



**STATE OF WEST VIRGINIA  
DEPARTMENT OF HEALTH AND HUMAN RESOURCES  
BUREAU FOR MEDICAL SERVICES**



**Office of Pharmacy Service  
Prior Authorization Criteria**

**SYNAGIS®  
(palivizumab)**

Palivizumab (Synagis) is a respiratory syncytial virus (RSV) F protein inhibitor monoclonal antibody indicated for the prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease.

**LENGTH OF AUTHORIZATION**

- Authorize for a maximum of 5 doses during RSV season (five monthly doses of 15 mg/kg IM).
- In infants and children < 24 months, already on prophylaxis and eligible, one post-op dose can be approved after cardiac bypass or after extracorporeal membrane oxygenation (ECMO).

**RSV SEASON**

- Generally considered to run from November to April. WV Medicaid will provide coverage for qualifying prescriptions until March 31<sup>st</sup>. A maximum of 5 doses during RSV season provides 6 months of RSV prophylaxis.

Only a maximum of 5 doses will be approved during RSV season. If prophylaxis is initiated later in the RSV season, the infant or child will receive less than 5 doses. For example if prophylaxis is initiated in January, the 3<sup>rd</sup> and final dose, will be administered in March. For eligible infants born during RSV season, fewer than 5 monthly doses may be needed.

**Approval Criteria**

Infant/Child Age at Start of RSV Season	Criteria
≤12 months (1 <sup>st</sup> year of life)	<ul style="list-style-type: none"> <li>▪ GA &lt;29 wks, 0 d (otherwise healthy)</li> <li>▪ CLD of prematurity (GA &lt;32 wks, 0 d requiring &gt;21% supplemental O<sub>2</sub> x first 28 d after birth)</li> <li>▪ Anatomic pulmonary abnormalities, or neuromuscular disorder, or congenital anomaly that impairs the ability to clear secretions</li> <li>▪ Profoundly immunocompromised</li> <li>▪ CF with CLD and/or nutritional compromise</li> <li>▪ CHD (hemodynamically <i>significant</i>) with <i>acyanotic</i> HD on CHF medications and who will require cardiac surgery or who have moderate to severe PH. For <i>cyanotic</i> heart defects consult a pediatric cardiologist</li> </ul>



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<p>&gt;12 months to ≤ 24 months (2<sup>nd</sup> year of life)</p>	<ul style="list-style-type: none"> <li>▪ CLD of prematurity (GA &lt;32 wks, 0 d and &gt;21% O<sub>2</sub> x first 28 d after birth) and medical support (chronic systemic steroids, diuretic therapy, or supplemental O<sub>2</sub>) within 6 months before start of 2<sup>nd</sup> RSV season</li> <li>▪ CF with severe lung disease* or weight for length &lt;10<sup>th</sup> percentile</li> <li>▪ Cardiac transplant during RSV season</li> <li>▪ Already on prophylaxis and eligible: give post-op dose after cardiac bypass or after ECMO</li> <li>▪ Profoundly immunocompromised</li> </ul>
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GA=gestational age; wks=weeks; d=day; CLD=chronic lung disease; CHD=congenital heart disease; O<sub>2</sub>=oxygen; HD=heart disease; CHF=congestive heart failure; PH=pulmonary hypertension; CF=cystic fibrosis; ECMO=extracorporeal membrane oxygenation

\* Examples of severe lung disease: previous hospitalization for pulmonary exacerbation in the 1<sup>st</sup> year of life, abnormalities on chest radiography [chest X-ray], or chest computed tomography [chest CT] that persist when stable

**Denial Criteria – Palivizumab will NOT be approved in the following scenarios**

Infant/Child Age at Start of RSV Season	Deny
<p>&gt;12 months to ≤ 24 months (2<sup>nd</sup> year of life)</p>	<ul style="list-style-type: none"> <li>▪ Based on prematurity alone</li> <li>▪ CLD without medical support (chronic systemic steroids, diuretic therapy, or supplemental O<sub>2</sub>)</li> <li>▪ CHD</li> <li>▪ Otherwise healthy children in 2<sup>nd</sup> year of life</li> </ul>
<p>Any age</p>	<ul style="list-style-type: none"> <li>▪ Breakthrough RSV hospitalization**</li> <li>▪ Hemodynamically <i>insignificant</i> CHD***</li> <li>▪ CHD lesions corrected by surgery (unless on CHF meds)</li> <li>▪ CHD and mild cardiomyopathy not on medical therapy</li> <li>▪ CHD in 2<sup>nd</sup> year of life</li> </ul>
<p>No specific age defined</p>	<ul style="list-style-type: none"> <li>▪ GA ≥29 wks, 0 d (otherwise healthy)</li> <li>▪ Asthma prevention</li> <li>▪ Reduce wheezing episodes</li> <li>▪ Down Syndrome</li> <li>▪ CF (otherwise healthy)</li> <li>▪ Healthcare-associated RSV disease****</li> </ul>

\*\* If any infant or child is receiving palivizumab prophylaxis and experiences a breakthrough RSV hospitalization, discontinue palivizumab, because the likelihood of a second RSV hospitalization in the same season is extremely low.

\*\*\* Examples of hemodynamically *insignificant* CHD: secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, patent ductus arteriosus.

\*\*\*\* No rigorous data exist to support palivizumab use in controlling outbreaks of health care-associated disease; palivizumab use is not recommended for this purpose.



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## REFERENCES

1. American Academy of Pediatrics. Position Statement. Updated guidance for palivizumab prophylaxis among Infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. *Pediatrics* 2014; 134;415. DOI: 10.1542/peds.2014-1665. Available at: [http://pediatrics.aappublications.org/content/134/2/415.full.pdf+html?sid=c5cf7568-4302-4ccd-9c71-  
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2. American Academy of Pediatrics. Technical Report. Updated guidance for palivizumab prophylaxis among Infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. DOI: 10.1542/peds.2014-1666. Available at: <http://pediatrics.aappublications.org/content/early/2014/07/23/peds.2014-1666>. Accessed July 29, 2014.
3. Synagis [package insert]. Gaithersburg, MD; MedImmune; March 2014.
4. Clinical criteria recommendations from Magellan Medicaid Administration, Inc.; August, 2014.