

GCHP Medi-Cal Clinical Guidelines Palivizumab (Synagis™)

PA Criteria	Criteria Details
Covered Uses (FDA Approved Indication)	Respiratory Syncytial Virus (RSV) infection prophylaxis to prevent serious infection of the lower respiratory tract in pediatric patients at high risk of RSV disease, including those with hemodynamically significant congenital heart disease.
Exclusion Criteria	Infant has already received nirsevimab (Beyfortus) within the same RSV season.
Required Medical Information	<p>One of the following:</p> <ul style="list-style-type: none"> • Infants born before 29 weeks, 0 days gestation who are less than 12 months of age at the start of the RSV season. • During the first year of life for preterm infants who develop chronic lung disease (CLD) of prematurity defined as gestational age less than 32 weeks, 0 days and a requirement for greater than 21 percent oxygen for at least the first 28 days after birth. • During the second year of life for preterm infants who develop chronic lung disease (CLD) of prematurity as defined above and continue to require medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the six-month period before the start of the second RSV season. • Infants who are 12 months or younger with acyanotic heart disease who are receiving medication to control congestive heart failure and will require cardiac surgical procedures and infants with moderate to severe pulmonary hypertension. • Infants with cyanotic heart defects in the first year of life may receive palivizumab prophylaxis if deemed warranted by the infant's pediatric cardiologist. • Children younger than 2 years of age who undergo cardiac transplantation during the RSV season. • An infant younger than 24 months receiving prophylaxis who undergoes cardiopulmonary bypass or extracorporeal membrane oxygenation and continues to require prophylaxis post-operatively may receive a post-operative dose of palivizumab (15 mg/kg). • During the first year of life, infants with neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough. • Children younger than 24 months of age who are profoundly immunocompromised during the RSV season, as assessed by a qualified pediatric Infectious Disease or Immunologic specialist. • During the first year of life, infant with cystic fibrosis with clinical evidence of CLD and/or nutritional compromise. • During the second year of life, infants with cystic fibrosis and manifestations of severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on



	chest radiography or chest computed tomography that persist when stable) or weight for length less than the tenth percentile.		
Age Restriction	Up to 24 months of age at the beginning of RSV season - Check for CCS eligibility		
Prescriber Restrictions	None		
Coverage Duration	Per current CDC recommendation (usually up to five doses during the RSV season).		
Other Criteria / Information	Adapted from DHCS Pharmacy Manual Immunizations October 2024		
	Qualifying infants born during the RSV season may require fewer doses. For example, infants born in January would receive their last dose in March.		
	HCP	Description	Dosing, Units
	90378	Palivizumab 50mg injection (Synagis)	15mg/kg Intramuscular Injection once a month up to five doses during the RSV season.

STATUS	DATE REVISED	REVIEW DATE	APPROVED / REVIEWED BY	EFFECTIVE DATE
Created	1/13/2025	N/A	Lily Yip, Director of Pharmacy Services; Yoonhee Kim, Clinical Programs Pharmacist	N/A
Approved	N/A	2/13/2025	Pharmacy & Therapeutics (P&T) Committee	3/1/2025