MEDICAL COVERAGE POLICY	
SERVICE: Synagis® (Palivizumab)	
Policy Number:	**235**
Effective Date:	**08/01/2020**
Last Review:	**06/29/2020**
Next Review Date:	**06/29/2021**

Important note:
Unless otherwise indicated, this policy will apply to all lines of business.
Even though this policy may indicate that a particular service or supply may be considered medically necessary and thus covered, this conclusion is not based upon the terms of your particular benefit plan. Each benefit plan contains its own specific provisions for coverage and exclusions. Not all benefits that are determined to be medically necessary will be covered benefits under the terms of your benefit plan. You need to consult the Evidence of Coverage (EOC) or Summary Plan Description (SPD) to determine if there are any exclusions or other benefit limitations applicable to this service or supply. If there is a discrepancy between this policy and your plan of benefits, the provisions of your benefits plan will govern. However, applicable state mandates will take precedence with respect to fully insured plans and self-funded non-ERISA (e.g., government, school boards, church) plans. Unless otherwise specifically excluded, Federal mandates will apply to all plans. With respect to Medicare-linked plan members, this policy will apply unless there are Medicare policies that provide differing coverage rules, in which case Medicare coverage rules supersede guidelines in this policy. Medicare-linked plan policies will only apply to benefits paid for under Medicare rules, and not to any other health benefit plan benefits. CMS's Coverage Issues Manual can be found on the CMS website. Similarly, for Medicaid-linked plans, the Texas Medicaid Provider Procedures Manual (TMPPM) supersedes coverage guidelines in this policy where applicable.

SERVICE: Synagis® (Palivizumab)

PRIOR AUTHORIZATION: Required.

POLICY: Scott & White Health Plan/FirstCare members who meet the criteria below may be eligible to receive Synagis® during the Respiratory Syncytial Virus season. These criteria are based on the criteria established by the American Academy of Pediatrics as published in the Red Book®:

Synagis® may be medically necessary for members ≤24 months of age at the start of the RSV season if:

1. At least ONE of the following criteria are met:
   a. Active diagnosis of chronic lung disease (CLD) of prematurity (defined as born ≤31 6/7 weeks gestational age who require >21% oxygen for at least 28 days after birth) **AND** required treatment with one of the following therapies within the 6 months prior to RSV season:
      - >21% supplemental oxygen
      - Medical support (i.e., chronic corticosteroid therapy, diuretic therapy, bronchodilator, or long-term ventilation)

   OR
   b. Hemodynamically Significant Congenital Heart Disease and patient has undergone a cardiac transplantation during the RSV season **OR**
   c. Cystic Fibrosis with 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) or weight for length <10th percentile on pediatric growth chart **OR**
   d. Immunocompromised due to one of the following:
      - Received or will receive a solid organ transplant, hematopoietic stem cell transplant, chemotherapy during the RSV season OR
      - Other condition that leaves infant profoundly immunocompromised (provide ICD-10)

IF CRITERIA are met, UP TO 5 DOSES, UNTIL END OF RSV SEASON, may be medically necessary.

Synagis® may be medically necessary for members ≤12 months of age at the start of the RSV if:

1. At least ONE of the following criteria are met:
   a. Premature infants (without other indications) defined as: born prematurely at or before ≤28 6/7 weeks gestation **OR**
   b. Active diagnosis of chronic lung disease (CLD) of Prematurity defined as born before ≤31 6/7 weeks gestation who require >21% oxygen for at least the first 28 days after birth **OR**

c. Severe Congenital Pulmonary Abnormality or Neuromuscular Disorder that impairs ability to clear secretions from the upper airway due to an ineffective cough **OR**
d. Cystic Fibrosis and clinical evidence of CLD and/or nutritional compromise (i.e. failure to thrive) **OR**
e. Hemodynamically significant congenital heart disease, defined as:
   - Acyanotic heart disease, requiring medication to control congestive heart failure, and will require a cardiac surgical procedure OR
   - Moderate to severe pulmonary hypertension
   - Cyanotic congenital heart disease (with consultation from a pediatric cardiologist)

OR

f. Meets any of the criteria for members <u><24 months of age</u> at the start of RSV season

IF CRITERIA are met, UP TO 5 DOSES, UNTIL END OF RSV SEASON, may be medically necessary.

Coverage is NOT medically necessary for any member, regardless of age, who has already experienced a breakthrough RSV hospitalization during the CURRENT season.

As of August 15, 2019, there has been no change in AAP guidelines for the 2019-2020 season.

OVERVIEW: Synagis® is a respiratory syncytial virus (RSV) F protein inhibitor monoclonal antibody indicated for the reduction of serious lower respiratory tract disease caused by RSV in children at high risk of RSV disease. The guidelines published by the AAP in 2014 remain in effect in 2019

CODES:

Important note:
CODES: Due to the wide range of applicable diagnosis codes and potential changes to codes, an inclusive list may not be presented, but the following codes may apply. Inclusion of a code in this section does not guarantee that it will be reimbursed, and patient must meet the criteria set forth in the policy language.

CPT Codes:	90378 Respiratory syncytial virus, monoclonal antibody
ICD-10 codes:	
ICD-10 Not covered:	
HCPCS	S9562 Home injectable therapy, palivizumab, including administrative services, professional pharmacy services

POLICY HISTORY:

Status	Date	Action
New	05/16/2017	New policy
Reviewed	03/20/2018	No changes
Reviewed	10/15/2018	Updated to align with pharmacy language.
Reviewed	08/22/2019	No changes
	06/29/2020	Logo changed to include FC

REFERENCES:

The following scientific references were utilized in the formulation of this medical policy. SWHP will continue to review clinical evidence related to this policy and may modify it at a later date based upon the evolution of the published clinical evidence. Should additional scientific studies become available and they are not included in the list, please forward the reference(s) to SWHP so the information can be reviewed by the Medical Coverage Policy Committee (MCPC) and the Quality Improvement Committee (QIC) to determine if a modification of the policy is in order.

1. "Updated Guidance for Palivizumab Prophylaxis Among Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection." Pediatrics 134.2 (2014): 415-420.
2. Synagis® (palivizumab) [prescribing information]. Gaithersburg, MD: Medimmune, LLC. 2014.
3. American Academy of Pediatrics Red Book 2015: 667-676.
4. FDA label for Synagis®: https://www.accessdata.fda.gov/drugsatfda_docs/label/2002/palimed102302LB.pdf. Accessed 03/19/2018