Synagis® Web Conference
2009-2010
RSV Season

August 14, 2009
10:00 AM CT

Hosted By

Alabama Medicaid
In conjunction with Health Information Designs, Inc.
Web Conference Agenda

I. Welcome/Introductions

II. Background/History

III. 2009-2010 Season Overview

IV. Changes for the Season

V. PA Criteria Review and Process

VI. Notification Process/Approval Letter

VII. Educational Opportunities/Outreach

VIII. Question/Answer
Welcome/Introductions

a. Alabama Medicaid
b. Health Information Designs, Inc.
c. Medicaid Pharmacy Specialists
d. MedImmune
Synagis® 2009-2010 Season

Background/History

Robert Moon, M.D.,
Alabama Medicaid Medical Director
AAP’s Red Book

For 70 years, the Red Book has set standards of quality, authority and value. Red Book experts have full access to the world’s literature to help establish their recommendations.¹

The Red Book is developed by the AAP Committee on Infectious Diseases, and its content, including contributions from hundreds of experienced practitioners, is reviewed by the CDC and FDA.¹

¹ Red Book 2009 “About the Red Book”
AMA’s Use of the Red Book

- Alabama Medicaid for the past several years has taken our criteria from the Red Book. Prior to what was released this summer, we had been using the most recent version: "AAP 2006 Redbook Recommendations for the Prevention of RSV".

- This summer, Red Book released its 2009 version and our criteria has been updated accordingly.

2 Red Book 2009, Section 3. Summaries of Infectious Diseases, Respiratory Syncytial Virus
“Reducing RSV hospitalizations AAP modifies recommendations for use of palivizumab in high-risk infants, young children”

We are aware that MedImmune is refuting the 2009 Red Book and is challenging the evidence basis of the AAP's recommendation and the use of existing FDA labeling.
The Red Book as a Standard

The Red Book is recognized as a standard of care guideline.

- The credentials of its committee members are very significant.
- Obviously just because the AAP did not share all of their references in the Red Book, does not mean they don't exist.
- We too look forward to them sharing more information, but also recognize that many guidelines are the work of expert opinion or consensus.
FDA Labeling

Physician Prescribing
Synagis® 2009-2010 Season

Prior Authorization

Overview

Kelli Littlejohn, Pharm.D.  Alabama Medicaid Director of Pharmacy
RSV Season

- The Alabama Medicaid Agency uses the RSV Season data from the Centers for Disease Control and Prevention (CDC) website.
- The National Respiratory and Enteric Virus Surveillance System (NREVSS).
- CDC lists RSV surveillance by:
  - State trends (AL)
  - Divisional trends (East South Central)
  - Regional trends (South)
  - National trends
RSV Season: AL State Trends

http://www.cdc.gov/surveillance/nrevss/rsv/state.html (accessed 8/10/09)

The National Respiratory and Enteric Virus Surveillance System (NREVSS)

State Trends
RSV Season: AL State Trends

http://www.cdc.gov/surveillance/nrevss/rsv/state.html (accessed 8/10/09)

The NREVSS participating labs in the AL area:
- Baptist South - Montgomery, AL
- Crestwood Medical Center - Clinical Laboratory - Huntsville, AL
- Cullman Regional Medical Center - Cullman, AL
- Elmore Community Hospital Laboratory - Wetumpka, AL
- George H. Lanier Memorial Hospital - Valley, AL
- Marshall Medical Center South - Boaz, AL
- Providence Hospital - Mobile, AL
- Southeast Alabama Medical Center - Dothan, AL
- Springhill Memorial Hospital - Mobile, AL
- UAHSF Diagnostic Virology Lab - Birmingham, AL
- University of South Alabama Medical Center - Mobile, AL
- Woodland Medical Center - Cullman, AL
RSV Season:

East South Central Division Trends

http://www.cdc.gov/surveillance/nrevss/rsv/state.html (accessed 8/10/09)

The NREVSS participating labs in the East South Central Division:

