



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



**Office of Pharmacy Service
Prior Authorization Criteria**

**Synagis® (palivizumab)
[Prior Authorization Request Form](#)**

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 five (5) doses during RSV season (five monthly doses of 15 mg/kg IM).
- In infants and children less than 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 31st. A maximum of five (5) doses during RSV season provides six (6) months of RSV prophylaxis.

Only a maximum of five (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 five (5) doses. For example if prophylaxis is initiated in January, the 3rd and final dose, will be administered in March. For eligible infants born during RSV season, fewer than five (5) monthly doses may be needed.

Approval Criteria

Infant/Child Age at Start of RSV Season	Criteria
≤12 months (1 st year of life)	<ul style="list-style-type: none"> ▪ GA <29 wks, 0 d (otherwise healthy) ▪ CLD of prematurity (GA <32 wks, 0 d requiring >21% supplemental O₂ x first 28 d after birth) ▪ Anatomic pulmonary abnormalities, or neuromuscular disorder, or congenital anomaly that impairs the ability to clear secretions ▪ Profoundly immunocompromised ▪ CF with CLD and/or nutritional compromise ▪ 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



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<p>>12 months to ≤ 24 months (2nd year of life)</p>	<ul style="list-style-type: none"> ▪ CLD of prematurity (GA <32 wks, 0 d and >21% O₂ x first 28 d after birth) and medical support (chronic systemic steroids, diuretic therapy, or supplemental O₂) within 6 months before start of 2nd RSV season ▪ CF with severe lung disease* or weight for length <10th percentile ▪ Cardiac transplant during RSV season ▪ Already on prophylaxis and eligible: give post-op dose after cardiac bypass or after ECMO ▪ Profoundly immunocompromised
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GA=gestational age; wks=weeks; d=day; CLD=chronic lung disease; CHD=congenital heart disease; O₂=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 1st 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>>12 months to ≤ 24 months (2nd year of life)</p>	<ul style="list-style-type: none"> ▪ Based on prematurity alone ▪ CLD without medical support (chronic systemic steroids, diuretic therapy, or supplemental O₂) ▪ CHD ▪ Otherwise healthy children in 2nd year of life
<p>Any age</p>	<ul style="list-style-type: none"> ▪ Breakthrough RSV hospitalization** ▪ Hemodynamically <i>insignificant</i> CHD*** ▪ CHD lesions corrected by surgery (unless on CHF meds) ▪ CHD and mild cardiomyopathy not on medical therapy ▪ CHD in 2nd year of life
<p>No specific age defined</p>	<ul style="list-style-type: none"> ▪ GA ≥29 wks, 0 d (otherwise healthy) ▪ Asthma prevention ▪ Reduce wheezing episodes ▪ Down Syndrome ▪ CF (otherwise healthy) ▪ Healthcare-associated RSV disease****

** 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-
ea785e33e241](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.

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