MEDICAL POLICY STATEMENT

Original Effective Date	Next Annual Review Date	Last Review / Revision Date
09/30/2005	07/30/2016	07/30/2015

Policy Name	Policy Number
Palivizumab (Synagis)	SRx-0033

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) are derived from literature based on and supported by clinical guidelines, nationally recognized utilization and technology assessment guidelines, other medical management industry standards, and published MCO clinical policy guidelines. Medically necessary services include, but are not limited to, those health care services or supplies that are proper and necessary for the diagnosis or treatment of disease, illness, or injury and without which the patient can be expected to suffer prolonged, increased or new morbidity, impairment of function, dysfunction of a body organ or part, or significant pain and discomfort. These services meet the standards of good medical practice in the local area, are the lowest cost alternative, and are not provided mainly for the convenience of the member or provider. Medically necessary services also include those services defined in any Evidence of Coverage documents, Medical Policy Statements, Provider Manuals, Member Handbooks, and/or other policies and procedures.

Medical Policy Statements prepared by CSMG Co. and its affiliates (including CareSource) do not ensure an authorization or payment of services. Please refer to the plan contract (often referred to as the Evidence of Coverage) for the service(s) referenced in the Medical Policy Statement. If there is a conflict between the Medical Policy Statement and the plan contract (i.e., Evidence of Coverage), then the plan contract (i.e., Evidence of Coverage) will be the controlling document used to make the determination.

For Medicare plans please reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

A. SUBJECT

Palivizumab (Synagis)

B. BACKGROUND

The intent of the **Palivizumab (Synagis)** (PA) Program is to encourage appropriate selection of therapy for patients according to product labeling and/or clinical guidelines and/or clinical studies, and also to encourage use of preferred agents.

Synagis is a respiratory syncytial virus (RSV) F protein inhibitor monoclonal antibody indicated for the prevention of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease.

C. DEFINITIONS

N/A

D. POLICY

CareSource follows the American Academy of Pediatrics Red Book Guidelines for Synagis and applies these guidelines to **ALL** requests for prior authorization of Synagis.

I. CareSource may reimburse for up to 5 injections of Synagis during the respiratory virus season for one of the following:
   A. Infants born before 29 weeks, 0 days gestation AND who are less than 12 months of age as of the beginning of respiratory virus (RSV) season.
   B. Children who are younger than 12 months at the beginning of respiratory virus season who have either congenital abnormalities of the airways or a neuromuscular disorder that compromises handling of respiratory secretions from the respiratory tract.

C. Children who are younger than 12 months of age with hemodynamically significant congenital heart disease: those with cyanotic heart disease, receiving medication for heart failure and will require cardiac surgical procedures AND/OR have moderate to severe pulmonary hypertension.
D. Infants born before gestational age 32 weeks, 0 days and have Chronic Lung Disease of Prematurity, defined as a requirement for >21% oxygen for the first 28 days after birth and are less than 12 months of age at the beginning of respiratory virus season.
E. Children who are less than 24 months of age who have Chronic Lung Disease of Prematurity, defined as a requirement for >21% oxygen for the first 28 days after birth and continue 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.
F. Children younger than 24 months of age who are profoundly immunocompromised during the RSV season may be considered for palivizumab prophylaxis.

II. Initiation of injections should be timed with the onset of laboratory confirmed cases of RSV activity in the community
III. Monthly prophylaxis should be discontinued in any child whom experiences a breakthrough RSV hospitalization.
IV. Routine prophylaxis for children with cystic fibrosis or Down syndrome is not recommended or covered.

NOTE: Documented diagnosis must be confirmed by contemporaneous portions of the individual's medical record which will confirm the presence of disease and will need to be supplied with prior authorization request. These medical records may include, but are not limited to test reports, chart notes from provider's office or hospital admission notes.

Refer to product package insert for dosing, administration and safety guidelines.

All other uses of Synagis are considered experimental/investigational and therefore, will follow CareSource's Off-Label policy.

For Medicare Plan members, reference the below link to search for Applicable National Coverage Descriptions (NCD) and Local Coverage Descriptions (LCD):

If there is no NCD or LCD present, reference the CareSource Policy for coverage.

CONDITIONS OF COVERAGE
PLACE OF SERVICE
Office, Outpatient, Home
**Preferred place of service is in the home
Note: The decision on the most appropriate setting for administration is based on the member's current medical condition and any required monitoring or additional services that may coincide with the delivery of the specific medication.

HCPCS See Policy Above
CPT The medical billing code for the Synagis medication is 90378.
Use CPT code G0154 for home nursing visits for Synagis administered in the member's home (home nursing visit for IM injection). Home nursing visits DO NOT require prior authorization for participating providers.

AUTHORIZATION PERIOD

Coverage may be approved for up to 5 doses, November through March. Consistent with epidemiologic findings, CareSource considers "RSV season" to be November 1 through March 31 (unless season is extended later by the state). If a provider requests that dosing begin prior to November 1, they may submit evidence for earlier administration. A maximum of 5 doses will be authorized for the RSV season in accordance with Red Book guidelines.

V. RELATED POLICIES/RULES

VI. REVIEW/REVISION HISTORY

Date Issued:	09/30/2005
Date Reviewed:	09/30/2005, 09/30/2006, 08/30/2007, 07/30/2008, 10/30/2009, 09/30/2010, 08/30/2011, 09/30/2012, 08/30/2013, 07/30/2014
Date Revised:	08/30/2007, 07/30/2008, 10/30/2009, 09/30/2010, 08/30/2011, 09/30/2012, 08/30/2013 07/30/2014 – Guidelines Revised

VII. REFERENCES

1. Palivizumab (Synagis) [prescribing information]. MedImmune, LLC, Gathersburg, MD: March 2014.
2. American Academy of Pediatrics (AAP). Updates Guidance on the Use of palivizumab for RSV Prophylaxis, Allan S. Lieberthal and H. Cody Meissner, AAP News 2014;35;1, DOI: 10.1542/aapnews.2014358-1, 2014
3. MCG Ambulatory Care 19th Edition, 2015 MCG Health LLC

This guideline contains custom content that has been modified from the standard care guidelines and has not been reviewed or approved by MCG Health, LLC.

The medical Policy Statement detailed above has received due consideration as defined in the Medical Policy Statement Policy and is approved.