



State of Louisiana
Department of Health and Hospitals
Bureau of Health Services Financing

September 18, 2009

Dear Pharmacist:

RE: Criteria for Reimbursement of Synagis®, Antipsychotic Agents, and Agents Used to Treat Attention Deficit Disorder

Louisiana Medicaid's Pharmacy Benefits Management (LMPBM) Program in concert with its Drug Utilization Review (DUR) Board and the Louisiana Chapter of the American Academy of Pediatrics have developed criteria for Medicaid reimbursement for the infectious disease - Respiratory Syncytial Virus (RSV).

As a result, we are notifying pharmacists of the following upcoming edits and limitations that the LMPBM Program is implementing regarding **palivizumab (Synagis®)**.

- Appropriate diagnosis
- Appropriate age
- Appropriate RSV season
- Maximum number of doses allowed

Additionally, the LMPBM Program and DUR Board collaborated with the Office of Mental Health to establish criteria for use of **atypical antipsychotic agents in children** as well as evaluation of concurrent prescribing of **drugs used to treat attention deficit disorder**.

All of these policies become effective October 1, 2009. The LMPBM Program will review pharmacy claims for adherence to program policy. Prescribers' records and prescriptions for patients receiving palivizumab (Synagis®), atypical antipsychotic agents and drugs used to treat attention deficit disorder may be requested to assure compliance with LMPBM Program policy.

If you have any concerns or comments regarding this correspondence, you may contact Melwyn B. Wendt at 225-342-9768 or send a fax to 225-342-1980. Your continued cooperation and support of Louisiana Medicaid's Pharmacy Benefits Management Program are greatly appreciated.

Sincerely,

Jerry Phillips
Medicaid Director

JP/MJT/mbw

Enclosure

Palivizumab (Synagis®)

Recommendations for immunoprophylaxis with Synagis® have been updated in the 2009 *Red Book* (Section 3) “Summaries of Infectious Diseases: Respiratory Syncytial Virus (RSV)” on pages 562-568 available at <http://aapredbook.aappublications.org/cgi/content/full/2009/1/3.110> .

Louisiana Medicaid has established parameters for payment of Synagis® prescriptions. Prescriptions for Synagis® will only be reimbursed by Louisiana Medicaid when prescriptions have met the following criteria.

Respiratory Syncytial Virus (RSV) Season

- RSV Season in Louisiana may vary depending on the geographic location.
- Louisiana’s RSV activity may be followed during the RSV season by frequently accessing the website <http://www.cdc.gov/surveillance/nrevss/rsv/state.html> .
- The RSV season may begin in either October or November and ends March 31st.
- The maximum number of doses any recipient should receive is five (5).
- If the initial dose is given in October, the fifth and final dose should be given in February.
- If initial dose is given in November, the fifth and final dose should be given in March.
- Synagis® claims with dates of service outside of RSV season will deny with:

**NCPDP rejection code 88 (DUR Reject Error)
mapped to EOB code 656 (Exceeds Maximum Duration of Therapy).**

- Claims billed for dates of service outside the RSV season will require **a hardcopy prescription with justification for Synagis® use handwritten by the prescriber**. This prescription may be faxed to the pharmacy and must be retained by the pharmacy for audit review.
- Medical records may be requested by the pharmacy compliance audit program for verification purposes of pharmacy claims billed for Synagis® outside the five (5) month RSV season.

Override: After consultation with the prescribing practitioner and receipt of a handwritten justification for use of Synagis® outside the RSV season, the pharmacist may override the maximum duration of therapy edit. The pharmacist must have justification from the prescriber and document the codes listed below and submit the override with:

**NCPDP 439-E4 field (Reason for Service Code)-MX (Exceeds Maximum Duration)
NCPDP 440-E5 field (Professional Service Code)-MØ (Prescriber Consulted)
NCPDP 441-E6 field (Result of Service Code)-1G (Filled with Prescriber Approval)**

Age Restriction

Claims for Synagis® therapy will only be reimbursed for recipients who are twenty-four (24) months or younger on November 1st of the RSV season. Once a recipient meets the age requirement for Synagis®, subsequent claims during that RSV season will continue to be reimbursed without further age evaluation. Claims for recipients who are twenty-five (25) months of age or older on November 1st will deny with:

**NCPDP rejection code 60 (Product/Service Not Covered for Patient Age)
mapped to EOB code 234 (P/F Age Restriction).**

When justified by the prescriber, pharmacy claims for Synagis® may be reimbursed for recipients twenty-five (25) months of age or older; however, these pharmacy claims will require a **hardcopy prescription with justification for Synagis® use handwritten by the prescriber.** This prescription may be faxed to the pharmacy and must be retained by the pharmacy for audit review.

