



Palivizumab (Synagis®) Criteria for Respiratory Syncytial Virus (RSV) Infection^{1,2,3}

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BACKGROUND

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. The American Academy of Pediatrics (AAP) has issued an updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for RSV. The palivizumab criteria below reflect the latest AAP guidance.

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

- There is variability in the onset and offset of RSV season. Generally, it runs from November to April within the continental US. A maximum of 5 doses during RSV season provides 6 months of RSV prophylaxis.
- Alaska- Due to the varied epidemiology of RSV infection, clinicians can use RSV surveillance data by the state of Alaska to determine the onset and offset of RSV season.
- Florida- Data from the Florida Department of Health can be used to determine the onset and offset of RSV season in different regions of Florida.
- Native American Indian infants- There is limited information about the burden of RSV infection among American Indian populations. Prophylaxis can be considered for Navajo and White Mountain Apache infants in the 1st year of life.
- Despite differences in onset and offset of RSV infection in some states or regions, 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 4th and final dose, will be administered in April. For eligible infants born during RSV season, fewer than 5 monthly doses may be needed.

APPROVAL CRITERIA

Palivizumab will be approved in the following scenarios.

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 and >21% 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
≤ 12 months (1 st year of life)	<ul style="list-style-type: none"> ▪ CHD (hemodynamically <i>significant</i>) with <i>acyanotic</i> HD on CHF medications and will require cardiac surgery or moderate to severe PH. For <i>cyanotic</i> heart defects consult a pediatric cardiologist
>12 months (2 nd year of life)	<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
<24 months (2 nd year of life)	<ul style="list-style-type: none"> ▪ Cardiac transplant during RSV season ▪ Already on prophylaxis and eligible: give post-op dose after cardiac bypass or after ECMO ▪ Profoundly immunocompromised

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
>12 months (2 nd year of life)	<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
Any age	<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
No specific age defined	<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.

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>. Accessed August 6, 2014.
- 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.