be eligible for prophylaxis during the first year of life. The diagnosis to justify severe neuromuscular disease or congenital airway abnormalities must be specific.

Prematurity

In addition to the 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, 2011
- Born at an EGA of 29 weeks 0 days to 31 weeks 6 days and DOB is on or after May 2, 2012

Five Dose Exceptions

Coverage of Synagis for CLD and HSCHD will terminate when the beneficiary exceeds 24 months of age AND has received a minimum of 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 beneficiary exceeds 12 months of age AND has received a minimum of three doses during the season.

Maximum of Three Doses; Last Dose Administered 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, 2012, 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 name of the day care facility must be submitted with the request.
 - ◆ Has a sibling younger than five years of age living permanently in the same household. Multiple births do not qualify as fulfilling this risk factor.

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

Synagis claims processing will begin on October 29, 2012, to allow sufficient time for pharmacies to provide Synagis by November 1, 2012. Payment of Synagis claims prior to October 29, 2012, and after March 31, 2013, will not be allowed. Point of sale 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. Physicians and pharmacy providers are subject to audits of beneficiary records by DMA Program Integrity.

Providers will fax each single dose authorization to the pharmacy distributor of choice. Single dose vial specific authorizations, up to the maximum number of doses approved for the beneficiary, will be issued by Medicaid. Please ensure the appropriate authorization is received before submitting a claim to Medicaid. The authorizations should be maintained in accordance with required record keeping time frames.

Provider Information

Providers without internet access should contact the Medicaid Outpatient Pharmacy Program at (919)855-4300 to facilitate submission of a PA request for Synagis. The Synagis program is found at www.documentforsafety.org. Providers should note the new website location for Synagis PA requests.

Technical Support

Technical support is available from 8am to 5pm by calling 855-272-6576 (local: 919-657-8843). Technical support can assist with provider registration, user name and password issues, beneficiary searches, and other registry functions.

Clinical Coverage Policies

The following new or amended combined N.C. Medicaid and N.C. Health Choice (NCHC) clinical coverage policies are available on the N.C. Division of Medical Assistance (DMA) website at www.ncdhhs.gov/dma/mp/:

1A-16, Surgery of the Lingual Frenulum (8/15/12)

1E-6, Pregnancy Medical Home (8/15/12)

1K-2, Bone Mass Measurement (8/1/12)

3H-1, Home Infusion Therapy (8/15/12)

8D-1, Psychiatric Residential Treatment Facilities for Children under the Age of 21 (8/1/12)

8D-2, Residential Treatment Services (8/1/12)

8E, Intermediate Care Facilities for Individuals with Intellectual and Developmental Disabilities (8/1/12)

8J, Children's Developmental Service Agencies (CDSAs) (8/1/12)

9, Outpatient Pharmacy Program (8/16/12)

11A-14, Placental and Umbilical Cord Blood as a Source of Stem Cells (3/12/12)

11B-1, Lung Transplantation (8/1/12)

11B-2, Heart Transplantation (8/1/12)

11B-3, Islet Cell Transplantation (8/1/12)

11B-5, Liver Transplantation (8/1/12)

11B-6, Heart/Lung Transplantation (8/1/12)

11B-7, Pancreas Transplant (8/1/12)

11B-8, Small Bowel and Small Bowel/Liver and Multivisceral Transplants (8/1/12)

These policies supersede previously published policies and procedures. Providers may contact HP Enterprise Services (HPES) at 1-800-688-6696 or 919-851-8888 with billing questions.

Updated Federal Upper Limit Reimbursement List

There are certain drugs that have been identified for which the Federal Upper Limit (FUL) reimbursement rate does not cover the cost of the drug. Medicaid pharmacy programs are required to reference this reimbursement information when pricing drug claims. In order to receive adequate reimbursement, pharmacy providers may use the DAW1 override to override the FUL reimbursement rate for the drugs listed below until the FUL rate has been adjusted to adequately cover the cost of the drug.