Override: After consultation with and approval from the prescribing practitioner, the pharmacist may override the age restriction edit. The pharmacist must document the codes listed below and submit the override with:

**NCPDP 439-E4 field (Reason for Service Code)-PA (Drug-Age)
NCPDP 440-E5 field (Professional Service Code)-MØ (Prescriber Consulted)
NCPDP 441-E6 field (Result of Service Code)-1G (Filled with Prescriber Approval)**

Early Refill

Claims for Synagis® will only process for payment every twenty-eight (28) days. When a pharmacy submits a claim for Synagis® and the same pharmacy previously submitted the active paid claim, the incoming claim will deny with:

**NCPDP rejection code 88 (DUR Reject Error)
mapped to EOB code 447 (Compliance Monitoring/Early or Late Refill).**

Override: After consultation with and written, electronic, or verbal approval from the prescribing practitioner, the pharmacist may override the early refill edit. The pharmacist must document the codes listed below and submit the override with:

**NCPDP 439-E4 field (Reason for Service Code)-ER (Overuse/Early Refill)
NCPDP 440-E5 field (Professional Service Code)-MØ (Prescriber Consulted)
NCPDP 441-E6 field (Result of Service Code)-1G (Filled with Prescriber Approval)**

When a pharmacy submits a claim for Synagis® and another pharmacy has previously submitted the active paid claim, the incoming claim will deny with:

**NCPDP rejection code 88 (DUR Reject Error)
mapped to EOB code 445 (Duplicate Drug Therapy).**

Override: After consultation with and written, electronic, or verbal approval from the prescribing practitioner, the pharmacist may override the duplicate drug therapy edit. The pharmacist must document the codes listed below and submit the override with:

NCPDP 439-E4 field (Reason for Service Code)-ID (Ingredient Duplication)
NCPDP 440-E5 field (Professional Service Code)-MØ (Prescriber Consulted)
NCPDP 441-E6 field (Result of Service Code)-1G (Filled with Prescriber Approval)

Note: An active prescription is a prescription in which the days supply has not expired.

Maximum Number of Doses Allowed

- Based upon the diagnosis code submitted, a maximum of five (5) doses of Synagis® will be reimbursed each RSV season.
- If a diagnosis code of 765.27 (33-34 completed weeks of gestation) is billed, then a maximum of three (3) doses will be reimbursed each RSV season.
- Claims billed for Synagis® outside the allowable number of doses will deny with:

NCPDP rejection code 88 (DUR Reject Error)
mapped to EOB code 656 (Exceeds Maximum Duration of Therapy).

- Claims billed for greater than the number of allowable doses of Synagis® will require a **hardcopy prescription which includes justification handwritten by the prescriber.**
- This prescription may be faxed to the pharmacy and must be retained by the pharmacy for audit review.
- Medical records may be requested by the pharmacy compliance audit program for verification purposes of pharmacy claims billed for Synagis® greater than the allowable number of maximum doses.

Override: After consultation with the prescribing practitioner and receipt of a handwritten justification for use of Synagis® in excess of the allowable number of doses, the pharmacist may override the maximum duration of therapy edit. The pharmacist must have justification from the prescriber and document the codes listed below and submit the override with:

NCPDP 439-E4 field (Reason for Service Code)-MX (Exceeds Maximum Duration)
NCPDP 440-E5 field (Professional Service Code)-MØ (Prescriber Consulted)
NCPDP 441-E6 field (Result of Service Code)-1G (Filled with Prescriber Approval)

ICD-9-CM Diagnosis Code Requirement

An appropriate ICD-9-CM diagnosis code must be documented on the hardcopy prescription after written, electronic, or verbal consultation with the prescribing practitioner. Claims for Synagis® shall be submitted with one of the following diagnosis codes entered in **NCPDP field 424-DO (Diagnosis Code)**:

