Palivizumab (Synagis®) Criteria for the 2016-2017 Respiratory Syncytial Virus (RSV) Season for Fee-For-Service Legacy Medicaid 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 for recipients in Fee-For-Service Medicaid require clinical pre-authorization. **Prescribing providers,** not the pharmacy, manufacturer or any other third party entity, must complete the Palivizumab Clinical Pre-Authorization Form and fax it **directly** to LA Medicaid Rx PA Operations at the University of Louisiana at Monroe School of Pharmacy at **866-797-2329**. Any requests submitted early will not be processed prior to 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, 2016 through March 31, 2017; AND

- Recipient must meet gestational age AND chronological age requirements for the ICD-10-CM diagnosis code(s) and/or other qualifying risk factor(s) submitted with the request. Supporting documentation (i.e. progress notes, hospital discharge notes, pediatric cardiologist consult notes, chart notes, pharmacy profiles, etc.) is required and must be submitted with each request. 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, 2016, AND was born before 29 weeks, 0 days' ($\leq$ 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, 2016, 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, 2016, 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 systemic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the six (6) months before November 1, 2016, 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, 2016; 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, 2016; AND
   - The infant has undergone or will undergo cardiac transplantation from November 1, 2016 through March 31, 2017.

5. **Infant with a congenital anatomic pulmonary abnormality or neuromuscular disease:**
   - The infant's first birthday is on or after November 1, 2016; 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, 2016; AND
   - The child is/will be profoundly immunocompromised (for example, receiving chemotherapy or immunosuppressive therapy) from November 1, 2016 through March 31, 2017.

Medical Reconsideration

Medical Reconsideration of a denied clinical pre-authorization decision may be requested by the prescribing provider. 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 provider. Signature stamps and proxy signatures are not acceptable and will be returned to the requesting provider. The completed form must be faxed from the prescribing provider 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, 2016 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 with:

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

Early Refill

- Palivizumab claims will only process for payment every twenty-eight (28) days.

PALIVIZUMAB CRITERIA ICD-10-CM CODE and MEDICATION LIST

Note: ANY accepted diagnosis/ICD-10-CM Code listed on the clinical pre-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 progress notes, hospital discharge notes, pediatric cardiologist consult notes, chart notes, pharmacy profiles, etc.

I. Neuromuscular Disorders

Acceptable ICD-10 codes include:

A80.0-A80.39	Infantile paralysis
G31.9	Cerebral degenerations
G25.3	Myoclonus
G11.1, G11.4	Spinocerebellar disease
G12.0	Werdnig-Hoffman disease (Infantile spinal muscular atrophy)
G12.1, G12.8, G12.9	Spinal muscular atrophy
G12.2*	Motor neuron disease

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

G80*	Cerebral palsy
G40.3*	Generalized convulsive epilepsy
G40.4*	Grand mal seizures
G40*	Epilepsy
Q05*	Spina bifida
P90	Newborn seizures
R56*	Infantile seizures

II. Congenital Abnormalities of the Airways

Acceptable ICD-10 codes include:

G47.35	Congenital central alveolar hypoventilation syndrome
Q32.0, Q32.1	Other diseases of the trachea and bronchus, not elsewhere classified (Must specify Tracheomalacia or tracheal stenosis)
Q31.1, Q31.5, Q32.1, Q32.4	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)
Q33.0	Congenital cystic lung
Q33.3, Q33.6	Agenesis, hypoplasia, and dysplasia of the lung
Q33.4	Congenital bronchiectasis
Q38.2	Macroglossia
Q38.5	Uvula anomaly
J98.6	Diaphragmatic paralysis
Q87.3	Beckwith-Wiedemann syndrome

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

Q33.9	Anomaly of lung, unspecified
Q33.1, Q33.8	Other anomaly of the lung

III. Chronic Lung Disease

Acceptable ICD-10 code:

P27*	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):

J05.0	Croup
J06*	URI
J20*	Bronchitis
J21*	Bronchiolitis
J45*	Asthma
R06.2	Wheezing

IV. Congenital Heart Diseases (CHD) Per AAP guidelines, prophylaxis with palivizumab in children 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 ICD-10 codes include:

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

Q23.0	Aortic stenosis
I37.0, I37.1, I37.2, Q22.1, Q22.2	Pulmonary valve disorders (incompetence, insufficiency, regurgitation, and stenosis)
I42*, I43	Cardiomyopathy (must be moderate to severe)
Q21.0	Ventricular septal defect
Q21.1	Atrial septal defect
Q21.2	Atrioventricular canal (endocardial cushion defect)
Q22.3	Anomalies of pulmonary valve congenital
Q22.1	Pulmonic stenosis
Q23.0	Congenital stenosis of aortic valve (congenital aortic stenosis) [Excludes: congenital subaortic stenosis; supravalvular aortic stenosis]
Q23.3	Congenital mitral insufficiency
Q25.0	Patent ductus arteriosus
Q25.1	Coarctation of the aorta
Q25.2, Q25.3	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

Q20.0	Truncus arteriosus
Q20.3	Transposition of the great vessels
Q21.3	Tetralogy of Fallot
Q22.0	Atresia, congenital
Q22.4	Tricuspid atresia and stenosis, congenital
Q22.5	Ebstein's anomaly
Q23.4	Hypoplastic left heart
Q22.6	Hypoplastic right heart
Q25.5	Pulmonary atresia
Q26.2	Total anomalous pulmonary venous return

C. Pulmonary Hypertension:

I26.0*	Acute cor pulmonale
I27.0	Primary pulmonary hypertension
I27.2	Other chronic pulmonary heart disease (pulmonary hypertension, secondary)
P29.3	Persistent fetal circulation (persistent pulmonary hypertension/primary pulmonary hypertension of newborn)

*****any number or letter or combination of UP TO FOUR numbers and letters of an assigned ICD-10-CM diagnosis code

ACCEPTABLE MEDICATIONS USED IN CHD

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