A comment should be entered when the DAW1 override code is used to indicate that the FUL is too low to cover the cost of the drug. If there is an active State Maximum Allowable Cost (SMAC) rate on file, the SMAC rate should be submitted.

Pharmacy providers should report reimbursement issues to the N.C. Medicaid program at 919-855-4300. Use of the *DAWI* override code for overriding FUL rates will continue to be monitored. Pharmacy providers should also monitor the FUL rates and discontinue use of the DAW1 override code once updates to the FUL rates have occurred.

NDC	DRUG NAME
00054003721	CLARITHROMYCIN 500 MG TABLET
00054302802	ACETYLCYSTEINE 20% VIAL
00093075701	PIROXICAM 20 MG CAPSULE
00093075705	PIROXICAM 20 MG CAPSULE
00168000215	TRIAMCINOLONE 0.5% CREAM
00168000315	TRIAMCINOLONE 0.025% CREAM
00168000380	TRIAMCINOLONE 0.025% CREAM
00168000415	TRIAMCINOLONE 0.1% CREAM
00168000416	TRIAMCINOLONE 0.1% CREAM
00168000480	TRIAMCINOLONE 0.1% CREAM
00168000615	TRIAMCINOLONE 0.1% OINTMENT

00168000616	TRIAMCINOLONE 0.1% OINTMENT
00168000680	TRIAMCINOLONE 0.1% OINTMENT
00168004046	BETAMETHASONE VA 0.1% CREAM
00168005515	BETAMETHASONE DP 0.05% CRM
00168005546	BETAMETHASONE DP 0.05% CRM
00168013460	FLUOCINONIDE 0.05% SOLUTION
00168025815	CLOTRIMAZOLE-BETAMETHASONE C
00168025846	CLOTRIMAZOLE-BETAMETHASONE C
00168031002	DESONIDE 0.05% LOTION
00168031004	DESONIDE 0.05% LOTION
00168038360	METRONIDAZOLE 0.75% LOTION
00185072401	CARISOPRODOL COMPOUND TAB
00185072405	CARISOPRODOL COMPOUND TAB
00228206710	OXAZEPAM 10 MG CAPSULE
00378135501	TRIAMTERENE-HCTZ 75-50
00378135505	TRIAMTERENE-HCTZ 75-50
00378537501	DOXEPIN 75 MG CAPSULE
00472016315	NYSTAIN 100,000 UNIT/GM CREAM
00472016330	NYSTAIN 100,000 UNIT/GM CREAM
00472016615	NYSTAIN 100,000 UNIT 15GMS
00472016630	NYSTAIN 100,000 UNITS 30GMS
00472037915	CLOTRIMAZOLE-BETAMETHASONE CRM
00472037945	CLOTRIMAZOLE-BETAMETHASONE CRM
00472080302	DESONIDE LOTION 0.05%
00472080304	DESONIDE 0.05% LOTION
00527142635	OXYCODONE CONC 20 MG/ML SOLN
00527142636	OXYCODONE CONC 20 MG/ML SOLN
00555095302	DEXTROAMPHETAMINE 10 MG TAB
00591578701	NORTRIPTYLINE 25MG CAP
00591578705	NORTRIPTYLINE HCL 25 MG CAP
00591578710	NORTRIPTYLINE HCL 25 MG CAP
00603459315	METHYLPREDNISOLONE 4MG D/P
00603459321	METHYLPREDNISOLONE 4 MG TABL
00603781874	NYSTATIN 100,000
00603781878	NYSTATIN 100,000 UNIT/GM CREAM
00781100801	TRIAMTERENE-HCTZ 75-50
00781100805	TRIAMTERENE-HCTZ 75-50
00781107101	METHAZOLAMIDE 50 MG TABLET
00781196160	CLARITHROMYCIN 250 MG TABLET
00781196260	CLARITHROMYCIN 500 MG TABLET
17478028310	GENTAK 3 MG/ML EYE DROPS
24208058060	GENTAMICIN OPTH SOLN