- Baptist South - Montgomery, AL
- Crestwood Medical Center - Clinical Laboratory - Huntsville, AL
- Cullman Regional Medical Center - Cullman, AL
- Elmore County Hospital Laboratory - Wetumpka, AL
- George H. Lanier Memorial Hospital - Valley, AL
- Marshall Medical Center South - Easley, AL
- Providence Hospital - Mobile, AL
- Southeast Alabama Medical Center - Dothan, AL
- Springhill Memorial Hospital - Mobile, AL
- UAHSC Diagnostic Virology Lab - Birmingham, AL
- University of South Alabama Medical Center - Mobile, AL
- Midland Medical Center - Cullman, AL
- Eufaula Regional Hospital - Danville, KY
- Fort Logan Hospital - Stanford, KY
- Jackson Purchase Medical Center - Mayfield, KY
- Norton Medical Pavilion - Louisville, KY
- University of Kentucky Hospital - Lexington, KY
- University of Louisville Hospital - Louisville, KY
- Alliance Health Care System - Holy Springs, MS
- Baptist Memorial Hospital North MS - Oxford, MS
- Baptist Memorial Union County - New Albany, MS
- Forrest General Hospital - Hattiesburg, MS
- Mississippi Baptist Medical Center - Jackson, MS
- Ocean Springs Hospital - Ocean Springs, MS
- University Hospitals & Clinics - Jackson, MS
- Winston Medical Center - Louisville, MS
- Blount Memorial Hospital - Microbiology Department - Maryville, TN
- DeKalb Community Hospital - Smithville, TN
- Dyersburg Regional Medical Center - Dyersburg, TN
- East Tennessee Children’s Hospital - Knoxville, TN
- Fort Loudoun Medical Center - Lenoir City, TN
- Methodist Hospital Microbiology Laboratory - Chattanooga, TN
- NorthCrest Medical Center - Springfiled, TN
- St. Jude's Children's Research Hospital - Memphis, TN
- St. Mary's Health System - Knoxville, TN
- Stonecrest Medical Center - Smyrna, TN
- Summit Medical Center - Herrin, IL
- TC Thompson Children's Hospital - Chattanooga, TN
- University of Tennessee - Memphis, TN
- Vanderbilt University Medical Center - Nashville, TN
- Volunteer Community Hospital Clinical Laboratory - Martin, TN

RSV Data for East South Central
2009-2010 Season Overview

- PAs will be accepted by HID beginning 9/1/2009.
- Up to 5 doses allowed per recipient. Some recipients may receive up to a max of 3 doses, depending on GA and CA.
- No circumstances will result in approval of a 6th dose.
2009-2010 Season Overview

- Date of any inpatient dose must be included on the PA form.
- Recipient must meet GA and CA (at the start of the RSV season- 10/1/2009).
- **Prescribers** must submit PA requests directly to HID.
- A copy of hospital discharge summary from birth is required on **ALL** Synagis® PA requests.
2009-2010 Season Overview

- If approved, each subsequent monthly dose will require submission of recipient weight/date of last dose to HID (prescriber or pharmacy).

- Approval/denial letters will be faxed to prescriber and dispensing pharmacy.

- All criteria/forms/ALERTs/web conferences are posted on the Medicaid website [www.medicaid.alabama.gov](http://www.medicaid.alabama.gov)
Synagis® 2009-2010 Season

Prior Authorization
Changes for this season

Kelli Littlejohn, Pharm.D.  Alabama Medicaid Director of Pharmacy
Changes for the Season

- All criteria posted on Medicaid website- complete transparency

- Prescribers, not the pharmacy, manufacturer, or any third party are to submit PA requests directly to HID (last season)

- A copy of the hospital discharge summary from birth is required on all Synagis® PA requests
Changes for the Season

- If approved, each subsequent monthly dose will require submission (by prescriber or pharmacy) of recipient current weight and last injection date utilizing the original PA approval letter.

- No stamped signatures accepted on PA form.