<u>ICD-9-CM Diagnosis Code</u>	<u>Description</u>
415.0	Acute cor pulmonale
416.0	Primary pulmonary hypertension
416.8	Pulmonary hypertension, secondary
745.0	Truncus arteriosus
745.10 -745.11	Transposition of the great vessels
745.19	Other transposition of the great vessels
745.2	Tetralogy of Fallot
746.1	Tricuspid atresia and stenosis, congenital
746.2	Ebstein's anomaly
747.41	Total anomalous pulmonary venous return
747.83	Persistent pulmonary hypertension, primary pulmonary hypertension of the newborn (Persistent fetal circulation)
765.21	Less than 24 completed weeks of gestation
765.22	24 completed weeks of gestation
765.23	25-26 completed weeks of gestation
765.24	27-28 completed weeks of gestation
765.25	29-30 completed weeks of gestation
765.26	31-32 completed weeks of gestation
765.27	33-34 completed weeks of gestation
770.7	Chronic respiratory disease arising in perinatal period (CLD/BPD/interstitial pulmonary fibrosis of infancy/Wilson-Mikity syndrome)

- Other diagnoses may be used to justify Synagis® depending on recipient-specific factors.
- As an example, in infants/children
 - with congenital heart disease, immunoprophylaxis with Synagis® is based on the degree of physiologic cardiovascular compromise;
 - with neuromuscular conditions, the decision to provide immunoprophylaxis is based on the degree to which the condition compromises the handling of respiratory secretions.
- The following diagnosis codes **could** be used to justify immunoprophylaxis with Synagis®, and are subject to prescriber assessment and judgment.

<u>ICD-9-CM Diagnosis Code</u>	<u>Description</u>
042	Human immunodeficiency virus (HIV) disease
045.00-045.13	Infantile paralysis
277.00 -277.09	Cystic fibrosis
279.00-279.90	Disorders involving the immune system
335.0	Werdnig-Hoffman disease
335.10-335.11	Spinal muscular atrophy
335.20-335.24	Motor neuron disease
343.0-343.9	Infantile cerebral palsy
358.0-358.9	Myoneural disorders
359.0-359.9	Muscular dystrophies and other myopathies

<u>ICD-9-CM Diagnosis Code</u>	<u>Description</u>
396.0-396.9	Diseases of mitral and aortic valves
424.1	Aortic stenosis
425.00-425.90	Cardiomyopathy
428.0-428.9	Heart failure
519.1	Other diseases of the trachea and bronchus, not elsewhere classified (Must specify tracheomalacia or tracheal stenosis)
745.4	Ventricular septal defect
745.5	Atrial septal defect
745.60-745.69	Atrioventricular canal (endocardial cushion defect)
746.7	Hypoplastic left heart
746.89	Hypoplastic right heart
748.3	Other anomalies of the larynx, trachea and bronchus (Must specify congenital tracheal stenosis, atresia of trachea, 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	Congenital malformation syndromes affecting multiple systems, not elsewhere classified (Beckwith Wiedmann syndrome)

Synagis® claims submitted without an appropriate diagnosis code or without any diagnosis code will deny with:

**NCPDP rejection code 39 (Missing or Invalid Diagnosis Code)
mapped to EOB code 575 (Missing or Invalid Diagnosis Code).**

Override: In the event, that the prescribing provider cannot be contacted, the pharmacist may override the missing or invalid diagnosis code edit. The pharmacist must document “Emergency Prescription” on the hard copy prescription and submit the override by:

Placing “03” in NCPDP field 418-DI (Level of Service) indicating an emergency.

Antipsychotic Agents

Maximum Daily Dose

Prescriptions for antipsychotic agents will only be reimbursed by Louisiana Medicaid when prescriptions have met the following criteria.* Daily doses for atypical antipsychotic agents used in recipients less than eighteen (18) years of age must not exceed an established maximum daily dose. Maximum daily doses for these agents are listed below.

Atypical Antipsychotic Maximum Daily Doses for Recipients Less Than 18 Years of Age			
Agent	<5 years old	5-12 years old	13-17 years old
Abilify®	5 mg daily	20 mg daily	30 mg daily
Risperdal®	3 mg daily	6 mg daily	8 mg daily
Invega®	3 mg daily	6 mg daily	9 mg daily
Seroquel®	100 mg daily	600 mg daily	1000 mg daily
Geodon®	30 mg daily	60 mg daily	120 mg daily
Zyprexa®	10 mg daily	20 mg daily	30 mg daily

Pharmacy claims billed which exceed these maximum daily doses will deny with:

**NCPDP rejection code 88 (DUR Reject Error)
mapped to EOB code 529 (Exceeds Maximum Daily Dose)**

With written, electronic, or verbal prescriber approval and justification, the pharmacist may override the denial.

