



MEDICAL COVERAGE POLICY

SERVICE: Palivizumab (Synagis®)

Policy Number: 235

Effective Date: 1/1/2025

Last Review: 10/14/2024

Next Review: 10/14/2025

Important note: Unless otherwise indicated, medical policies will apply to all lines of business.

Medical necessity as defined by this policy does not ensure the benefit is covered. This medical policy does not replace existing federal or state rules and regulations for the applicable service or supply. In the absence of a controlling federal or state coverage mandate, benefits are ultimately determined by the terms of the applicable benefit plan documents. See the member plan specific benefit plan document for a complete description of plan benefits, exclusions, limitations, and conditions of coverage. In the event of a discrepancy, the plan document always supersedes the information in this policy.

SERVICE: Synagis® (Palivizumab)

PRIOR AUTHORIZATION: Required

POLICY: Please review the plan's EOC (Evidence of Coverage) or Summary Plan Description (SPD) for details.

For Medicare plans, please refer to appropriate Medicare NCD (National Coverage Determination) or LCD (Local Coverage Determination). Medicare NCD or LCD specific InterQual criteria may be used when available. If there are no applicable NCD or LCD criteria, use the criteria set forth below.

For Medicaid plans, please confirm coverage as outlined in the [Texas Medicaid Provider Procedures Manual | TMHP](#) (TMPPM). Texas Mandate HB154 is applicable for Medicaid plans.

BSWHP 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 (AAP) as published in the Red Book®:

For all eligible members, Synagis® will only be approved if nirsevimab is NOT available or feasible to administer.

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 $\leq 31\frac{6}{7}$ 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



MEDICAL COVERAGE POLICY

SERVICE: Palivizumab (Synagis®)

Policy Number: 235

Effective Date: 1/1/2025

Last Review: 10/14/2024

Next Review: 10/14/2025

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 <24 months of age at the start of RSV season

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

Newer recommendations from the AAP or ACIP (Advisory Committee on Immunization Practices) on palivizumab not listed in this policy will be followed for medical necessity.

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

Coverage is NOT medically necessary for any member, regardless of age, who has already received a dose of nirsevimab during the CURRENT season.



MEDICAL COVERAGE POLICY

SERVICE: Palivizumab (Synagis®)

Policy Number: 235

Effective Date: 1/1/2025

Last Review: 10/14/2024

Next Review: 10/14/2025

BACKGROUND: 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 AAP and ACIP (Advisory Committee on Immunization Practices) recommend that palivizumab be used in eligible infants if nirsevimab is not available or not feasible to administer.

CODES:

Important note: 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
HCPCS Codes:	S9562 Home injectable therapy, palivizumab, including administrative services, professional pharmacy services
ICD10 codes:	
ICD10 Not covered:	

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
Reviewed	06/29/2020	Logo changed to include FC
Reviewed	07/22/2021	No changes
Reviewed	07/28/2022	No changes
Reviewed	07/27/2023	No changes
Update	10/26/2023	Added nirsevimab related information. Applied new layout and format.
Updated	10/14/2024	Updated policy name to match naming convention of other policies. Updated to reflect most recent AAP/ACIP recommendations used.

REFERENCES:



MEDICAL COVERAGE POLICY

SERVICE: Palivizumab (Synagis®)

Policy Number: 235

Effective Date: 1/1/2025

Last Review: 10/14/2024

Next Review: 10/14/2025

The following scientific references were utilized in the formulation of this medical policy. BSWHP will continue to review clinical evidence related to this policy and make modifications 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 BSWHP 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. American Academy of Pediatrics. News Release: American Academy of Pediatrics Recommends Medication to Prevent RSV Be Given to All Infants and Urges Equitable Access. August 15, 2023. <https://www.aap.org/en/news-room/news-releases/aap/2023/american-academy-of-pediatrics-recommends-medication-to-prevent-rsv-be-given-to-all-infants-and-urges-equitable-access/> Accessed September 26, 2023.
2. American Academy of Pediatrics. Resources: AAP Recommendations for the Prevention of RSV Disease in Infants and Children. February 21, 2024. <https://publications.aap.org/redbook/resources/25379/AAP-Recommendations-for-the-Prevention-of-RSV>. Accessed August 28, 2024.
3. American Academy of Pediatrics Red Book 2021: 628-636.
4. American Academy of Pediatrics Red Book 2024: 713-721.
5. Caserta, Mary T et al. "Palivizumab Prophylaxis in Infants and Young Children at Increased Risk of Hospitalization for Respiratory Syncytial Virus Infection." Pediatrics vol. 152,1 (2023): e2023061803. doi:10.1542/peds.2023-061803
6. FDA label for Synagis®: https://www.accessdata.fda.gov/drugsatfda_docs/label/2002/palimed102302LB.pdf. Accessed 03/19/2018
7. Jenco, Melissa. American Academy of Pediatrics. AAP News: FDA approves RSV vaccine for pregnant people to protect infants. August 22, 2023. <https://publications.aap.org/aapnews/news/25580/FDA-approves-RSV-vaccine-for-pregnant-people-to> Accessed September 26, 2023.
8. Synagis® (palivizumab) [prescribing information]. Gaithersburg, MD: Medimmune, LLC. 2014.
9. "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.

Note:

Health Maintenance Organization (HMO) products are offered through Scott and White Health Plan dba Baylor Scott & White Health Plan, and Scott & White Care Plans dba Baylor Scott & White Care Plan. Insured PPO and EPO products are offered through Baylor Scott & White Insurance Company. Scott and White Health Plan dba Baylor Scott & White Health Plan serves as a third-party administrator for self-funded employer-sponsored plans. Baylor Scott & White Care Plan and Baylor Scott & White Insurance Company are wholly owned subsidiaries of Scott and White Health Plan. These companies are referred to collectively in this document as Baylor Scott & White Health Plan.

RightCare STAR Medicaid is offered through Scott and White Health Plan in the Central Texas Medicaid Rural Service Area (MRSA); FirstCare STAR is offered through SHA LLC dba FirstCare Health Plans (FirstCare) in the Lubbock and West MRSAs; and FirstCare CHIP is offered through FirstCare in the Lubbock Service Area.