- Current forms must be submitted. Old forms will not be accepted.
Changes for the Season

- Some recipients may receive up to a maximum of 3 doses, depending on GA and CA:

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<tr>
<th>If Birthdate is:</th>
<th>Then receive approval thru:</th>
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Synagis® 2009-2010 Season

Prior Authorization Criteria Review

Kelli Littlejohn, Pharm.D.  Alabama Medicaid Director of Pharmacy
Welcome to the
Alabama Medicaid Agency

Medicaid is a state/federal program that pays for medical and long-term care services for low-income pregnant women, children, certain people on Medicare, disabled individuals and nursing home residents. These individuals must meet certain income and other requirements.

What's New:

- Alerts - Updated 7/15/09
- Syraxis - Register for August 14 web conference
- Together for Quality (TFQ) Initiative
- Long Term Care Rebalancing Committee - Updated July 10, 2009
- Medicaid Matters - Online newsletter
- Health Reform - Join the Agency’s new email discussion list
Criteria Review

http://www.medicaid.alabama.gov/programs/pharmacy_svcs/pharmacy_services.aspx

Pharmacy Services

The Alabama Medicaid Agency pays for most medicines legally prescribed by a doctor or authorized health professional when dispensed by a licensed doctor or pharmacist in accordance with state and federal laws. In FY 2007, Medicaid paid for approximately 7 million prescriptions for qualifying Alabama recipients.

- Billing Resources /Policy for Providers - Includes instructions for billing compound prescription claims
- Prior Authorization/Oversides Criteria and Pharmacy Forms Includes External Criteria/PA instructions effective 4/1/09
- SMAC - Link to Alabama Medicaid Pharmacy State Maximum Allowable Cost (SMAC)/ Myers and Stauffer webpage
- Synanis - Important information for the 2009-2010 season
- Tamper-Resistant Prescription Pads - Information on federal mandate
Synagis - Information for 2009 - 2010

To inform providers about changes impacting the 2009-2010 Synagis® season, the Alabama Medicaid Agency will present a statewide Web conference on August 14, 2009 at 10:00 a.m. for all Synagis® providers. A question and answer session will be held at the end of the presentation so providers may ask questions or obtain clarification as needed.

Providers may participate in the Synagis® web conference via physical attendance in the Medicaid Boardroom or join via an iLinc web conferencing feature. In order to join via iLinc, participants must register by August 10, 2009.

To register, email your name, phone number and email address to:
Earnestine.Rhodes@medicaid.alabama.gov

or by calling (334) 242-5050 and providing your name, phone number and email address during normal business hours. Participants should register early as space for the web conference is limited.

- Synagis Prior Authorization Form - Updated 7/27/09
- Synagis Prior Authorization Criteria - Updated 7/27/09
- Synagis Appendix A - Updated 7/27/09
- Synagis Instruction Worksheet - Updated 7/27/09
- Synagis 2009-2010 ALERT - Updated 7/27/09
Criteria Review: ALERT


To: All Providers and Associations

RE: Synagis® Criteria for 2009-2010 Season

The Alabama Medicaid Agency has updated its prior authorization criteria for Synagis®.

Highlights of the updated criteria include:

- The approval time frame for Synagis® will begin October 1, 2009 and will be effective through March 31, 2010.
- Up to five doses will be allowed per recipient in this timeframe. Some recipients may only receive up to a max of 3 doses, depending on the gestational and chronological age.
- There are no circumstances that will result in approval of a sixth dose.
- If a dose was administered in an inpatient setting, the date the dose was administered must be included on the request form.
- For approval of requests, the recipient must meet gestational and chronological age requirements. In order to meet chronological age requirements, the recipient must not exceed the specified age at the start of the RSV season.
- Prescribers, not the pharmacy, manufacturer or any other third party entity, are to submit requests for Synagis® on a separate prior authorization form (Form 351) directly to Health Information Designs and completed forms may be accepted beginning September 1, 2009 (for an October 1 effective date).
- A copy of the hospital discharge summary from birth is required on all Synagis® PA requests.
- If approved, each subsequent monthly dose will require submission of the recipient’s current weight and last injection date and may be faxed to HID by the prescribing physician or dispensing pharmacy utilizing the original PA approval letter.
- Letters will be faxed to both the prescriber and the dispensing pharmacy noting approval or denial.

