

Evidence Based Guideline

Respiratory Syncytial Virus Prophylaxis

File Name: respiratory_syncytial_virus_prophylaxis
Guideline Number: EBG.DRU4170
Origination: 1/1999
Last Review: 3/2009
Next Review: 3/2011

Description of Procedure or Service

Respiratory syncytial virus (RSV) is the most common cause of lower respiratory infections in children. Those at highest risk include those less than 2 years old with prematurity, chronic lung disease (CLD, formerly known as bronchopulmonary dysplasia), congenital heart disease, multiple congenital anomalies, and certain immunodeficiencies. Infections typically occur in the winter months, starting from October to December and ending from March to May. In the U.S., RSV is associated with 90,000 pediatric hospitalizations annually and 45,000 deaths.

Since 1993, immune prophylaxis has been available with the use of intravenous immunoglobulin (IVIg) prepared from donors screened for high titers of RSV neutralizing antibody (RSV-IVIg or RespiGam). In 1998, the FDA approved palivizumab (Synagis), a humanized RSV monoclonal antibody that can be administered intramuscularly. The FDA-labeled indications for the 2 products are similar, in that both are intended for use in the prevention of severe RSV lower respiratory tract disease in infants and children younger than 24 months with bronchopulmonary dysplasia or a history of premature birth (less than or equal to 35 weeks' gestational age).

For either product, patients receive monthly infusions or injections throughout the RSV winter season. RSV prophylaxis should be initiated at the onset of the RSV season and terminated at the end of the RSV season. In North Carolina, the typical season for RSV runs from November through April. RSV immune prophylaxis may be administered between October and the end of the RSV season. Typically, a total of 5 monthly dosages are given during the RSV winter season. Once a child qualifies for initiation of prophylaxis at the start of the RSV season, administration should continue throughout the season and not stop at the point an infant or child reaches applicable age limits noted in the guidelines below.

Evidence Based Guideline for Respiratory Syncytial Virus Prophylaxis

Monthly administration of immune prophylaxis for respiratory syncytial virus with either of the above products may be appropriate in the following infants and children based on guidelines from the American Academy of Pediatrics:

A. Chronic Lung Disease

1. Infants and children younger than 2 years of age with chronic lung disease who have required medical therapy for their chronic lung disease within 6 months before the anticipated RSV season.

B. Prematurity

1. Infants born at 32 weeks of gestation or earlier, without chronic lung disease or who do not meet the criteria under (A.1.) above, according to the following schedule:

- ◆ Infants born at 28 weeks of gestation or earlier are candidates for prophylaxis during their first RSV

Policy: Respiratory Syncytial Virus Prophylaxis

season, whenever that occurs during the first 12 months of life.

- ◆ Infants born at 29 to 32 weeks of gestation (32 weeks' gestation refers to an infant born on or before the 32nd week of gestation) are candidates for prophylaxis if they are less than 6 months of age at the start of the RSV season.
2. Infants born between 32 weeks and 35 weeks gestation who are younger than 6 months at the start of the RSV season and who also have 2 or more of the following high risk factors:
 - ◆ child care attendance
 - ◆ school-aged siblings
 - ◆ exposure to environmental air pollutants
 - ◆ congenital abnormalities of the airways
 - ◆ severe neuromuscular disease

C. Congenital Heart Disease

1. Monthly administration of immune prophylaxis with palivizumab only (NOT RespiGam as it is contraindicated in this instance) may be considered medically necessary for children who are 24 months of age or younger *with hemodynamically significant cyanotic and acyanotic heart disease*. Decisions regarding prophylaxis with palivizumab in children with congenital heart disease should be made on the basis of the degree of physiologic cardiovascular compromise. Infants younger than 12 months of age with congenital heart disease who are most likely to benefit from immunoprophylaxis include:
 - ◆ infants who are receiving medication to control congestive heart failure
 - ◆ infants with moderate to severe pulmonary hypertension
 - ◆ infants with cyanotic heart disease
2. For children with heart disease meeting the above criteria for palivizumab, an additional postoperative dose of palivizumab may be considered medically necessary after a surgical procedure requiring cardiopulmonary bypass.

