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State of Louisiana

Department of Health and Hospitals
Bureau of Health Services Financing

MEMORANDUM

DATE: October 16, 2014

TO: All Louisiana Medicaid Providers

FROM: J. Ruth Kennedy, Medicaid Director

SUBJECT: Clinical Pre-Authorization for Palivizumab (Synagis®) for La. Medicaid Pharmacy Program

Effective November 1, 2014, the Louisiana Medicaid Pharmacy Program in collaboration with the Louisiana Medicaid Drug Utilization Review (DUR) Board has established clinical pre-authorization criteria for palivizumab (Synagis®). The criteria follow the 2014 American Academy of Pediatrics (AAP) guidelines.

Claims for palivizumab (Synagis®) will be reimbursed at Point of Sale (POS) when the prescriber has obtained an approved clinical pre-authorization and POS requirements are met. Prescribers must complete the *Palivizumab Clinical Pre-Authorization Form* in full and fax to 866-797-2329. The criteria and form are included with this memo. Refer to www.lamedicaid.com.

Pharmacy claims for palivizumab (Synagis®) without clinical pre-authorization will deny at POS with:

NCPDP rejection code 88 (DUR Reject Error) mapped to
EOB code 066 (Clinical Pre-Authorization Required)

Your continued cooperation and support of the Louisiana Medicaid Program efforts to coordinate care and improve health are greatly appreciated.

If you have questions about the contents of this memo, you may contact the Pharmacy Help Desk at 800-437-9101 or refer to www.lamedicaid.com.

MCJ/MBW/ESF

c: Bayou Health Plans
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Palivizumab (Synagis®) Criteria for the 2014-2015 Respiratory Syncytial Virus (RSV) Season For Legacy Medicaid and Shared Health Plan Recipients

Palivizumab is indicated for the prevention of serious lower respiratory tract infection caused by respiratory syncytial virus (RSV) in selected infants and young children at high risk of RSV disease. Monthly prophylaxis should be discontinued in any infant receiving monthly palivizumab prophylaxis who experiences a breakthrough RSV hospitalization.

Clinical Pre-Authorization Criteria

All prescriptions for palivizumab require clinical pre-authorization. Prescribing providers must complete the Palivizumab Clinical Pre-Authorization Form and fax to LA Medicaid Rx PA Operations at the University of Louisiana at Monroe School of Pharmacy at 866-797-2329. Clinical pre-authorization requests for palivizumab will be processed beginning on November 1, 2014, the start of RSV season. Prescribing providers will be notified by fax or mail of the outcomes of clinical pre-authorization requests.

Clinical Pre-Authorization will be considered for approval when requests meet the following criteria:

- Palivizumab clinical pre-authorization requests will be considered in accordance with an RSV season of November 1, 2014 through March 31, 2015; AND

- Recipient must meet gestational age AND chronological age requirements for the ICD-9-CM diagnosis code(s) and/or other qualifying risk factor(s) submitted with request. Attach supporting documentation (i.e. progress notes, discharge notes, pediatric cardiologist consult notes and/or chart notes). Requests for palivizumab will be considered for approval when **ONE** of the following 'high-risk' criteria are met:

  1. **Infant born prematurely without Chronic Lung Disease (CLD) or without hemodynamically significant cyanotic or acyanotic heart disease or without other listed 'high-risk' factors:**
     - The infant is younger than 12 months of age on November 1, 2014, AND was born before 29 weeks, 0 days' (≤ 28 weeks, 6 days') gestation.

  2. **Infant with Chronic Lung Disease (CLD) (one of the criteria sets below must be met):**
     - SET 1: Infant diagnosed with CLD who is 12 months of age or younger, whose first birthday is on or after November 1, 2014, AND the infant was born at < 32 weeks, 0 days' gestation AND the infant required > 21% oxygen for at least 28 days after birth; OR
     - SET 2: Infant diagnosed with CLD who is 24 months of age or younger, whose second birthday is on or after November 1, 2014, infant's second dosing season, AND the infant was born at < 32 weeks, 0 days' gestation AND the infant required > 21% oxygen for at least 28 days after birth AND the infant has required medical therapy (i.e., chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the six (6) months before November 1, 2014, the start of the infant's second RSV season.

  3. **Infant with Congenital Heart Disease (CHD):**
     - The infant's first birthday is on or after November 1, 2014; AND
     - The infant meets one of the following hemodynamically significant conditions:
       - The infant has cyanotic heart defect(s) and decision for use of palivizumab was made with pediatric cardiologist consultation; OR
       - The infant has acyanotic heart disease AND is receiving medication to control congestive heart failure AND will require a cardiac surgical procedure; OR
       - The infant has moderate to severe pulmonary hypertension; OR
       - The infant has lesions that have been adequately corrected by surgery but continues to require medication for congestive heart failure.

4. **Infant with cardiac transplant:**
   - The infant is younger than 2 years of age on November 1, 2014; AND
   - The infant has undergone or will undergo cardiac transplantation from November 1, 2014 through March 31, 2015.

5. **Infant with a congenital anatomic pulmonary abnormality or neuromuscular disease:**
   - The infant's first birthday is on or after November 1, 2014; AND
   - The infant's congenital anatomic pulmonary abnormality or neuromuscular disease impairs the ability to clear secretions from the upper airways because of ineffective cough.

6. **Immunocompromised infant:**
   - The infant's second birthday is after November 1, 2014; AND
   - The infant is/will be profoundly immunocompromised (for example, receiving chemotherapy or immunosuppressive therapy) from November 1, 2014 through March 31, 2015.