Criteria

Educational Presentation / Web Conference
To inform providers about changes impacting the 2009-2010 Synagis® season, the Alabama Medicaid Agency will present a statewide Web conference on August 14, 2009 at 10:00 a.m. for all Synagis® providers. A question and answer session will be held at the end of the presentation so providers may ask questions or obtain clarification as needed.
Criteria Review: Criteria

http://www.medicaid.alabama.gov/documents/program-RX/PA_Forms/3J-6k_Synagis_PA_Criteria_7-27-09.pdf

Alabama Medicaid Agency
Synagis® Prior Authorization Criteria

1. Is the infant's gestational age <= 28 wks and chronological age <= 12 months old?
   - Yes (If yes, go to #7)
   - No (If no, go to #2)

2. Is the infant’s gestational age 29 wks up to 31 wks, 6 days and chronological age <= 6 months old?
   - Yes (If yes, go to #7)
   - No (If no, go to #3)

3. Is the infant’s gestational age 32 wks, 0 days-34 wks, 6 days and born <= 3 months before the start of RSV season OR born during the RSV season? The infant must meet at least one of the two identified AAP risk factors (childcare attendance, sibling younger than 5 yrs of age).
   - Yes (If yes, go to #7)
   - No (If no, go to #4)

4. Is the infant’s gestational age = 35 wks and chronological age <= 12 months with a diagnosis of congenital abnormalities of the airway or neuromuscular disease that compromises handling of respiratory secretions? Supporting documentation of diagnosis/ICD-9 code must be included.
   - Yes (If yes, indicate treatment below and go to #7)
   - No (If no, go to #7)

5. Is the patient less than 24 months of age with a diagnosis of Chronic Lung Disease (CLD) of prematurity (defined as gestational age less than 35 weeks) and has received medical therapy (supplemental oxygen, bronchodilator, diuretic, or chronic corticosteroid therapy) within 6 months before the start of the RSV season or who continues to require medical therapy (as defined above)? Supporting documentation of diagnosis/ICD-9 code and medical therapy must be included.
   - Yes (If yes, indicate treatment below and go to #7)
   - No (If no, go to #6)

6. Is the patient 24 months of age or younger with a diagnosis of hemodynamically significant cyanotic or acyanotic Congenital Heart Disease (CHD) with one of the following:
   - Congenital heart disease patient who is receiving medication to control congestive heart failure (CHF), or
   - Moderate to severe pulmonary hypertension, or
   - Cyanotic heart disease with no or incomplete surgical correction of defect? Supporting documentation of diagnosis/ICD-9 code as well as medications (if applicable) must be included.
   - Yes (If yes for 6a, 6b or 6c, go to #7)
   - No (If no, deny)

7. Is the patient currently an outpatient and has not been enrolled as an inpatient within 2-weeks of the date the Synagis® is requested? Enter discharge date (if applicable)
   - Yes (If yes, approve request)
   - No (If no, deny)

(Note: If discharge date does not reflect a 2 week period, approval may be given to be effective 2 weeks post hospital discharge)

One of the first 6 criteria and the final criterion must be met before approval can be granted. A copy of the hospital discharge summary from birth is required on all Synagis PA requests. RSV prophylaxis approval will terminate March 31. RSV season is defined by the Alabama Medicaid Agency as October 1 through March 31.

(Note: Approval authorizes 4000 mg once daily based on patient weight every twenty-eight days up to a five (5) dose maximum through March 31. A dose is defined as the calculated dosage (patient weight [lbs] X 2.1mg/kg = 100 mg/kg of Synagis®). The results of the calculation will be the number of hits the patient needs. Use the appropriate combination of tabs to get the correct dose. No dose may be given after March 31. Requests for more than one dose in a 30 day period cannot be approved. If the patient received a dose in an inpatient setting, approval will not be retroactive for any prior Synagis® dose even if prior to the start of Synagis® eligibility.)
ICD-9 CODE and MEDICATION LIST FOR USE WITH SYNAGIS® CRITERIA

Note: ANT accepted diagnosis/ICD-9 Code listed on the prior authorization form MUST have supporting documentation attached. Supporting Documentation is supplemental information submitted to support the patient meeting the criteria and may include copies of hospital discharge notes, progress notes, pharmacy profiles, etc.

