

## Medical Affairs Policy & Procedure

**Title/Service:** Synagis (palivizumab)

<b>Revised</b>	
<b>Reviewed</b>	02/25/00, 03/24/00, 05/05/00, 01/26/01, 09/28/01, 01/25/02, 06/17/03, 04/28/06, 12/28/09, 02/05/10, 11/18/11
<b>Developed</b>	
<b>Policy Committee Approval</b>	11/18/2011

### **Description:**

Synagis is a humanized monoclonal antibody designed to prevent respiratory syncytial virus (RSV) infection. It is given monthly to high risk infants during the RSV season (October through April).

### **Indications of Coverage:**

Synagis is considered medically necessary for any of the following conditions:

Five doses are allowed for the following:

Infants and children younger than twenty four months of age with chronic lung disease, congenital anomalies of the airway, neuromuscular disease, or severe immunodeficiency who have required medical therapy within the six months before the anticipated RSV season.

Infants twenty nine to thirty two weeks gestation at birth and less than six months old chronological age at the time of the start of the RSV season.

Infants less than or equal to twenty eight weeks gestation at birth and less than twelve months old chronological age at the time of the start of the RSV season.

Infants and children 24 months or younger with hemodynamically significant cyanotic or acyanotic congenital heart disease

Three doses are allowed for the following:

Infants from thirty two to thirty five weeks gestation at birth, when at least one of the following additional risk factors is documented:

Underlying conditions that predispose to respiratory

One or more siblings under the age of five years in the



household

Daycare attendance

If criteria are met, treatment with Synagis may be allowed. The medication may be administered in the clinic or by home health services. If a dose is administered in the hospital prior to discharge, it is considered as one of the three or five allowable doses.

### **Limitations of Coverage:**

Review contract and endorsements for exclusions and prior authorization or benefit requirements.

If used for a condition/diagnosis other than is listed in the Indications of Coverage, deny as experimental or investigative.

If used for a condition/diagnosis that is listed in the Indications of Coverage, but the criteria are not met, deny as not medically necessary.

### **Documentation Required:**

- Office visit notes OR hospital progress notes or discharge summary
- Documentation of gestational age at birth

### **Rationale:**

Respiratory syncytial virus (RSV) is a common cause of respiratory tract infections in children in the first 2 years of life. For children with lung disease, heart disease, or other risk factors such as premature birth at thirty-two weeks or earlier, contracting the virus presents the possibility of severe respiratory illness. Synagis administration has been shown to decrease the likelihood of severe illness for these children.

### **References:**

1. [Committee On Infectious Diseases](#). Policy Statement--Modified Recommendations for Use of Palivizumab for Prevention of Respiratory Syncytial Virus Infections. Pediatrics Volume 124, Number 6, December 2009.
2. Committee on Infectious Diseases and Committee on Fetus and Newborn. Policy Statement. Revised Indications for the Use of Palivizumab and Respiratory Syncytial Virus Immune Globulin Intravenous for the Prevention of Respiratory Syncytial Virus Infections. Pediatrics Vol. 112 No. 6 December 2003, pp. 1442-1446.
3. Fenton C, Scott LJ, Plosker GL. Palivizumab: a review of its use as prophylaxis for serious respiratory syncytial virus infection. Paediatr Drugs. 2004;6(3):177-97.
4. [Greenough A](#), [Alexander J](#), [Boit P](#), [Boorman J](#), [Burgess S](#), [Burke A](#), [Chetcuti PA](#), [Cliff I](#), [Lenney W](#), [Lytle T](#), [Morgan C](#), [Raiman C](#), [Shaw NJ](#), [Sylvester KP](#), [Turner J](#). School

age outcome of hospitalisation with respiratory syncytial virus infection of prematurely born infants. *Thorax* 2009;64:490-495.

5. [Lanctot KL](#), [Masoud ST](#), [Paes BA](#), [Tarride JE](#), [Chiu A](#), [Hui C](#), [Francis PL](#), [Oh PI](#). The cost-effectiveness of palivizumab for respiratory syncytial virus prophylaxis in premature infants with a gestational age of 32-35 weeks: a Canadian-based analysis. [Curr Med Res Opin.](#) 2008 Oct 16.
6. Ontario Risk Assessment Tool for Infants. Available at: [www.transfusionontario.org/ministry%20letters/final%202.pdf](http://www.transfusionontario.org/ministry%20letters/final%202.pdf). Accessed: 16 Jan 10.
7. Synagis (palivizumab). Gaithersburg, MD: Medimmune. Revised: April 11.
8. The IMPact RSV Study Group. Palivizumab, a Humanized Respiratory Syncytial Virus Monoclonal Antibody, Reduces Hospitalization From Respiratory Syncytial Virus Infection in High-Risk Infants. *Pediatrics* 1998; 102:531-537.
9. [Wang D](#), [Cummins C](#), [Bayliss S](#), [Sandercock J](#), [Burls A](#). Immunoprophylaxis against respiratory syncytial virus (RSV) with palivizumab in children: a systematic review and economic evaluation. [Health Technol Assess.](#) 2008 Dec;12(36):iii, ix-x, 1-86.
10. [Wu H](#), [Pfarr DS](#), [Losonsky GA](#), [Kiener PA](#). Immunoprophylaxis of RSV infection: advancing from RSV-IGIV to palivizumab and motavizumab. [Curr Top Microbiol Immunol.](#) 2008;317:103-23.

*Approved by the Medical Director*