Premier Health Plan

POLICY AND PROCEDURE

POLICY TITLE: **Synagis (Palivizumab)**
DEPARTMENT: **Clinical Pharmacy Services- Utilization Management**
ORIGINAL DATE: ***September 2003***

Last P & T Committee Approval Date: *February 2018*

Product Applicability: *mark all applicable products below:*

COMMERCIAL	[ ] HMO [ ] PPO *Products*: [ ] Small [ ] Indiv. [ ] Large *Exchange*: [ ] Shop [ ] Indiv. [x] All
OTHER	[x] Self-funded/ASO

PURPOSE

The purpose of this policy is to define the prior authorization process for Synagis (Palivizumab).

Synagis (Palivizumab) is indicated for the prevention of serious lower respiratory tract disease caused by respiratory syncytial virus (RSV) in children at high risk of RSV disease. Safety and efficacy were established in children with bronchopulmonary dysplasia (BPD), infants with a history of premature birth (less than or equal to 35 weeks gestational age), and children with hemodynamically significant congenital heart disease (CHD). The safety and efficacy of Synagis (Palivizumab) have not been established for treatment of RSV disease.

The recommendations for use are based upon the American Academy of Pediatrics guidelines as well as standards of practice of regional practitioners.

The season in which Synagis (Palivizumab) is covered may be determined yearly based upon the recommendations of regional neonatologists and the American Academy of Pediatrics.

DEFINITIONS

Acyanotic Heart Disease – heart defect present at birth that results in a low blood oxygen level, such as heart valve defects (e.g. tricuspid valve, pulmonary valve, and aortic valve), coarction or complete interruption of the aorta, Epstein anomaly, hypoplastic left heart syndrome, tetralogy of Fallot, total anomalous pulmonary venous return, transposition of the great arteries, and truncus arteriosus.

POLICY

It is the policy of the 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 & 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.

PROCEDURE

Initial Authorization Criteria:

Must meet all of the criteria listed under the respective diagnosis:

For all Diagnoses:

- Children under the age of 24 months at the beginning of Respitory Syncytial Virus (RSV) season with Chronic Lung Disease (CLD) of prematurity
    - Member must have CLD of prematurity, which is defined as gestational age < 32 weeks, 0 days and a requirements for > 21% oxygen for at least the first 28 days of life
    - During the second year of life, member must have met criteria for CLD of prematurity AND have continued to require medical support (chronic corticosteroid therapy, diuretic therapy, or supplemental oxygen) during the 6 month period before the start of the second RSV season
- Children under the age of 12 months at the beginning of RSV season with hemodynamically significant congenital heart disease (CHD) including
    - Member must have one of the following conditions:
        - Hemodynamically significant CHD AND receiving medication to control heart failure
        - Acyanotic heart disease AND is receiving medication to control heart failure AND will require cardiac surgical procedures
        - Moderate to severe pulmonary hypertension
        - Cardiac lesions adequately corrected by surgery AND continues to receive medication to control heart failure
- Children under the age of 12 months as the beginning of RSV season with a gestational age of less than 29 weeks
- Children under the age of 12 months at the beginning of RSV season with neuromuscular disease or congenital anomaly that impairs the ability to clear secretions from the upper airway because of ineffective cough
- Children under the age of 24 months who are profoundly immunocompromised during the RSV season, such as children with severe combined immunodeficiency syndrome (SCID), severe T-cell deficiency, severe acquired immunodeficiency syndrome, acute myeloid leukemia, acute lymphoblastic leukemia, receiving chemotherapy, or hematopoietic stem cell transplant
- Children under the age of 24 months with cystic fibrosis
    - For children in the first year of life, must have clinical evidence of CLD and/or nutritional compromise
    - For children in the second year of life, must have one of the following manifestations of severe lung disease:
        - Previous hospitalization for pulmonary exacerbation in the first year of life
        - Abnormalities on chest radiography or chest computed tomography that persist when stable
        - Weight for length < 10th percentile

Reauthorization Criteria:
All prior authorization renewals are reviewed each Synagis (palivizumab) season and are subject to the above initial authorization criteria.

Limitations:

Length of Authorization (if above criteria met)	
Initial Authorization	5 doses per RSV season
Reauthorization	N/A
Quantity Level Limit	
50mg Vial	1 vial per month
100 mg Vial	1 vial per month
Maximum of 5 doses per season (season typically runs from November to March; dependent on local virology)	

Synagis is covered according the following weight based does:

Synagis Dose	Weight (lbs)	Weight (kg)
50mg	0 to 7 lbs, 11 oz	0 to 3.5kg
100mg	7 lbs, 12oz to 15lbz, 6oz	3.51 to 7 kg
150mg	15 lbs, 7oz to 23 lbs, 1 oz	7.1 to 10.5 kg
200mg	23 lbs, 2 oz to 30 lbs, 13 oz	10.6 to 14 kg

If the established criteria are not met, the request is referred to a Medical Director for review.

REFERENCES

1. Synagis [package insert]. Gaithersburg, MD: MedImmune, LLC; March 2014.
2. Committee on Infectious Diseases and Bronchiolitis Guidelines Committee. Updated guidance for palivizumab prophylaxis amoung infants and young children at increased risk of hospitalization for respiratory syncytial virus infection. Pediatrics; originally published online July 28, 2014; DOI:10.1542/peds.2014-1665.

RECORD RETENTION
Records Retention for Evolent Health documents, regardless of medium, are provided within the Evolent Health records retention policy and as indicated in CORP.028.E Records Retention Policy and Procedure.

REVIEW HISTORY

DESCRIPTION OF REVIEW / REVISION	DATE APPROVED
Annual Review	*02/17, 02/18*