I. Neuromuscular Disorders
Acceptable ICD-9 codes include:
- 045.00-045.13 Infantile paralysis
- 330.0-330.1 Cerebral degenerations
- 333.2 Myoclonus
- 334.0-334.1 Spinocerebellar disease
- 335.0 Werdnig-Hoffman disease (Infantile spinal muscular atrophy)
- 335.10-335.11 Spinal muscular atrophy
- 335.20-335.24 Motor neuron disease

Exclude (but not limited to) the following (ie the following are NOT accepted):
- 343.0-343.9 Cerebral Palsy
- 345.10 Generalized Convulsive epilepsy
- 345.9 Grand mal seizures
- 345.5-345.9 Epilepsy
- 741.90 Spina bifida
- 777.0 Newborn seizures
- 780.3 Infantile seizures

II. Congenital Abnormalities of the Airways
Acceptable ICD-9 codes include:
- 519.1 Other diseases of the trachea and bronchi, not elsewhere classified
  (Must specify Tracheomalacia or tracheal stenosis)
- 748.3 Other anomalies of larynx, trachea, and bronchi (Must specify congenital tracheal stenosis, stenosis of trachea, or absence or agenesis of bronchus, trachea)
- 748.4 Congenital cystic lung
- 748.5 Agenesis, hypoplasia, and dysplasia of the lung
- 748.61 Congenital bronchiectasis
- 750.15 Macroglossia
- 750.9 Uvula anomaly
- 759.89 Beckwith (-Wiedemann) Syndrome

Exclude (but not limited to) the following (ie the following are NOT accepted):
- 748.60 Anomaly of lung, unspecified
- 748.69 Other anomaly of the lung
Criteria Review: PA Form 351

http://www.medicaid.alabama.gov/documents/program-RX/PA_Forms/3J-6-j_Synagis_Form351_7-14-09.pdf

Alabama Medicaid Pharmacy
Synagis® PA Request Form

FAX: (800) 748-0116
Phone: (800) 748-0130
Fax or Mail to
 HEALTH INFORMATION DESIGNS
P.O. Box 3210
Auburn, AL 36832-3210

Incomplete Forms Will Be Returned

PATIENT INFORMATION

Patient Name _______________________________ Patient Medicaid # _________________________

Patient DOB ________________________________ Patient phone # with area code ________________

PRESCRIBER INFORMATION

Prescriber name ___________________________ NPI # __________________ License # _______________

Phone # with area code ______________________ Fax # with area code _________________________

Address (Optional)

(Address/City/State/Zip)

I certify that this treatment is indicated and necessary and meets the guidelines for use as outlined by the Alabama Medicaid Agency. I will be supervising the patient’s treatment. Required supporting documentation from the patient’s medical record is attached.

Prescribing Practitioner Signature (Required) ___________________________ Date ____________________
DRUG/CLINICAL INFORMATION

Drug requested ___________________________ NDC/J Code _______________

Strength ___________________________ Qty. per month _______________ Number of doses requested _______________
(if applicable)

Current weight _______________ kg. Gestational age ______ wks _______ days Chronological age__________

ICD-9 Codes ___________________________ ___________________________

Check applicable age, condition and risk factors

☐ Gestational age ≤ 28 wks, 6 days & infant is < 12 months†
☐ Gestational age 29 wks, 0 days-31 wks, 6 days & infant is < 6 months†
☐ Gestational age 32 wks, 0 days-34 wks, 6 days & infant < 3 months old at the start of RSV season OR born during the RSV season with one of the two AAP risk factors*
☐ Gestational age < 35 wks & infant ≤ 12 months† with congenital abnormalities of the airway or neuromuscular disease that compromises handling of respiratory secretions**

☐ Child is < 24 months† old with Chronic Lung Disease** of prematurity (gestational age < 35 wks)
☐ Child is ≤ 24 months† old with hemodynamically significant (cyanotic or acyanotic) Congenital Heart Disease** (must not have had or completed surgical correction)

† Chronological age at start of RSV season
* Document AAP risk factor(s) below
** Include ICD-9 codes for the indicated disease states. Attach supporting documentation (i.e. progress notes, discharge notes, and/or chart notes) as outlined in the criteria for any submitted diagnosis/ICD-9 code.

