SUBJECT: Palivizumab (Synagis®)
INDEX TITLE: Clinical Pharmacy Services
ORIGINAL DATE: 9/24/03

This policy applies to the following lines of business: (Check those that apply.)

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I. POLICY

It is the policy of UPMC Health Plan to maintain a prior authorization process that promotes appropriate utilization of specific drugs with potential for misuse or limited indications. This process involves a review using Food and Drug Administration (FDA) criteria to make a determination of Medical Necessity, as defined in CRM.015-Medical Necessity, and approval by the Pharmacy and Therapeutics Committee of the criteria for prior authorization, as described in RX.003-Prior Authorization Process.

The drug Palivizumab (Synagis) is subject to the prior authorization process.

II. DEFINITIONS

N/A

III. PURPOSE

The purpose of this policy is to define the Prior Authorization Process for Palivizumab (Synagis).

IV. SCOPE

This policy applies to the Pharmacy Services Department.
V. PROCEDURE

1. Criteria for Palivizumab:
   a. Children under the age of 24 months at the beginning of Respiratory Syncytial Virus (RSV) season with Chronic Lung Disease (CLD) who have required medical treatment such as oxygen, bronchodilator, diuretic, or corticosteroid therapy for CLD within 6 months before the start of RSV season.
   b. Children under the age of 24 months at the beginning of RSV season with hemodynamically significant congenital heart disease, including congestive heart failure (CHF), severe pulmonary hypertension, or cyanotic heart disease.
   c. Premature infants’ recommendations are based upon gestational age:
      i. Less than 28 weeks, 0 days gestational age and 12 months of age or less at the start of RSV season
      ii. 28 weeks, 1 day – 32 weeks, 0 days gestational age and 6 months of age or less at the start of RSV season
      iii. 32 weeks, 1 day – 35 weeks, 0 days gestational age and 6 months of age or less at the start of RSV season with TWO or more of the following risk factors:
          a. Day care attendance
          b. Exposure to environmental air pollutants
          c. School-aged siblings
          d. A diagnosis of severe neuromuscular disease
          e. A diagnosis of congenital abnormality of the airways

• The medication will be approved based upon the above criteria for a maximum of 6 doses per RSV season.

These recommendations are based upon the American Academy of Pediatrics guidelines as well as standards of practice of Western Pennsylvania practitioners.

The season in which UPMC Health Plan will cover Synagis will be determined yearly based upon the recommendations of our local Western Pennsylvania neonatologists and American Academy of Pediatrics.

Reauthorization Criteria:
All prior authorization renewals will be reviewed each Synagis season.

Limitations
If a member does not meet the above approval criteria, the request will be referred to a UPMC Health Plan Medical Director for review.