24208058064	GENTAMICIN 3 MG/ML EYE DROPS
24208067004	SULFACETAMIDE 10% EYE DROPS
29033001301	PIROXICAM 20 MG CAPSULE
29033001305	PIROXICAM 20 MG CAPSULE
43538051012	GENADUR NAIL LACQUER
45802002146	BETAMETHASONE DP 0.05% LOT
45802004811	NYSTATIN
45802004835	NYSTATIN OINTMENT
45802006405	TRIAMCINOLONE 0.1% CREAM
45802006435	TRIAMCINOLONE 0.1% CREAM
45802006436	TRIAMCINOLONE 0.1% CREAM
45802042235	DESONIDE 0.05% CREAM
45802042237	DESONIDE 0.05% CREAM
48102010101	METHAZOLAMIDE 50 MG TABLET
49884024601	CARISOPRODOL COMPOUND TAB
49884024605	CARISOPRODOL COMPOUND TAB
50111033401	METRONIDAZOLE 500 MG TABLET
50111033402	METRONIDAZOLE 500 MG TABLET
50383026760	CLOBETASOL 0.05% CREAM
51672125301	FLUOCINONIDE 0.05% CREA
51672125302	FLUOCINONIDE 0.05% CREA
51672125303	FLUOCINONIDE 0.05% CREA
51672125304	FLUOCINONIDE 0.05% CREA
51672125903	CLOBETASOL 0.05% OINTMENT
51672126301	NYSTATIN-TRIAMCINOLONE CREAM
51672126302	NYSTATIN-TRIAMCINOLONE CREAM
51672126303	NYSTATIN-TRIAMCINOLONE CREAM
51672127201	NYSTATIN-TRIAMCINOLONE OINT
51672127202	NYSTATIN-TRIAMCINOLONE OINTM
51672127203	NYSTATIN-TRIAMCINOLONE OINTM
51672127304	FLUOCINONIDE 0.05% SOLUTION
51672128003	DESONIDE 0.05% CREAM
51672128202	TRIAMCINOLONE 0.1% CREAM
51672128901	NYSTATIN 100,000 UNIT/GM CRE
51672128902	NYSTATIN 100,000 UNIT/GM CRE
51672129201	HYDROCORTISONE VAL 0.2% OINT
51672129203	HYDROCORTISONE VAL 0.2% OINT
51672129206	HYDROCORTISONE VAL 0.2% OINT
51672404709	CARBAMAZEPINE 100 MG/5 ML SU
51672404801	CLOTRIMAZOLE-BETAMETHASONE CRM
51672404806	CLOTRIMAZOLE-BETAMETHASONE CRM

59746000103	METHYLPREDNISOLONE 4 MG DOSE
60758018805	GENTAMICIN 3 MG/ML EYE DROPS
61314063136	NEOMYC-POLYM-DEXAMET EYE OINTMENT
61314063305	GENTAMICIN 3MG/ML EYE DROPS (3%)
61314064305	TOBRAMYCIN 0.3% EYE DROPS
61314070101	SULFACETAMIDE 10% EYE DROPS
64679094901	CLARITHROMYCIN 500 MG TABLET
67405011045	METRONIDAZOLE 0.75% CREAM
68382076214	CLARITHROMYCIN 500 MG TABLET
68462034737	OXYCODONE CONC 20 MG/ML SOLN

Changes in Drug Rebate Manufacturer

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

Addition

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

<i>Code</i>	<i>Manufacturer</i>	<i>Date</i>
42195	Xspire Pharma	09/19/2012
55150	Auromedics Pharma, LLC	09/13/2012

Checkwrite Schedule

September 05, 2012	October 02, 2012	November 06, 2012
September 11, 2012	October 10, 2012	November 14, 2012
September 18, 2012	October 16, 2012	November 21, 2012
September 27, 2012	October 25, 2012	

Electronic Cut-Off Schedule

August 30, 2012	September 27, 2012	November 01, 2012
September 06, 2012	October 04, 2012	November 08, 2012
September 13, 2012	October 11, 2012	November 15, 2012
September 20, 2012	October 18, 2012	

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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