DRUG DETERMINATION POLICY

Title: DDP-28 Synagis

Effective Date: 12/15/2021

Physicians Health Plan
PHP Insurance Company
PHP Service Company

Important Information - Please Read Before Using This Policy

The following policy applies to health benefit plans administered by PHP and may not bte covered by all PHP plans. Please refer to the member's benefit document for specific coverage information. If there is a difference between this general information and the member's benefit document, the member's benefit document will be used to determine coverage. For example, a member's benefit document may contain a specific exclusion related to a topic addressed in a coverage policy.

Benefit determinations for individual requests require consideration of:

1. The terms of the applicable benefit document in effect on the date of service.
2. Any applicable laws and regulations.
3. Any relevant collateral source materials including coverage policies.
4. The specific facts of the particular situation.

Contact PHP Customer Service to discuss plan benefits more specifically.

1.0 Policy:

This policy describes the determination process for coverage of specific drugs.

This policy does not guarantee or approve benefits. Coverage depends on the specific benefit plan. Drug Determination Policies are not recommendations for treatment and should not be used as treatment guidelines.

2.0 Background or Purpose:

Synagis is a specialty drug indicated for prophylaxis of Respiratory Syncytial Virus (RSV) in infants with specific age or disease risk factors. These criteria were developed and implemented to ensure appropriate use for the intended at risk infants.

3.0 Clinical Determination Guidelines:

Document the following with chart notes:

I. Chronic lung disease [must meet all listed below]:

   A. Age [must meet both listed below]:

      1. Gestational: less than 32 weeks.

      2. Chronological: less than or equal to 24 months of age.

   B. Diagnosis and severity: chronic lung disease (required at least 28 days of greater than 21 percent oxygen).

   C. Other therapies: above 12 months of age [must meet both listed below]:

      a. Chronic therapy: corticosteroid therapy, diuretic therapy or supplemental oxygen

      b. Timeframe: received within six months of the onset of approaching RSV season .

II. Prematurity [must meet all listed below]:

A. Age:

1. Gestational: born at less than 29 weeks gestational age.

2. Chronological: at or below 12 months of age at the beginning of the RSV season.

B. Diagnosis: prematurity.

III. Heart disease [must meet both listed below]:

A. Age: at or below 12 months of age.

B. Diagnosis and severity: hemodynamically significant acyanotic heart disease [must meet one listed below]:

1. Receiving medication to control congestive heart failure (CHF) and will require future cardiac surgical procedures; or

2. Moderate to severe pulmonary hypertension:

IV. May consider RSV prophylaxis.

A. Anatomical pulmonary abnormalities or neuromuscular disorder [must meet both listed below]:

1. Age: below 12 months of age.

2. Diagnosis and severity [must meet both listed below]:

a. Neuromuscular disease or congenital anomaly.

b. Impaired clearance of secretions from upper airways because of ineffective cough.

B. Immunocompromised children [must meet both listed below]:

1. Age: below 24 months.

2. Diagnosis and severity: profoundly immunocompromised during RSV season due to solid organ, stem cell transplant or receiving chemotherapy.

V. Dosage and administration.

A. Dosage frequency: administer five monthly doses from November to March (see AAP statement excerpt for 2020-2021 RSV season in Appendix 1).

B. Dosage range: allow for 50mg dosage range from beginning to end of season to accommodate weight change (below half vial - round down, above half vial - round up).

C. Breakthrough RSV hospitalization during treatment: discontinue Synagis.

D. Influenza vaccine: administer to patients greater than six months of age.

VI. Exclusions [must meet one listed below]:

A. Born at or above 29 weeks gestational age unless currently being treated for chronic lung disease (see Appendix 1).

B. Heart disease [must meet one listed below]:

1. Age: above 12 months of age.

2. Hemodynamically insignificant heart disease: secundum atrial septal defect, small ventricular septal defect, pulmonic stenosis, uncomplicated aortic stenosis and mild coarctation of the aorta and patent ductus arteriosus.

3. Cardiac lesions: adequately corrected by surgery unless requires medication(s) for CHF.

4. Mild cardiomyopathy without medical therapies.

C. Downs Syndrome.

D. Cystic Fibrosis.

E. Primary asthma prevention or to decrease subsequent episodes of wheezing.

4.0 Coding:

AFFECTED CODES				
HCPCS Code	**Brand Name**	**Generic name**	**Billing unit (1U)**	**Prior Approval**
90378	Synagis	palivizumab	50mg	Y

5.0 References, Citations & Resources:

1. Pediatric Infectious Disease Journal. 2012:18(3);223-231.
2. Pediatrics 1999:104(3);419-427.
3. Update Guidance for Palivizumab Prophylaxis Among Infants and Young children at Increased Risk of Hospitalization for RSV Infections. Pediatrics 2014:134;415.
4. Lexicomp Online®, Lexi-Drugs®, Hudson, Ohio: Lexi-Comp, Inc.; Synagis, accessed September 2021.
5. American Academy of Pediatrics Interim Guidance for use of Palivizumab prophylaxis to prevent hospitalization from severe respiratory syncytial virus infections during the current atypical interseasonal RXV spread https://www.aap.org/en/pages/2019-novel-coronavirus-covid-19-infections/clinical-guidance/interim-guidance-for-use-of-palivizumab-prophylaxis-to-prevent-hospitalization/ accessed October 2021.

6.0 Appendices:

See page 4.

7.0 Revision History:

Original Effective Date: 10/1999

Next Review Date: 11/10/2022

Revision Date	Reason for Revision
7/19	Moved to new format
8/19	Replaced abbreviations, fixed numbering, edited code chart
10/20	Annual review; modified language regarding age criteria, removed some ancillary statements, clarified criteria language.
10/21	Annual review; added AAP statement on 2020-21 RSV season in Appendix 1; reformatted

Appendix 1: AAP Interim Guidance During the Current Atypical Inter-Seasonal RXV Spread

The American Academy of Pediatrics (AAP) policy adopted in 2014 states that palivizumab, a humanized monoclonal antibody directed against the fusion protein of RSV, may be considered for use to decrease the risk of hospitalization in selected infants at significantly increased risk of severe RSV disease during the typical season. Up to 5 monthly doses are recommended to provide serum levels associated with protection for the approximately 6 months that comprise the typical RSV season. Given the current atypical interseasonal change in RSV epidemiology, which may represent a delayed onset of the 2020-2021 season, the AAP strongly supports consideration for use of palivizumab in patients who would be candidates per current eligibility recommendations. This recommendation applies to regions experiencing high rates of RSV circulation, consistent with a typical fall-winter season. The Centers for Disease Control and Prevention (CDC) monitors RSV activity in the United States in collaboration with state and county health departments and commercial and clinical laboratories. Guidelines for determining seasonal activity depend on the type of testing used for RSV.

Appendix 2: Monitoring and Patient Safety

Drug	Adverse Reactions	Monitoring	REMS
Synagis (palivizumab)	• Dermatology: skin rash (12%) • Miscellaneous: fever (27%)	Anaphylaxis: monitor for an appropriate time post infusion	Not needed