

POLICY AND PROCEDURE	
TITLE: Palivizumab (Synagis) Authorization	
DEPARTMENT: Medical Management - Pharmacy	POLICY #: PH20
EFFECTIVE DATE: 01/10/08	REVIEW/REVISION DATE: 02/14, 02/16, 02/17, 02/18, 05/19
COMMITTEE APPROVAL DATE: P&T 05/14/2019; PRC 06/19/2019 QMUM 07/10/2019	RETIRE DATE: None
PRODUCT TYPE: Medi-Cal	REPLACES: None

I. PURPOSE

Palivizumab (trade name Synagis) is a humanized monoclonal antibody produced by recombinant DNA technology licensed by the FDA and indicated for the prevention of lower respiratory disease caused by respiratory syncytial virus (RSV) in infants at high risk for serious RSV infection.

II. POLICY

HPSJ authorizes Synagis for infants at high risk for RSV disease (as defined by American Academy of Pediatrics (AAP) Policy: *Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection*, Pediatrics 2014 134(2): 415-420) when it is not covered by the California Children's Services Program (as outlined in State of California Department of Health Services CCS program Letter N.L 11-1006 dated October 17, 2006).

III. PROCEDURE

- A. Criteria eligible for coverage through HPSJ
 1. Meet AAP criteria as outlined in CCS Criteria below, but are not eligible for CCS coverage
- B. Criteria eligible for coverage through CCS (CCS Preauthorization is required)
 1. Children with CLD (chronic lung disease) who are 24 months of age or younger at the start of the RSV season (most years on November 1st), and who have required medical therapy for their chronic lung disease within 6 months of the start of RSV season.
 2. Ex-premature infants 28 weeks and 6 days or less at birth, and chronological age less than 12 months on November 1st.

3. Ex-premature infants 29 through 32 weeks and 0 days gestation at birth, and chronological age less than 6 months on November 1st.
4. Infants 32 weeks and 1 day to 35 weeks and 0 day gestation at birth, and less than 6 months chronological age on November 1st, with at least two additional risk factors (e.g., child care attendance, school-age siblings, attendance in daycare, exposure to environmental air pollutants, or severe neurological disease) will be considered on an individual basis.
5. Children who are 24 months of age or younger at the start of the RSV season with cyanotic or acyanotic CHD and the request for service is from the CCS approved Cardiac Special Care Center or a cardiologist from a CCS approved Cardiac SCC or the request is from a CCS approved Cardiac SCC or a CCS approved cardiologist from the Cardiac SCC
6. Children with severe immunodeficiencies e.g. severe combined immunodeficiency, acquired immunodeficiency syndrome, transplant recipients, or children who are immunocompromised due to chemotherapy and the request for service is from a CCS approved Infectious Disease and Immunologic Disorders SCC, transplant SCC, Hematology/Oncology SCC or the request is from a CCS approved pediatrician authorized in conjunction with one of these CCS approved SCCs.
7. Children who are 48 months of age or younger at the start of the RSV season who are at risk of developing severe complications due to RSV infection and have one or more of the following conditions:
 - a. CCS qualifying respiratory system disease (cystic fibrosis, chronic lung disease requiring oxygen therapy, noninvasive or invasive respiratory support, pulmonary hypoplasia, severe upper airway anomalies, a history requiring mechanical ventilation the previous RSV season due to RSV disease
 - b. CCS qualifying hemodynamically significant cardiovascular system disease including pulmonary hypertension or CHF requiring medical therapy, and cyanotic heart disease
 - c. CCS qualifying neuromuscular conditions causing poor cough due to weak or ineffective respiratory muscles and inadequate clearance of respiratory secretions.

C. CCS Authorization

1. **CCS will require either a prescription or written documentation of need for Synagis from a CCS Special Care Center pulmonologist, neonatologist, or intensivist.** Community based pediatricians may request authorization for Synagis when

collaboration between the SCC physician and community-based pediatrician is documented. Updated evaluation by a SCC pulmonologist should be requested by the community pediatrician, if not current, to determine medical eligibility and/or RSV risk prior to requesting Synagis.

- D. Children who meet prematurity criteria as stated above and are open to CCS for a condition that may worsen with RSV infection will be considered by CCS for RSV prophylaxis on a case by case basis when accompanied by a request from child’s authorized **CCS specialist**.

IV. ATTACHMENT(S)

None

V. REFERENCES

- A. American Academy of Pediatrics (AAP) Policy: *Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection*, Pediatrics 2014; DOI: 10.1542/peds.2014-1665.
- B. California Children’s Services Program (as outlined in State of California Department of Health Services CCS program Letter N.L 13-0914 dated September 19, 2014).

VI. REGULATORY AGENCY APPROVALS

DHCS Approved on (pending).

VII. REVISION HISTORY

STATUS	DATE REVISED	REVISION SUMMARY
Reviewed	02/16/16	No content change, annual review.
Reviewed	02/15/17	No content change, annual review.
Revised	02/13/18	Updated definition for RSV season and minor grammatical edits.
Reviewed	05/14/19	No content change, updated in-line reference to match reference listed since guideline update in 2014, annual review.

VIII. GLOSSARY/DEFINITIONS

RSV Season: Per the AAP (American Academy of Pediatrics) Policy, prophylaxis against RSV should be initiated just before onset of the RSV season (1st of every November) and terminated at the end of RSV season (31st of every March). In most seasons and in most regions of the Northern Hemisphere, the first dose of palivizumab should be administered at the beginning of November

and the last dose at the beginning of March (providing protection into April). The decision about the specific duration of the RSV season will be determined by the HPSJ Medical Director using RSV epidemiologic information from regional hospital admissions, San Joaquin County Public Health Services, State of California Department of Health Services, and/or the Centers for Disease Control.

Health Plan of San Joaquin Approval: Signatures on File in C360