Bulletin

October 28, 2009

Blue Cross medical policy regarding RSV prophylaxis

The Blue Cross and Blue Shield of Minnesota and Blue Plus medical policy II-62, ***Respiratory Syncytial Virus (RSV) Prophylaxis*** *is being updated with dosing guidelines in accordance with the recommendations recently announced by the American Academy of Pediatrics (AAP).* Changes in this medical policy apply to commercial lines of business only. Blue Plus public program members currently follow the AAP guidelines and require prior authorization; this process will remain the same.

For ease of understanding, the medical policy has been revised into categories of maximum doses (three or five) to be given. This policy revision, which will take effect on November 23, 2009, was posted to the "Upcoming Policies" section of the Medical Policy manual on August 26, 2009.

How has the medical policy changed?

Prior to November 23, 2009, the medical policy allowed up to 5 monthly doses in infants or children whose conditions met medical policy criteria. Effective November 23, 2009, the policy has been revised into categories of maximum doses to be given for the patient's medical condition. The updated policy also distinguishes between prophylaxis for the child's **initial** and **second** RSV seasons.

The use of Palivizumab (Synagis) as immune prophylaxis, for the **initial** RSV season, may be considered **medically necessary** when used in the following patient populations with the described number of doses:

Maximum of five (5) doses

Infants with chronic lung disease

- Medical therapy (supplemental oxygen, bronchodilator, diuretic, or chronic corticosteroid therapy) was required within six months before the anticipated RSV season, and
- Less than two (2) years of age at onset of RSV season
- Maximum of 5 monthly doses

Infants with hemodynamically significant cyanotic and acyanotic congenital heart disease

- Infants less than two (2) years of age at onset of RSV season, and
- 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)
- 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
- Maximum of 5 monthly doses

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Infants with congenital abnormalities of the airway or neuromuscular disease

- Infants less than 35 weeks' gestation
- Infants have either congenital abnormalities of the airway or a neuromuscular condition that compromises handling of respiratory secretions
- Maximum of 5 monthly doses

Infants born before 32 weeks' gestation (i.e., 31 weeks, 6 days or less)

- All infants born ≤ 28 weeks of gestation and less than one year of age at onset of RSV season
- Infants born at 29 to 32 weeks of gestation and less than 6 months old at onset of RSV season
- Maximum of 5 monthly doses

Once a child qualifies for initiation of prophylaxis, administration should continue for the entire RSV season through the maximum monthly doses allowed as described above.

Maximum of three (3) doses

Infants born 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:

- Infants less than 3 months old at onset of RSV season or who are born during the RSV season and who have at least *one* of the following high-risk factors:
  1. Sibling younger than 5 years of age, or
  2. Infant attends childcare
- Infants may receive prophylaxis until they reach 3 months of age (many will receive only 1 or 2 doses until they reach 3 months of age)
- Maximum of *3 monthly doses*

The use of palivizumab (Synagis) as immune prophylaxis for the patient's **second** RSV season year of treatment may be considered **medically necessary** for the following indications:

- Children with chronic lung disease who require treatment with oxygen, ventilation, and/or diuretics; and
- Children with hemodynamically significant cyanotic and acyanotic congenital heart disease, as described above

The use of palivizumab (Synagis) as immune prophylaxis for RSV is considered **not medically necessary** for infants and children with hemodynamically insignificant heart disease.

Administration of more than the number of doses described above in one RSV season is considered **not medically necessary** without documented widespread local community RSV activity, indicating early onset of season or extending past April.

Immune prophylaxis for RSV for all other indications is considered **investigative and not medically necessary** including, but not limited to the following:

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

Coverage

Initially, as posted on August 26, 2009, on **providers.bluecrossmn.com** under "Upcoming Policies," of the medical policy manual we did not intend to change our prior authorization recommendation from "Yes, only after the age of two years." However, due to community and provider feedback as well as complexity in policy content, we are **advising prior authorization for *all* RSV prophylaxis doses in children of all ages, effective November 23, 2009.** The broadening of the prior authorization recommendation is to promote provider and member satisfaction. This change streamlines prior authorization, thereby reducing confusion around the policy criteria; especially in light of the new changes recommended by the American Academy of Pediatrics.

Individuals who have obtained doses of RSV prophylaxis prior to November 23, 2009 without a prior authorization (i.e. under age two), should begin submitting prior authorization requests on November 23, 2009 for any remaining doses to be given after this date.

Individuals who have obtained prior authorization for the 2009-2010 RSV season do not need to resubmit a prior authorization request.

We are required to make medical necessity decisions within 10 business days. However, requests submitted with complete information are generally completed in much less time. Please consider this when submitting prior authorization requests.

Medical Documentation

Medical records supporting medical policy criteria are necessary for reviewing RSV prophylaxis requests. When the servicing provider differs from the ordering provider, it is important to remember to send the appropriate medical documentation for review in order to process requests accurately and timely.

Adherence and enforcement of policy

This bulletin is a reminder that providers must abide by the requirements of all medical policies. Blue Cross is taking action to enforce Medical Policy II-62. If prior authorization is not obtained prior to services being performed, claims for the use of respiratory syncytial virus prophylaxis will be subject to retrospective review to determine if criteria are met. Retrospective denial may result if medical policy criteria are not met.

All claims will be reviewed according to the medical policy in effect on the date the RSV prophylaxis was administered. Blue Cross will be strictly enforcing the maximum doses outlined in the above policy criteria.

To view the entire medical policy on RSV Prophylaxis go to **providers.bluecrossmn.com** and select "medical policy" under "tools & resources."

The "Upcoming Policies" section lists new or revised policies approved by the Blue Cross Medical and Behavioral Health Policy Committee and are effective 90 days from the date they were posted to the "Upcoming Policies" section of the Medical and Behavioral Health Policy Manual.

American Academy of Pediatrics recommendations on RSV Prophylaxis administration

To view the American Academy of Pediatrics modified recommendations, go to http://pediatrics.aappublications.org/cgi/content/abstract/peds.2009-2345v1

The following is a the Summary from those recommendations:

1. Recommendations for initiation and termination of prophylaxis are modified to reflect current descriptions from the Centers for Disease Control and Prevention (CDC) of respiratory syncytial virus (RSV) seasonality in different geographic locations within the United States.

2. The recommendations remain unchanged for infants with congenital heart disease (CHD), chronic lung disease of prematurity (CLD [formerly called bronchopulmonary dysplasia]), and birth before 32 weeks' 0 days' gestation.

3. Regardless of the month in which the first dose is administered, the recommendation for a maximal number of 5 doses for all geographic locations is emphasized for infants with hemodynamically significant CHD, CLD or birth before 32 weeks' 0 days' gestation. A maximal number of 3 doses is recommended for infants with a gestational age of 32 weeks 0 days to 34 weeks 6 days without hemodynamically significant CHD or CLD who qualify for prophylaxis.

4. Because of inconsistencies among studies that attempted to define risk factors identifying children at greatest risk of serious RSV lower respiratory tract disease, the new recommendations were designed to target children at the highest risk of severe disease with risk factors that are most consistent and predictive.

Questions?

If you have questions, please contact provider service at **(651) 662-5200** or **1-800-262-0820**.