Division: Pharmacy Policy	Subject: Prior Authorization Criteria
Effective Date: Original Effective Date: Revision Date	September 9, 2014 October 30, 2014, November 19,2014, June 30, 2015, June 14, 2018, April 3, 2020

SYNAGIS® (palivizumab)[i,ii,iii]

LENGTH OF AUTHORIZATION:

Authorization may be granted for a maximum of five monthly doses at 15 mg/kg intramuscularly based upon the specific region per the FLDOH website: http://www.floridahealth.gov/diseases-and-conditions/respiratory-syncytial-virus/. **All recipients except:**

- In infants and children < 24 months, already on prophylaxis and eligible, one post-op dose may be approved after cardiac bypass or after extracorporeal membrane oxygenation (ECMO).

CLINICAL NOTES:

Palivizumab 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.

- There is variability in the onset and offset of RSV season. Generally, it runs from November to April within the continental United States.
- Data from the Florida Department of Health may 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 may be considered for Navajo and White Mountain Apache infants in their first year of life.

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APPROVAL CRITERIA

Palivizumab may be approved in the following scenarios and when clinically appropriate:

Infant/Child Age at Start of RSV Season	Criteria
< 12 months (first year of life)	▪ GA< 29 wks, 0 d (otherwise healthy) ▪ CLD of prematurity (GA<32 wks, 0 d and with supplemental O_2 for at least the first 28 d after birth) ▪ Anatomic pulmonary abnormalities or neuromuscular disorder, or congenital anomaly that impairs the ability to clear secretions ▪ Profoundly immunocompromised with conditions such as SCID, immunocompromised infant with stem cell transplant, severe acquired immunodeficiency syndrome (AIDS) ▪ CF with CLD and/or nutritional compromise
≤ 12 months (first year of life)	▪ CHD (hemodynamically *significant*) with *acyanotic** heart disease on medications to control CHF and will require cardiac surgery or infants with moderate to severe PH. For *cyanotic** heart defects, a pediatric cardiologist should be consulted.
> 12 months to 23 months	▪ CLD of prematurity (GA < 32 wks, 0 d and supplemental O_2 for at least the first 28 d after birth) and medical support (chronic systemic steroids, diuretic therapy, or supplemental O_2) within 6 months before start of 2nd RSV season ▪ CF with severe lung disease** or weight for length < 10th percentile
< 24 months (2nd year of life)	▪ Cardiac transplant during RSV season ▪ Already on prophylaxis and eligible; give post-op dose after cardiac bypass or after ECMO ▪ Profoundly immunocompromised with conditions such as SCID, immunocompromised infant with stem cell transplant, severe acquired immunodeficiency syndrome (AIDS)

GA=gestational age; wks=weeks; d=day; CLD=chronic lung disease; SCID= severe combined immune deficiency; 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 acyanotic heart defects include ventricular septal defects, atrial septal defects, pulmonary valve stenosis and aortic valve stenosis. For *cyanotic* heart defects, a pediatric cardiologist should be consulted.

** 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.

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DENIAL CRITERIA:

Infant/Child Age at Start of RSV Season	Deny
> 12 months (2nd year of life)	▪ Based on prematurity alone ▪ CLD without medical support (chronic systemic steroids, diuretic therapy or supplemental O_2) ▪ CHD ▪ Otherwise healthy children in 2nd year of life
Any age	▪ Breakthrough RSV hospitalization *** ▪ Hemodynamically *insignificant* 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	▪ 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

[i] 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 27, 2014

[ii] 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 August 27, 2014

[iii] Synagis [package insert]. Gaithersburg, MD; MedImmune; March 2014.