DRUG DETERMINATION POLICY

Title: DDP-28 Synagis

Effective Date: 11/05/2019

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 be 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:

A. Chronic Lung Disease (all below):

1. Age (both below):

   a. Gestational: less than 32 weeks.

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

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

3. Other therapies (greater than 12 months of age):

   a. Chronic corticosteroid therapy, diuretic therapy or supplemental oxygen meet all criteria as listed).

b. Received within six months (June to October) of the onset of RSV season (mid-November).

B. Prematurity (all below):

1. Age:

a. Gestational: less than 29 weeks gestational age.

b. Chronological: less than or equal to 12 months of age at the beginning of the RSV season.

2. Diagnosis: prematurity.

C. Heart Disease (both below):

1. Age: less than or equal to 12 months of age.

2. Diagnosis and severity: hemodynamically significant acyanotic heart disease.(one below):

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

b. Moderate to severe pulmonary hypertension:

D. May consider RSV Prophylaxis (no population-based data and/or prospective studies available).

1. Anatomical pulmonary abnormalities or neuromuscular disorder.

a. Age: less than 12 months of age.

b. Diagnosis and severity.

i. Neuromuscular disease or congenital anomaly.

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

2. Immunocompromised children (solid organ or stem cell transplant or receiving chemotherapy).

a. Diagnosis: profoundly immunocompromised during RSV season.

b. Age: less than 24 months.

E. Dosage and Administration.

1. Dosage frequency: administer five monthly doses from November to March.

a. Administration of more than five doses not recommended in the continental United States.

b. Five doses provides six months of coverage.

2. Dosage range: allow for 50mg dosage range from beginning to end of season to accommodate weight change (less than half vial - round down, greater than half vial - round up).

3. Breakthrough RSV hospitalization during treatment: discontinue Synagis.

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

F. Exclusions.

1. Equal to or greater than 29 weeks gestational age.

2. Heart disease:

   a. Age: greater than 12 months of age.

   b. 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.

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

   d. Mild cardiomyopathy without medical therapies.

3. Downs Syndrome: insufficient data.

4. Cystic Fibrosis: not recommended.

5. 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 August 2019.

6.0 Appendices:

Appendix I: 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

7.0 Revision History:

Original Effective Date: 10/1999

Next Review Date: 11/05/2020

Revision Date	Reason for Revision
7/19	Moved to new format
8/19	Replaced abbreviations, fixed numbering, edited code chart