Medical Evidence regarding Respiratory Syncytial Virus Prophylaxis indicates it is not recommended in the following situations:

- A. Immune prophylaxis is not recommended for infants and children with hemodynamically insignificant heart disease including but not limited to:
 - secundum atrial septal defect
 - small ventricular septal defect
 - pulmonic stenosis
 - uncomplicated aortic stenosis
 - mild coarctation of the aorta
 - patent ductus arteriosus
- B. Immune prophylaxis for respiratory syncytial virus is also not recommended for:
 - children over the age of 2 years, and
 - adults with any diagnosis,
 - patients undergoing stem-cell transplantation,

Policy: Respiratory Syncytial Virus Prophylaxis

- children with cystic fibrosis, immunodeficiencies, or other diagnoses in the absence of one of the conditions specifically addressed by the above guidelines for when RSV prophylaxis is indicated.
- C. Use of RespiGam (RSV-IVIg) is contraindicated in infants and children with cyanotic congenital heart disease.

Benefits Application

Please refer to certificate for availability of benefit. This guideline relates only to the services or supplies described herein. Benefits may vary according to benefit design; therefore certificate language should be reviewed before applying the terms of the policy.

Note: services rendered in the home require prior review. Refer to certificate for home health benefits.

Billing/Coding/Physician Documentation Information

This policy may apply to the following codes. Inclusion of a code in this section does not guarantee that it will be reimbursed. For further information on reimbursement guidelines, please see Administrative Policies on the Blue Cross Blue Shield of North Carolina web site at www.bcbsnc.com. They are listed in the Category Search on the Medical Policy search page.

Applicable codes: J1565, 90378, 90379

Scientific Background and Reference Sources

Article: "Prevention of Respiratory Syncytial Virus Infections: Indications for the Use of Palivizumab and Update on the Use of RSV-IVIg", American Academy of Pediatrics, 1998; Committee on Infectious Diseases, 1998-1999.

BCBSNC Pharmacy Consultant - 1998.

Pediatrics in Review; Volume 19, No. 2, February 1998, pages 55-60.

USPDI - 1998 - RSV-IVIg (Respigam):page 3145; Palivizumab (Synagis):

Clearinghouse Update - Technologica - BCBS Association - BCBS Association - September 1998, page 5.

American Academy of Pediatrics (AAP) Member Alert: 10/6/98.

October 1998 update, page 1705-1706.

Vice President - Healthcare Management - 1/99.

Medical Policy Advisory Group - 3/99

Medical Policy Advisory Group - 8/12/99

Center for Disease Control -9/99

Specialty Matched Consultant Advisory Panel - 5/2001

BCBSA Medical Policy Reference Manual, 2/15/2002; 5.01.10

Specialty Matched Consultant Advisory Panel - 5/2003

BCBSA Medical Policy Reference Manual [Electronic Version]. 5.01.10, 10/09/03.

American Academy of Pediatrics. (2003, December). Revised indications for the use of palivizumab and RSV IVIG for the prevention of respiratory syncytial virus infections. Retrieved on 12/23/2003 from <http://>

Policy: Respiratory Syncytial Virus Prophylaxis

www.aap.org/policy/t020305.html.

