RESPIRATORY SYNCYTIAL VIRUS IMMUNOPROPHYLAXIS
RX504.009

COVERAGE:

Coverage is allowed for use of RespiGam (Respiratory Syncytial Virus Immune Globulin Intravenous [Human], [RSV-IGIV], and Synagis (Palivizumab) for the prevention of serious lower respiratory tract infection caused by Respiratory Syncytial Virus (RSV).

DESCRIPTION:

Respiratory Syncytial Virus (RSV) is the single most important respiratory pathogen in infancy and early childhood. Primary RSV infection results in significant morbidity and, sometimes death; especially in high-risk children. RSV is an RNA virus, classified as a Pneumovirus. RSV is associated with a sharp outbreak of acute respiratory disease occurring annually in late autumn or in winter. Risk factors for serious RSV infection include:

- Young age (under 1 year, especially under 6 months);
- Underlying medical problems, (e.g., prematurity, lung disease, Congenital Heart Disease [CHD], other major congenital anomalies, and immunodeficiency);
- Hospitalization during RSV season, (ie, nosocomial RSV); and
- Low levels of transplacentally acquired RSV antibody.

The use of RespiGam (Respiratory Syncytial Virus Immune Globulin Intravenous [Human], [RSV-IGIV], and Synagis (Palivizumab) is for the prevention of serious lower respiratory tract infection caused by Respiratory Syncytial Virus (RSV) for infants and children, younger than 2 years of age, with:

- Bronchopulmonary Dysplasia (BPD); or
- A history of premature birth.

Respiratory Syncytial Virus Immune Globulin Intravenous (Human), (RSV-IGIV), RespiGam, is a sterile liquid immunoglobulin G (IgG) containing neutralizing antibody to Respiratory Syncytial Virus (RSV). RespiGam is supplied in a 50-ml single-dose vial containing 2,500-mg +or - 500-mg immunoglobulin. RespiGam is administered at a dose of 750 mg/kg. The single-use vial should be entered only once for administration purposes and is given intravenously over a 2-3 hour period on a monthly basis for five months during the RSV season.

Synagis (Palivizumab) is a genetically engineered antibody for use against the RSV virus. Synagis is supplied in single use vials as lyophilized powder to deliver either 50 milligrams or 100 milligrams when reconstituted with sterile water for injection. Synagis is administered in a dose of 15mg/kg and administered by intramuscular
(IM) injection monthly for five months during the RSV season.

RSV-IGIV and Synagis are safe and effective in reducing the incidence and duration of RSV hospitalization and the severity of RSV illness in selected high-risk infants. RSV-IGIV was licensed for marketing by the FDA on January 18, 1996; Synagis was licensed on June 19, 1998.

RATIONALE:

Several randomized clinical trials have demonstrated the success of immune prophylaxis of RSV. One study reported a 41% reduction in hospitalization due to RSV infection and reductions in other measures of severity of RSV infection when it did occur. A study on Palivizumab showed similar results.

DISCLAIMER:

State and federal law, as well as contract language, including definitions and specific inclusions/exclusions, takes precedence over Medical Policy and must be considered first in determining coverage. The member’s contract benefits in effect on the date that services are rendered must be used. Any benefits are subject to the payment of premiums for the date on which services are rendered. Medical technology is constantly evolving, and we reserve the right to review and update Medical Policy periodically.

HMO Blue Texas physicians who are contracted/affiliated with a capitated IPA/medical group must contact the IPA/medical group for information regarding HMO claims/reimbursement information and other general polices and procedures.

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