Override: After verbal or written consultation with the prescribing practitioner, the pharmacist may override the maximum daily dose edit. The pharmacist must have justification from the prescriber and document the codes listed below and submit the override with:

**NCPDP 439-E4 field (Reason for Service Code)-HD (High Dose)
NCPDP 440-E5 field (Professional Service Code)-MØ (Prescriber Consulted)
NCPDP 441-E6 field (Result of Service Code)-1G (Filled with Prescriber Approval)**

*Existing policies on antipsychotic agents remain in effect. (Correspondence dated 07/25/05)

Iloperidone (Fanapt®)

When available, iloperidone (Fanapt®) will require an appropriate diagnosis code as do other antipsychotic agents. Claims submitted without an appropriate diagnosis code or without any diagnosis code will deny with:

**NCPDP rejection code 39 (Missing or Invalid Diagnosis Code)
mapped to EOB code 575 (Missing or Invalid Diagnosis Code).**

Override: In the event, that the prescribing provider cannot be contacted, the pharmacist may override the missing or invalid diagnosis code edit. The pharmacist must document “Emergency Prescription” on the hard copy prescription and submit the override by:

Placing “03” in NCPDP field 418-DI (Level of Service) indicating an emergency.

Incoming pharmacy claims for antipsychotics billed for recipients who have two (2) active prescriptions for antipsychotic agents will deny with:

**NCPDP rejection code 88 (DUR Reject Error)
mapped to EOB code 482 (Therapeutic Duplication)**

Override: After written, electronic, or verbal consultation with the prescribing practitioner, the pharmacist may override the therapeutic duplication edit. The pharmacist must have justification from the prescriber and document the codes listed below and submit the override with:

**NCPDP 439-E4 field (Reason for Service Code)-TD (Therapeutic Duplication)
NCPDP 440-E5 field (Professional Service Code)-MØ (Prescriber Consulted)
NCPDP 441-E6 field (Result of Service Code)-1G (Filled with Prescriber Approval)**

The maximum recommended daily dose of iloperidone (Fanapt®) is 24mg/day. Pharmacy claims billed in excess of this dose will deny with:

**NCPDP rejection code 88 (DUR Reject Error)
mapped to EOB code 529 (Exceeds Maximum Daily Dose)**

Override: After written, electronic, or verbal consultation with the prescribing practitioner, the pharmacist may override the maximum daily dose edit. The pharmacist must have justification from the prescriber and document the codes listed below and submit the override with:

**NCPDP 439-E4 field (Reason for Service Code)-HD (High Dose)
NCPDP 440-E5 field (Professional Service Code)-MØ (Prescriber Consulted)
NCPDP 441-E6 field (Result of Service Code)-1G (Filled with Prescriber Approval)**

Agents Used to Treat Attention Deficit Disorder

Incoming prescription claims for any agent listed in the following table will deny if there is an active prescription for any of these agents on the recipient’s file written by a different prescriber. An active prescription is a prescription where the days supply has not expired.

Atomoxetine (Strattera®)	Dexmethylphenidate (Focalin®)	Dextroamphetamine/amphetamine
Lisdexamfetamine (Vyvanse®)	Dextroamphetamine	Methylphenidate

When therapeutic duplication is noted, the incoming claim will deny with:

**NCPDP rejection code 88 (DUR Reject Error)
mapped to EOB code 482 (Therapeutic Duplication)**

Override: After written, electronic, or verbal consultation with the prescribing practitioner, the pharmacist may override the therapeutic duplication edit. The pharmacist must have justification from the prescriber and document the codes listed below and submit the override with:

**NCPDP 439-E4 field (Reason for Service Code)-TD (Therapeutic Duplication)
NCPDP 440-E5 field (Professional Service Code)-MØ (Prescriber Consulted)
NCPDP 441-E6 field (Result of Service Code)-1G (Filled with Prescriber Approval)**