

Louisiana Fee-For-Service Medicaid
Palivizumab (Synagis®) for the 2018-2019 Respiratory Syncytial Virus (RSV) Season

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 College 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, 2018 through March 31, 2019; **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, 2018, **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, 2018, **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, 2018, 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, 2018, 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, 2018; **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, 2018; **AND**
- The infant has undergone or will undergo cardiac transplantation from November 1, 2018 through March 31, 2019.

5. Infant with a congenital anatomic pulmonary abnormality or neuromuscular disease:

- The infant’s first birthday is on or after November 1, 2018; **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, 2018; **AND**
- The child is/will be profoundly immunocompromised (for example, receiving chemotherapy or immunosuppressive therapy) from November 1, 2018 through March 31, 2019.

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 College 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, 2018 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; supraaortic 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 | ACE Inhibitors | Supplemental oxygen |
| Beta Blockers | Nitroglycerin | Diuretics |
| Calcium Channel Blockers | Anti-Coagulants | |

Reference

STAT!Ref - Red Book®: 2018-2021 Report of the Committee on Infectious Diseases. Online.statref.com.
<http://online.statref.com/publictitleinfo/titleinfo.aspx?fxid=76> Published 2018.