AND

Is patient currently outpatient with no inpatient stay in the last 2 weeks? ☐ Yes ☐ No If no, indicate discharge date _______________

Was a dose of Synagis® administered while patient was hospitalized? ☐ Yes ☐ No If yes, indicate date dose administered _______________
Synagis® 2009-2010 Season

Notification Process Approval Letter

Christina Daniels-Faulkner, Pharm.D.

Health Information Designs, Inc.
2009-10 Approval Letter

DATE: 10/01/09

To: PRESCRIBING NAME
   ADRS1
   CITY, ST 12345

Other Provider: PHARMACY NAME
   ADRS1
   CITY, ST 12345

Prescription Review Outcome - Approval

RE: LNAME, FNAME

Submitted Medicaid ID Number: 123456789012     HID #: 2672671

We have received your request for prior authorization for DRUGNAME NDC 60574411301. The request has been APPROVED. The PA# is 7009065289 and is valid from 10/01/09 until 03/31/10 for a total of 8 doses.

COMMENTS
The Alabama Medicaid Agency has updated its prior authorization criteria for Synagis. The approval time frame for Synagis will begin October 1, 2009 and will be effective through March 31, 2010. A total of up to five (5) doses will be allowed per recipient in this time frame. Some recipients may only receive up to a max of 3 doses, depending on the gestational and chronological age. There are no circumstances that will allow for approval of a sixth dose.
Subsequent monthly doses will require submission of the recipient’s current weight and last injection date. This information can be included in the chart below and may be faxed to HID by the prescribing physician or dispensing pharmacy.

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*Not required for the first dose. This information must be completed and sent to HID for each subsequent dose.

If you have any questions, please call us at 1-800-748-0130.

Thank You,
Christina Daniels, PharmD
HID Pharmacy Services

Confidentiality Notice: This communication, including any attachments, is for the sole use of the intended recipient(s) and may contain confidential and privileged information. Any unauthorized review, use, disclosure or distribution is prohibited. If you are not the intended recipient, please contact the sender by reply telephone (1-800-748-0180) or fax (1-800-748-0116) and destroy all copies of the original message.
2009-10 Approval Letter

PHARMACY SERVICES

DATE: 10/01/09

To: PRESC NAME
ADR1
CITY, ST 12345

Other Provider: PHARMACY NAME
ADR1
CITY, ST 12345

Prescription Review Outcome - Approval

RE: LNAME, FNAME

Submitted Medicaid ID Number: 123456789012 HID #: 2672671

We have received your request for prior authorization for DRUGNAME NDC 60574411301. The request has been APPROVED. The PA# is 7009065289 and is valid from 10/01/09 until 03/31/10 for a total of 5 doses.
**COMMENTS**
The Alabama Medicaid Agency has updated its prior authorization criteria for Synagis. The approval timeframe for Synagis will begin October 1, 2009 and will be effective through March 31, 2010. A total of up to five (5) doses will be allowed per recipient in this timeframe. Some recipients may only receive up to a max of 3 doses, depending on the gestational and chronological age. There are no circumstances that will allow for approval of a sixth dose.

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If you have any questions, please call us at 1-800-748-0130.
Synagis® 2009-2010 Season

Educational Opportunities/Outreach

Kelli Littlejohn, Pharm.D.    Alabama Medicaid Director of Pharmacy
Educational Opportunities/Outreach

- Web conference: live and recording posted
- All criteria on website
- HID: 1-800-748-0130 (dedicated staff person: Cissy Davis, RN, BSN)
- MPS/Academic Detailers
  - Top Provider Visits (completed)
  - Upon request
Thank you for participating in this web conference.