Article: "Brief Report: Respiratory Syncytial Virus Activity-United States, 2005-2006" (January 24, 2007). *JAMA*, 297:356-357

BCBSA Medical Policy Reference Manual [Electronic Version]. 5.01.10, 12/13/07

Policy Implementation/Update Information

- 1/99 Original policy issued.
- 5/99 Reviewed, "Description of Procedure and Service" changed. Reformatted, Medical Term Definitions added.
- 8/99 Reviewed, Reformatted, Description of Procedure or Service changed, Medical Term Definitions added.
- 8/99 Medical Policy Advisory Group 8/12/99.
- 9/99 Statement added to the policy - RSV Vaccine is considered investigational.
- 4/01 System change.
- 5/01 Specialty Matched Consultant Advisory Panel review (5/2001). Changed statements regarding the RSV season to indicate that they season may be extended due to the prevalence of RSV in the community.
- 5/02 Revised criteria under when it is not covered to include the statement that other indications for immune prophylaxis for respiratory syncytial virus are considered **investigational** including, but not limited to adults and children with congenital heart disease or immunodeficiencies, or cystic fibrosis, not otherwise addressed by the above criteria. Format changes. Typos corrected. Codes 90780 - 90782 added to Billing and Coding section.
- 5/03 Specialty Matched Consultant Advisory Panel review. Revised under "when it is not covered" section to remove indications for children with congenital heart disease. Term "cyanotic" removed from Medical Term Definitions. Codes IJ013, IJ014, IJ025, IV825, and IV900 deleted from Billing/Coding section. Typos corrected. Format changes.
- 8/12/04 Code S9562 added to Billing/Coding section.
- 12/23/04 Policy Description, When Covered, and Policy Guidelines sections revised. What is covered section updated to add that infants born between 32 weeks and 35 weeks of gestation and are younger than 6 months at the start of the RSV season should have at least 2 or more risk factors. Risk factors are listed as well. Policy number added to Key Words section. Title changed from "RSV-IVIG Palivizumab" to "Respiratory Syncytial Virus Prophylaxis". Benefits Application and Billing/Coding sections reformatted for consistent policy language. References added. Notification 12/23/2004. Effective 03/03/2005.
- 3/03/05 Statement, "For pre-exposure prophylaxis...." statement removed from Benefits Application section.
- 5/05/05 Specialty Matched Consultant Advisory Panel review on April 22, 2005. No changes made to the policy coverage criteria. Definition of gestation changed to say, " the length of time from the first day of the last menstrual period until birth." Definition of premature birth changed to say, "infants born before the thirty-seventh week." Fourth paragraph phrase [less than or equal to 35 weeks gestational age] removed.
- 10/08/05 Updated section "Description of Procedure or Service" to clarify statement regarding applicable age limit. Sixth paragraph phrase indicating administration should continue beyond 6 or 12 months

Policy: Respiratory Syncytial Virus Prophylaxis

of age changed to read, "administration should continue throughout the season and not stop at the point a child reaches the applicable age limit in the policy below."

- 1/05/06 Deleted CPT codes 90780, 90781, 90782 from Billing/Coding section.
- 10/16/06 Medical Policy reformatted and changed to Evidence Based Guideline. HCPCS Code S9562 removed from Billing/Coding section and statement added to Benefits Application section to indicate that services rendered in the home require prior plan approval.
- 4/23/07 Routine biennial review. Speciality Matched Consultant Advisory Panel review March 15, 2007. No changes to guidelines. (adn)
- 4/27/09 Routine biennial review. Description section revised. Medical criteria sections reformatted into outline format. Indications added to the "Not Recommended" section. RSV prophylaxis is not recommended for patients undergoing stem-cell transplantation and for children over the age of 2 years. Also, use of RespiGam (RSV-IVIg) is contraindicated in infants and children with cyanotic congenital heart disease. Speciality Matched Consultant Advisory Panel review meeting 3/26/09.

Medical policy is not an authorization, certification, explanation of benefits or a contract. Benefits and eligibility are determined before medical guidelines and payment guidelines are applied. Benefits are determined by the group contract and subscriber certificate that is in effect at the time services are rendered. This document is solely provided for informational purposes only and is based on research of current medical literature and review of common medical practices in the treatment and diagnosis of disease. Medical practices and knowledge are constantly changing and BCBSNC reserves the right to review and revise its medical policies periodically.