Status
Active

Medical and Behavioral Health Policy
Section: Medicine
Policy Number: II-62
Effective Date: 06/25/2014

Blue Cross and Blue Shield of Minnesota medical policies do not imply that members should not receive specific services based on the recommendation of their provider. These policies govern coverage and not clinical practice. Providers are responsible for medical advice and treatment of patients. Members with specific health care needs should consult an appropriate health care professional.

RESPIRATORY SYNCYTIAL VIRUS PROPHYLAXIS

Description: Humanized respiratory syncytial virus (RSV) monoclonal antibody (e.g., palivizumab [Synagis, IM injection]) provides passive immunity to protect the lower respiratory tract from respiratory syncytial virus infection. Palivizumab is administered on a monthly basis, during the RSV winter season (November through March), with each administered dose providing protection for the following month. According to the American Academy of Pediatrics, in the continental United States, a maximum of 5 monthly doses for infants and young children with congenital heart disease or chronic lung disease of prematurity or preterm birth before 32 weeks' gestation will provide optimal benefit, even with variation in season onset and end. Infants born between 32 and 35 weeks' gestation with no significant health conditions but with risk factors will receive optimal benefit from a maximum of 3 monthly doses. Studies in high risk infants and children who have received RSV prophylaxis have demonstrated reductions in the incidence of RSV lower respiratory tract infections, duration of RSV hospitalization, and severity of RSV illness in high risk infants.

Policy:

I. INITIAL RSV SEASON

The use of immune prophylaxis (e.g., palivizumab [Synagis]) for RSV for the initial RSV season, may be considered **MEDICALLY NECESSARY** when used in the following patient populations with the described number of doses:

A. **Maximum of Five (5) Doses**

1. **Infants with Chronic Lung Disease**
   a. Medical therapy (supplemental oxygen, bronchodilator, diuretic, or chronic corticosteroid therapy) was required within six months before the anticipated RSV season; AND
   b. Less than two (2) years of age at onset of RSV season;
   c. Maximum of 5 monthly doses.

2. **Infants with hemodynamically significant cyanotic and acyanotic congenital heart disease**
    a. Infants less than two (2) years of age at onset of RSV season; AND
    b. Infants who are receiving medication to control congestive heart failure; infants with moderate to severe pulmonary hypertension; infants with cyanotic heart disease; or infants who have received a heart transplant. (Decisions regarding prophylaxis with palivizumab in children with congenital heart disease should be made on the basis of the degree of physiologic cardiovascular compromise);
    c. For children with heart disease meeting the above criteria for palivizumab, an additional postoperative dose of palivizumab may be given after a surgical procedure requiring cardiopulmonary bypass.
    d. Maximum of 5 monthly doses.
3. **Infants with congenital abnormalities of the airway or neuromuscular disease**
    a. Less than two (2) years of age at onset of RSV season; AND
    b. Infants have either congenital abnormalities of the airway or a neuromuscular condition that compromises handling of respiratory secretions.
    c. Maximum of 5 monthly doses.
4. **Infants born before 32 weeks' gestation (i.e., 31 weeks, 6 days or less)**
    a. All infants born ≤ 28 weeks of gestation and less than one year of age at onset of RSV season;
    b. Infants born on or after May 1st at 29 to 32 weeks of gestation and less than 6 months old at onset of RSV season;
    c. Maximum of 5 monthly doses.

B. **<u>Maximum of Three (3) Doses</u>**
1. **Infants born on or after August 1st at 32 to less than 35 weeks' gestation (i.e., 32 weeks, 0 days through 34 weeks, 6 days) who do not meet the above criteria:**
    a. Infants less than 3 months old at onset of RSV season or who are born during the RSV season and who have at least <u>one</u> of the following high-risk factors:
        - Sibling (not a twin or a multiple) younger than 5 years of age; or
        - Infant attends child care
    b. Infants may receive prophylaxis through 3 months of age (i.e., through the 3rd month until the infant reaches 4 months of age);
    c. Maximum of <u>3 monthly doses.</u>

II. <u>SECOND RSV SEASON</u>

The use of immune prophylaxis (e.g., palivizumab [Synagis]) for RSV for the patient's second year of treatment (maximum of 5 monthly doses) may be considered **MEDICALLY NECESSARY** for the following indications:

A. Children with chronic lung disease who require treatment with oxygen, ventilation, and/or diuretics;
B. Children with hemodynamically significant cyanotic and acyanotic congenital heart disease, as described above; and
C. All infants born ≤ 28 weeks of gestation and less than one year of age at onset of RSV season.

III. ADMINISTRATION OF RSV PROPHYLAXIS

A. Once a child qualifies for prophylaxis, administration should continue the entire season through the maximum monthly doses allowed as described above.
B. The first dose of immune prophylaxis for RSV will be approved for coverage of administration on or after November 1st.
C. Administration of more than the number of doses described above in one RSV season (defined as November 1st through March 31st) is considered **NOT MEDICALLY NECESSARY** without documented widespread local community RSV activity, indicating early onset of season or extending past April.

IV. The use of immune prophylaxis for RSV for all other indications is considered **INVESTIGATIVE** due to a lack of evidence demonstrating an impact on improved health outcomes. Investigative indications include, but are not limited to, the following:

A. Adults with any diagnosis;
B. Patients undergoing stem-cell transplantation;
C. Children 24 months or older prior to the commencement of the RSV season;
D. Cystic fibrosis patients without reduced lung reserve

Coverage: Blue Cross and Blue Shield of Minnesota medical policies apply generally to all Blue Cross and Blue Plus plans and products. Benefit plans vary in coverage and some plans may not provide coverage for certain services addressed in the medical policies.

Medicaid products and some self-insured plans may have additional policies and prior authorization requirements. Receipt of benefits is subject to all terms and conditions of the member's summary plan description (SPD). As applicable, review the provisions relating to a specific coverage determination, including exclusions and limitations. Blue Cross reserves the right to revise, update and/or add to its medical policies at any time without notice.

For Medicare NCD and/or Medicare LCD, please consult CMS or National Government Services websites.

Refer to the Pre-Certification/Pre-Authorization section of the Medical Behavioral Health Policy Manual for the full list of services, procedures, prescription drugs, and medical devices that require Pre-certification/Pre-Authorization. Note that services with specific coverage criteria may be reviewed retrospectively to determine if criteria are being met. Retrospective denial of claims may result if criteria are not met.

Coding: *The following codes are included below for informational purposes only, and are subject to change without notice. Inclusion or exclusion of a code does not constitute or imply member coverage or provider reimbursement.*

CPT:

90378 Respiratory syncytial virus, monoclonal antibody, recombinant, for intramuscular use, 50 mg, each

Policy History:

Developed April 10, 1996

Most recent history:
Revised June 8, 2011
Reviewed June 13, 2012
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Reviewed June 11, 2014

Cross Reference:

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