# Palivizumab (Synagis®) Criteria for Respiratory Syncytial Virus (RSV) Infection[1,2,3,4,5]

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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. In 2014, the American Academy of Pediatrics (AAP) issued an updated guidance for palivizumab prophylaxis among infants and young children at increased risk of hospitalization for RSV. In 2017, and subsequently in 2019, the Committee on Infectious Diseases and the Subcommittee on Bronchiolitis reviewed and reaffirmed the guideline. The AAP policy statements are reviewed at least every 3 years and updated when appropriate. The palivizumab criteria below reflect the latest AAP guidance.

## LENGTH OF AUTHORIZATION

- Authorize for a maximum of 5 doses during RSV reason (5 monthly doses of 15 mg/kg intramuscularly).
- In infants and children < 24 months, already on prophylaxis and eligible, 1 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 United States (US).
- A maximum of 5 doses during RSV season provides 6 months of RSV prophylaxis.
- A total of 5 monthly doses beginning in November and the last dose given in March will provide protection for most infants through April and is recommended for most areas in the US. However, according to the AAP, if the first dose is given in October, the fifth and final dose should be given in February, which will provide protection through March. Similarly, if the first dose is given in December, the fifth and final dose should be administered in April, which will provide protection for most infants through May.
- 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 the local RSV season.



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- Florida– Data from the Florida Department of Health can be used to determine the onset and offset of the RSV season in the 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 first 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 the RSV season. If prophylaxis is initiated later in the RSV season, the infant or child will receive less than 5 doses.

## APPROVAL CRITERIA

Palivizumab will be approved in the following scenarios.

| Infant/Child Age at Start of RSV Season | Criteria |
|---|---|
| < 12 months (1st year of life) | ▪ GA < 29 wks, 0 d (otherwise healthy)<br>▪ Profoundly immunocompromised<br>▪ |
| ≤ 12 months (1st year of life) | ▪ CHD (hemodynamically *significant*) with *acyanotic* HD on CHF medications and will require cardiac surgery or with moderate to severe PH. For *cyanotic* heart defects consult a pediatric cardiologist<br>▪ CLD of prematurity (GA < 32 wks, 0 d and > 21% $O_2$ x first 28 d after birth)<br>▪ Anatomic pulmonary abnormalities, or neuromuscular disorder, or congenital anomaly that impairs the ability to clear upper airway secretions<br>▪ CF with CLD and/or nutritional compromise |
| > 12 months (2nd year of life) | ▪ CLD of prematurity (GA < 32 wks, 0 d and > 21% $O_2$ x first 28 d after birth) and medical support (chronic steroids, diuretic therapy, or supplemental $O_2$) within 6 months before start of 2nd RSV season<br>▪ CF with severe lung disease* or weight for length < 10th percentile |
| < 24 months (2nd year of life) | ▪ Cardiac transplant during RSV season<br>▪ Already on prophylaxis and eligible: give post-op dose after cardiac bypass or after ECMO<br>▪ Profoundly immunocompromised |

GA=gestational age; d=day; CF=cystic fibrosis; CHD=congenital heart disease; CHF=congestive heart failure; CLD=chronic lung disease; ECMO=extracorporeal membrane oxygenation; HD=heart disease; $O_2$=oxygen; PH=pulmonary hypertension; wks=weeks

*Examples of severe lung disease: previous hospitalization for pulmonary exacerbation in the first year of life, abnormalities on chest radiography (chest X-ray), or chest computed tomography (chest CT) that persist when stable.

## DENIAL CRITERIA

If a patient meets approval criteria in the above table, palivizumab will be approved. Palivizumab will NOT be approved in the following scenarios.

| Infant/Child Age at Start of RSV Season | Deny |
|---|---|
| > 12 months (2nd year of life) | ▪ Based on prematurity alone<br>▪ CLD *without* medical support (chronic steroids, diuretic therapy, or supplemental $O_2$)<br>▪ CHD<br>▪ Otherwise healthy children in 2nd year of life |
| Any age | ▪ Outpatient RSV infection or breakthrough RSV hospitalization**<br>▪ Hemodynamically *insignificant* CHD***<br>▪ CHD lesions corrected by surgery (unless on CHF meds)<br>▪ CHD and mild cardiomyopathy not on medical therapy<br>▪ CHD in 2nd year of life |
| No specific age defined | ▪ GA ≥ 29 wks, 0 d (otherwise healthy)<br>▪ Asthma prevention<br>▪ Reduce wheezing episodes<br>▪ Down Syndrome<br>▪ CF (otherwise healthy)<br>▪ Healthcare-associated RSV disease**** |

CF=cystic fibrosis; CHF=congestive heart failure; CHD=congenital heart disease; CLD=chronic lung disease; GA=gestational age;

**If any infant or child is receiving palivizumab prophylaxis and experiences an outpatient RSV infection of 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. Reaffirmed February 2019. Pediatrics. 2014; 134; 415. DOI: 10.1542/peds.2014-1665. Available at: http://www.aappublications.org/search/palivizumab%20numresults%3A10%20sort%3Arelevance-rank%20format_result%3Astandard?facet%5Bseries-name%5D%5B0%5D=Policy%20Statement. February March 6, 2020.

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. Reaffirmed February 2019. DOI: 10.1542/peds.2014-1666. Available at: http://www.aappublications.org/search/palivizumab%20numresults%3A10%20sort%3Arelevance-rank%20format_result%3Astandard?facet%5Bseries-name%5D%5B0%5D=Technical%20Report. Accessed March 6, 2020.

3 Synagis [package insert]. Gaithersburg, MD; MedImmune; May 2017.

4 Munoz FM, Ralston SL, Meissner HC. RSV recommendations unchanged after review of new data. AAP News. Oct 2017. Available at http://www.aappublications.org/news/2017/10/19/RSV101917. Accessed March 6, 2020.

5 AAP publications reaffirmed. Pediatrics. Aug 2019: 144 (2) e20191767. DOI: 10.1542/peds.2019-1767. Available at: https://pediatrics.aappublications.org/content/144/2/e20191767. Accessed March 6, 2020