Geisinger Health Plan

POLICIES AND PROCEDURE MANUAL

Policy: MBP 2.0

Section: Medical Benefit Pharmaceutical Policy

Subject: Synagis (palivizumab)

I. Policy:
Synagis (palivizumab)

II. Purpose/Objective:
To provide a policy of coverage regarding Synagis

III. Responsibility:
A. Medical Directors
B. Medical Management
C. Pharmacy Department

IV. Required Definitions
1. Attachment – a supporting document that is developed and maintained by the policy writer or department requiring/authoring the policy.
2. Exhibit – a supporting document developed and maintained in a department other than
3. the department requiring/authoring the policy.
4. Devised – the date the policy was implemented.
5. Revised – the date of every revision to the policy, including typographical and grammatical changes.
6. Reviewed – the date documenting the annual review if the policy has no revisions necessary.

V. Additional Definitions
Medical Necessity or Medically Necessary means Covered Services rendered by a Health Care Provider that the Plan determines are:

a. appropriate for the symptoms and diagnosis or treatment of the Member's condition, illness, disease or injury;
b. provided for the diagnosis and the direct care and treatment of the Member's condition, illness disease or injury;
c. in accordance with current standards good medical treatment practiced by the general medical community;
d. not primarily for the convenience of the Member, or the Member's Health Care Provider; and
e. the most appropriate source or level of service that can safely be provided to the Member. When applied to hospitalization, this further means that the Member requires acute care as an inpatient due to the nature of the services rendered or the Member's condition, and the Member cannot receive safe or adequate care as an outpatient

Medicaid Business Segment
Medical Necessity shall mean a service or benefit that is compensable under the Medical Assistance Program and if it meets any one of the following standards:

(i) the service or benefit will, or is reasonably expected to, prevent the onset of an illness, condition or disability.

(ii) the service or benefit will, or is reasonably expected to, reduce or ameliorate the physical, mental or development effects of an illness, condition, injury or disability.

(iii) the service or benefit will assist the Member to achieve or maintain maximum functional capacity in performing daily activities, taking into account both the functional capacity of the Member and those functional capacities that are appropriate for members of the same age

DESCRIPTION:
Palivizumab is a humanized monoclonal antibody (IgG1k) produced by recombinant DNA technology used as a prophylaxis against lower respiratory tract infection with respiratory syncytial virus (RSV).

CRITERIA FOR USE: Requires Prior Authorization by Medical Director or Designee

Synagis (palivizumab) will be considered medically necessary when all of the following criteria are met:

The indication criteria is based on the American Academy of Pediatrics policy statement. Listed indications would need to be met on November 1 of the calendar year that prophylaxis is initiated. Members born after November 1 during RSV season who meet criteria will receive monthly prophylaxis until March 31st.

- Infants ≤ 12 months of age, and born before < 29 weeks gestation at the onset of RSV season
- Infants ≤ 12 months of age, who have a diagnosis of a congenital abnormality of the airway or a diagnosis of a neuromuscular condition that compromises handling of respiratory secretions
- Infants and children ≤ 24 months of age who will be profoundly immunocompromised during the RSV season (e.g., severe combined immunodeficiency or severe acquired immunodeficiency syndrome)
  - Infants ≤ 12 months of age, born at < 32 weeks gestation, with chronic lung disease of prematurity, defined as > 21% oxygen for at least 28 days after birth
  - Infants and children ≤ 24 months of age with chronic lung disease (CLD) who have required at least 28 days of supplemental oxygen after birth and who continue to require medical intervention (supplemental oxygen, chronic steroid use, bronchodilator use or diuretic use)
  - Infants ≤ 12 months of age with hemodynamically significant acyanotic heart disease who:
    - are receiving medication to control congestive heart failure; or
    - have moderate to severe pulmonary hypertension
  - Infants ≤ 12 months of age with cyanotic heart disease who have been evaluated and recommended for treatment by a cardiologist
  - Infants or children who have been receiving prophylaxis and undergo cardiopulmonary bypass during RSV season should receive an additional dose of Synagis® post-operatively as soon as possible after procedure (even if sooner than a month from previous dose) when medically stable (serum concentrations decrease by a mean of 58% following by-pass)
  - Children less than two years of age who undergo cardiac transplantation during the RSV season
  - Infants in the first year of life with CF and clinical evidence of CLD and/or nutritional compromise
  - Infants in the second year of life with CF and who have severe lung disease (previous hospitalization for pulmonary exacerbation in the first year of life or abnormalities on chest radiography or chest computed tomography that persist when stable) or whose weight for length is less than the 10th percentile.

AUTHORIZATION DURATION: Prophylaxis of up to 5 doses should be initiated on November 1 (prior to RSV season) and continue until March 31. Listed indications would need to be met on November 1 of the calendar year that prophylaxis is initiated. Members born after November 1 during RSV season who meet criteria will receive monthly prophylaxis until March 31st.

LIMITATIONS:
- Prophylaxis should be discontinued in any child who experiences a breakthrough RSV hospitalization
- Synagis is limited to 5 monthly doses per RSV season

Note: Infants not at increased risk from RSV and who generally should not receive immunoprophylaxis include:
- Infants and children with hemodynamically insignificant heart disease (eg. secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta and patent ductus arteriosus);
- Infants with lesions adequately corrected by surgery unless they continue to require medication for congestive heart failure;
- Infants with mild cardiomyopathy who are not receiving medical therapy.

DOSING SCHEDULE:
- Every 28-30 days throughout the RSV season
- Dose: 15 mg/kg IM
- Administration should continue throughout the season regardless of whether or not the child reaches the maximum age (i.e. 6 or 12 months) during that time frame

LINE OF BUSINESS:
Eligibility and contract specific benefit limitations and/or exclusions will apply. Coverage statements found in the line of business specific benefit document will supersede this policy.

This policy will be revised as necessary and reviewed no less than annually**.**

Devised: 10/01

Revised: 1/02, 5/04; 4/05 (Prior auth requirement); 7/06; 8/07(coding); 9/08(criteria revision), 8/09 (criteria revision); 9/10 (criteria revision), 10/01/14 (criteria revision), 10/07/14 (DPW's criteria), 1/6/16 (criteria revision per PARP)

Reviewed: 2/03, 10/11, 10/01/14, 10/07/14, 10/1/15, 9/20/16, 7/31/17, 7/10/18, 5/31/19, 2/1/20, 1/1/21, 12/23/21