Medical Reconsideration

Medical Reconsideration of a denied clinical pre-authorization decision may be requested by the prescribing practitioner. Reconsideration requires completion of the Palivizumab Request for Reconsideration form available at www.lamedicaid.com. The form must be completed in full and signed by the prescribing practitioner. Signature stamps and proxy signatures are not acceptable. The completed form must be faxed from the prescribing practitioner to the LA Medicaid Rx PA Operations at the University of Louisiana at Monroe School of Pharmacy at 318-812-2940.

Point-of-Sale (POS) Requirements

Age Restriction

- Palivizumab claims for recipients who are twenty-four (24) months of age or younger as of November 1, 2014 meet the POS age requirement.

Maximum Number of Doses

- Up to a maximum number of five (5) doses will be reimbursed during the RSV season. Qualifying infants born during the RSV season require fewer doses. For example, infants born in January would receive their last dose in March. A claim submitted for palivizumab outside the maximum number of doses allowed will deny at POS with:

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

PALIVIZUMAB CRITERIA ICD-9 CODE and MEDICATION LIST

*Note: ANY accepted diagnosis/ICD-9 Code listed on the Clinical Pre-Authorization Form **MUST** have supporting documentation attached (i.e. progress notes, discharge notes, pediatric cardiologist consult notes and/or chart notes).*

I. Neuromuscular Disorders

Acceptable ICD-9 codes:

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 (i.e. the following are NOT accepted):

343.0-343.9	Cerebral palsy
345.10	Generalized convulsive epilepsy
345.3	Grand mal seizures
345.5-345.9	Epilepsy
741.90	Spina bifida
779.0	Newborn seizures
780.3	Infantile seizures

II. Congenital Abnormalities of the Airways

Acceptable ICD-9 codes:

327.25	**Congenital central alveolar hypoventilation syndrome**
519.1	**Other diseases of the trachea and bronchus, not elsewhere classified (Must specify Tracheomalacia or tracheal stenosis)**
748.3	**Other anomalies of larynx, trachea, and bronchus (Must specify congenital tracheal stenosis, subglottic stenosis, atresia of trachea, laryngomalacia, 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**
756.6	**Diaphragmatic paralysis**
759.89	**Beckwith-Wiedemann syndrome**

Exclude (but not limited to) the following (i.e. the following are NOT accepted):

748.60	Anomaly of lung, unspecified
748.69	Other anomaly of the lung

III. Chronic Lung Disease

Acceptable ICD-9 code:

770.7	**Chronic respiratory disease arising in the perinatal period (CLD/BPD/Interstitial pulmonary fibrosis of prematurity/Wilson-Mikity syndrome)**

Exclude (but not limited to) the following (i.e. the following are NOT accepted):

464.4	Croup
465.8-465.9	URI
466.0	Bronchitis
466.1-466.19	Bronchiolitis
493	Asthma
786.07	Wheezing

IV. Congenital Heart Diseases (CHD)
Acceptable ICD-9 codes:

A. Acyanotic CHD: Must currently be receiving medication to control CHF (see below)

424.1	**Aortic stenosis***
424.3	**Pulmonary valve disorders (incompetence, insufficiency, regurgitation, and stenosis)**
425	**Cardiomyopathy (must be moderate to severe)**
745.4	**Ventricular septal defect***
745.5	**Atrial septal defect***
745.6	**Atrioventricular canal (endocardial cushion defect)**
746.0	**Anomalies of pulmonary valve congenital**
746.02	**Pulmonic stenosis***
746.3	**Congenital stenosis of aortic valve (congenital aortic stenosis) Excludes: congenital subaortic stenosis; supravalvular aortic stenosis**
746.6	**Congenital mitral insufficiency**
747.0	**Patent ductus arteriosus***
747.10/747.11	**Coarctation of the aorta***
747.22	**Atresia and stenosis of aorta (absence, aplasia, hypoplasia, stricture of the aorta) Supra (valvular)-aortic stenosis Excludes: congenital aortic (valvular) stenosis or stricture; hypoplasia of aorta in hypoplastic left heart syndrome**

B. Cyanotic CHD: Does not require use of medication/must not have had or completed surgical correction

745.0	**Truncus arteriosus**
745.10	**Transposition of the great vessels**
745.2	**Tetralogy of Fallot**
746.01	**Atresia, congenital**
746.1	**Tricuspid atresia and stenosis, congenital**
746.2	**Ebstein's anomaly**
746.7	**Hypoplastic left heart**
746.89	**Hypoplastic right heart**
747.3	**Pulmonary atresia**
747.41	**Total anomalous pulmonary venous return**

C. Pulmonary Hypertension:

415.0	**Acute cor pulmonale**
416.0	**Primary pulmonary hypertension**
416.8	**Other chronic pulmonary heart disease (pulmonary hypertension, secondary)**
747.83	**Persistent fetal circulation (persistent pulmonary hypertension/primary pulmonary hypertension of newborn)**

*Per AAP guidelines, prophylaxis with palivizumab in infants with CHD should be made on the degree of cardiovascular compromise. CHD that is deemed hemodynamically insignificant will not meet criteria. Documentation must specifically support CHD being hemodynamically significant (e.g. medications, etc.).

ACCEPTABLE MEDICATIONS USED IN CHD

Digoxin	ACE Inhibitors	Supplemental oxygen
Beta Blockers	Nitroglycerin	Diuretics
Calcium Channel Blockers	Anti-Coagulants	